S. HRG. 100-636

PEER REVIEW ORGANIZATIONS UNDER THE MEDICARE PROGRAM

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

FIRST SESSION

MARCH 27, 1987

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FRIDAY, MARCH 27, 1987

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

The committee met, pursuant to notice, at 10:00 a.m. in Room SD-215, Dirksen Senate Office Building, the Honorable George Mitchell (chairman) presiding.

Present: Senators Mitchell, Baucus, Pryor, Rockefeller, Heinz, and Durenberger.

[The press release announcing the hearing and the prepared written statements of Senators Bentsen, Pryor, and Heinz, and Durenberger and a background paper prepared by CRS follows:]

[Press Release No. H-26]

FINANCE SUBCOMMITTEE ON HEALTH TO HOLD HEARING ON MEDICARE PEER REVIEW ORGANIZATIONS

Washington, D.C.—Senator George J. Mitchell (D., Maine), Chairman, announced Thursday that the Subcommittee on Health of the Senate Finance Committee will hold a hearing to examine the role and performance of utilization and quality control peer review organizations under the Medicare program.

Senator Mitchell stated that the purpose of the hearing is to examine how the Health Care Financing Administration is implementing the peer review program, how the peer review organizations are carrying out their duties to ensure that quality care is being provided to Medicare beneficiaries, and whether they are adequately funded to carry out appropriate quality review. The Subcommittee will also seek information on special problems which may exist in rural areas, and special problems which may affect review of services provided by health maintenance organizations.

Senator Mitchell further stated that the Congress relies heavily on the peer review organizations to safeguard quality of care for beneficiaries under Medicare's prospective payment system, and the Subcommittee wants to make sure that the peer review program is carrying out this mandate in the most appropriate manner.

The hearing will begin at 10:00 A.M. on Friday, March 27, 1987 in Room SD-215 of the Dirksen Senate Office Building.

OPENING STATEMENT
SENATOR DAVID PRYOR
at a hearing on
PEER REVIEW ORGANIZATIONS
March 27, 1987

Mr. Chairman, I'd like to congratulate you on the scheduling of this hearing today. I know that the Finance Committee (and the Health Subcommittee in particular) has had a rigorous hearing schedule so far this session, and from what I can tell that trend will continue. I am pleased to have been given the opportunity to serve on this very important subcommittee.

This Committee has a long history of oversight in the area of peer review. The program has historically served a very important function -- to help ensure that appropriate, quality health care is provided senior citizens under the Medicare program. Unfortunately, for almost as long as the program has been in existence, there has been controversy associated with it.

For some time I have heard concerns expressed over PRO inaccessibility and goals or quotas set for the denial of hospital claims. More recently concerns over lack of due process and appeal rights, inadequate funding for the PROs to carry out their review functions appropriately, and the provider sanctioning process have been added to the list. I am hopeful that we will be able to address some of these problems at the national level. I've become increasingly interested in the possibility of providing the full range of appeal rights now afforded beneficiaries to health care providers. A major result would be a significant increase in cases reviewed at the administrative law judge level, and that is one area I'm interested in discussing with some of our witnesses

today, particularly those on our second panel.

Once again, Mr. Chairman, I'd like to commend you on the scheduling of this hearing, and look forward to the testimony of our witnesses.

SENATOR JOHN HEINZ

SENATE FINANCE COMMITTEE'S SUBCOMMITTEE ON HEALTH
MARCH 27, 1987

HEARING ON PEER REVIEW ORGANIZATIONS

MR. CHAIRMAN, I KNOW I JOIN MY COLLEAGUES IN THANKING YOU FOR CALLING THIS HEARING TO REVIEW THE STATUS OF THE PEER REVIEW ORGANIZATIONS. SO MANY OF OUR RECENT REFORMS IN MEDICARE--FROM PROSPECTIVE PAYMENT FOR HOSPITALS TO THE SECOND SURGICAL OPINIONS PROGRAM--ALL DEPEND HEAVILY ON THE OVERSIGHT OF THESE WATCHDOGS. IF WE TIE THE PROS ON TOO SHORT A LEASH, OR IF THEY DO THEIR JOBS BADLY, THEN MUCH OF OUR LABORS WILL HAVE BEEN FOR NAUGHT AND WE WILL HAVE A WHOLE NEW SET OF ISSUES ON OUR PLATE.

WHILE CHAIRMAN OF THE SENATE SPECIAL COMMITTEE ON AGING, I HAD THE OPPORTUNITY TO SPEND A LOT OF TIME EXAMINING THE HEALTH CARE FINANCING ADMINISTRATIONS' GUIDELINES FOR PROS. IN EARLY 1985, WHEN THE COMMITTEE BEGAN ITS INVESTIGATION OF THE EFFECTS OF PPS ON QUALITY OF CARE, THE PROS WERE STUMBLING ALONG, LACKING STRONG, SHARPLY FOCUSED INSTRUCTIONS AND APPROPRIATE SANCTION AUTHORITIES. SAVING DOLLARS THROUGH UTILIZATION REVIEW--NOT SAVING LIVES THROUGH QUALITY CONTROL--DOMINATED THEIR EFFORTS.

CONTROL--DOMINATED THEIR EFFORTS. PROs WERE BEING GUIDED BY TRANSMITTALS AND VERBAL INSTRUCTIONS; MUCH OF THE ADMINISTRATION AND MONITORING OF THE PROGRAM WAS FUNCTIONING IN A BLACK BOX, SHIELDED FROM PUBLIC SCRUTINY.

A LOT HAS CHANGED SINCE THAT INVESTIGATION BEGAN. WITH THE HELP OF SOME OF THE PEOPLE WHO ARE TESTIFYING HERE TODAY, WE CONVINCED CONGRESS AND THE ADMINISTRATION THAT REFORMS WERE NEEDED. WITH THE SUPPORT OF MANY MEMBERS OF THIS COMMITTEE, MANY OF THOSE CHANGES BECAME LAW IN COBRA AND OBRA, BOTH ENACTED IN 1986. WE ADDED TO THE RESPONSIBILITIES OF THE PROs TO SAFEGUARD THE QUALITY OF CARE FOR MEDICARE BENEFICIARIES BOTH IN AND OUTSIDE OF THE HOSPITAL. AND, WE IN THE CONGRESS SENT A CLEAR MESSAGE TO THE PROs THAT THEY ARE FIRST AND FOREMOST WATCHDOGS OF QUALITY -- THAT THAT THEY SHOULD NEVER PUT THE SAVING OF DOLLARS AHEAD OF THEIR MISSION TO SAVE LIVES.

NO DOUBT, SERIOUS WRINKLES REMAIN IN THE PRO PROGRAM. SOME ARE ATTRIBUTABLE TO THE SCOPE AND RELATIVELY YOUNG AGE OF THE PROGRAM. SOME ARE CAUSED BY THE RELUCTANCE OF PHYSICIANS TO HAVE SOMEONE LOOKING OVER THEIR SHOULDERS -- A RELUCTANCE WHICH SEEMS TO BE GREATEST IN AREAS OF THE COUNTRY WHERE PEER REVIEW IS RELATIVELY NEW. SOME ARE ROOTED IN THE CONTRACTING AND EVALUATION PROCESS WHICH APPEARS TO ENCOURAGE PROs TO WORRY MORE ABOUT THEIR RATE OF PAYMENT DENIALS THAN THEIR QUALITY ASSURANCE RESPONSIBILITIES.

I AM SURE THAT MANY OF THESE WRINKLES WILL BE HIGHLIGHTED IN TODAY'S TESTIMONY. I AM ESPECIALLY ANXIOUS TO HEAR DR. ROPER'S TESTIMONY ON HCFA'S EFFORTS TO BEEF UP QUALITY ASSURANCE AND ENFORCEMENT ACTIVITIES. I AM ALSO CONVINCED THAT MORE CHANGES MAY BE NEEDED IN THE MEDICARE LAW TO ENSURE THAT PROS ARE ABLE TO DO THEIR JOBS PROPERLY. FOR EXAMPLE, WE MAY NEED TO BUILD IN AN ALLOWANCE FOR THE PROS TO ALLOW "SOCIAL" ADMISSIONS FOR CERTAIN PATIENTS WHO WOULD ORDINARILY HAVE TO BE TREATED IN AMBULATORY SETTINGS. FINALLY, I SHARE THE CONCERNS OF THE CHAIRMAN ABOUT THE EFFECTS OF THE PRO PROGAM ON RURAL COMMUNITIES. I THINK WE NEED TO EXAMINE WHY IT IS THAT SO MANY OF THE SANCTIONS ARE FALLING ON PHYSICIANS AND PROVIDERS IN OUR NATION'S RURAL COMMUNITIES.

IN THE COMING WEEKS, AS WE PUT ON OUR GREEN EYE SHADES AND RUN OUR RED PENS DOWN THE FEDERAL LEDGER LOOKING FOR BUDGET CUTS, I HOPE THAT WE WILL NOT CUT QUALITY ASSURANCE. OUR NATION'S HEALTH CARE PROGRAMS HAVE BEEN BUILT ON A FOUNDATION OF QUALITY CARE FOR ALL, AND IT IS OUR RESPONSIBILITY TO KEEP THIS FOUNDATION FIRM.

STATEMENT OF SEN DAVE DURENBERGER

MARCH 27,1987

MR. CHAIRMAN, I WANT TO APPLAUD YOU FOR HOLDING THIS HEARING. THERE IS NO RESPONSIBILITY MORE IMPORTANT FOR THIS COMMITTEE THAN ITS OVERSIGHT OF THE PROGRAM WHICH CONGRESS SET UP TO ENSURE THAT BENEFICIARIES ARE PROTECTED AND GIVEN HIGH QUALITY MEDICAL CARE. THE PRO ALSO MAKES CERTAIN THAT THE GOVERNMENT PURCHASES QUALITY CARE, NOT MEDIOCRE OR BAD CARE, AND APPROPRIATE CARE, NOT INAPPROPRIATE OR LESS APPROPRIATE CARE. FINALLY THE PRO PROGRAM HELPS CONGRESS KEEP FAITH WITH THE WORKING TAXPAYERS OF AMERICA, WHO FINANCE ROUGHLY 92% OF MEDICARE, BY GUARANTEEING THAT THE MEDICARE PROGRAM IS A WISE AND PRUDENT PURCHASER. BUT WITH THE ECONOMIC INCENTIVES TURNED AROUND, THE ROLE OF THE PROS IS PARAMOUNT IN MAKING CERTAIN THAT BENEFICIARIES ARE GIVEN THE BEST QUALITY CARE AND THAT THERE IS NO UNDERSERVICE.

THE PROS HAVE A TOUGH JOB BUT THEIR JOB IS MORE IMPORTANT TODAY THAN EVER BEFORE. WE COUNT ON THEM TO HELP US SEE WHAT MIDCOURSE CORRECTIONS ARE NEEDED AS WE ALL UNDERGO THIS REVOLUTION IN HEALTH CARE. AS WE UNDERTAKE TO ADD SERVICES, ENCOURAGE BETTER USE OF OUTPATIENT CARE AND LIVE WITH CHANGES IN CLINICAL PRACTICE THAT AFFECT ALL OF US, WE MUST LOOK OUT FOR THE FRAIL ELDERLY.

I HAVE BEEN HOLDING SPECIAL MEETINGS THOROUGHOUT MINNESOTA AND HEARD FROM HUNDREDS OF SENIORS, DISABLED BENEFICIARIES , PHYSICIANS , NURSES, ALLLIED HEALTH PERSONNEL, ADMINISTRATORS AND CITIZEN GROUPS. THE BEST SUMMARY THAT I HEARD FROM MANY PEOPLE WAS GIVEN IN VERY IMPRESSIVE TESTIMONY BY DR. ANN VOGEL OF NEW ULM MINNESOTA. I AM SUBMITTING HER STATEMENT WITH THIS ONE. IT IS NOT ONLY AN EXCELLENT DESCRIPTION OF WHAT SHE AND HER COLLEAGUES ARE EXPERIENCING TODAY BUT IT BRINGS TOGETHER SO ARTICULATELY AND HUMANELY WHAT MANY ARE EXPERIENCING THROUGHOUT THE COUNTRY. I HOPE YOU ALL WILL HAVE A CHANCE TO READ HER TESTIMONY FROM THE HEAD AND THE HEART OF THIS IMPRESSIVE PHYSICIAN IN RURAL AMERICA.

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THE PEER REVIEW ORGANIZATION (PRO) PROGRAM

Prepared for the use of the
Senate Committee on Finance

Joseph A. Cislowski
Analyst in Social Legislation
Education and Public Welfare Division
March 25, 1987

II. LEGISLATIVE HISTORY

A. Tax Equity and Fiscal Responsibility Act of 1982

The Tax Equity and Fiscal Responsibility Act of 1982 (P.L. 97-248, commonly referred to as TEFRA) required the Secretary to enter into performance-based contracts with utilization and quality peer review organizations (PROs). A PRO is defined as an entity which either (1) is composed of a substantial number of licensed doctors of medicine or 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.

TEFRA required the Secretary to designate the geographic areas 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 PRO for each geographic area for an initial period of 2 years, renewable every 2 years.

The contract is required to include negotiated objectives against which the organizations'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 noninstitutional 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 generally binding. 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. Social Security Amendments of 1983

The Social Security Amendments of 1983 (P.L. 98-21) authorized the establishment of Medicare's prospective payment system (PPS) for inpatient hospitals.

P.L. 98-21 required hospitals receiving payment under PPS to enter into an agreement with a peer review organization. Under these agreements, PROs 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 paid for on an "outlier" basis (outlier payments are made for cases which are extremely expensive or which have extremely long lengths of stay).

Hospitals were required to enter into such agreements by October 1, 1984 (later changed to November 15, 1984 by P.L. 98-369) as a condition for receiving Medicare payments. If a contract between the Secretary and a PRO is terminated, hospitals are not penalized during the six-month period during which the Secretary is required to enter into a new contract.

C. Deficit Reduction Act of 1984

The Deficit Reduction Act of 1984 (P.L. 98-369, commonly referred to as DEFRA) contained the following two sections modifying the PRO program.

Section 2334 allowed limited representation for providers on a PRO governing board. Specifically, up to 20 percent of the members of a PRO board can be affiliated with providers

Section 2334 also permitted entities whose board members include a representative of a self-insured employer to quality as a PRO. It also permitted an organization which had no more than one member affiliated with a health maintenance organization to qualify as a PRO.

Section 2347 continued funding for professional standards review organizations (PSROs) which were still in existence until a contract was signed with a PRO. Payments for PSROs were made from the Medicare Hospital Insurance Trust Fund.

The date by which hospitals were required to have an agreement with a PRO was delayed from October 1, 1984 to November 15, 1984. Similarly, November 14, 1984 was the first date a health benefit payer organization could qualify as a PRO.

D. Consolidated Omnibus Budget Reconciliation Act of 1985

The Consolidated Omnibus Budget Reconciliation Act of 1985 (P.L. 99-272, commonly referred to as COBRA) contained the following five sections affecting the status of PROs:

Section 9401 would require PROs to perform 100 percent pre-procedure reviews for at least 10 elective surgical procedures. That is, a review must be performed prior to performance of the procedure in the case of an outpatient procedure and, in the case of an inpatient procedure, before the patient is admitted to the hospital for services related to the procedure. Pre-procedure review would not be required in a medical emergency and in certain other circumstances.

The procedures subject to pre-procedure review are to be specified in the contracts negotiated between the PRO and the Secretary. The Secretary is required to establish guidelines, consistent with the following criteria, for determining whether a procedure is appropriate for pre-procedure review:

--The procedure is one which can generally be postponed without undue risk to the patient;

--The procedure is a high volume procedure for Medicare beneficiaries or is a high cost procedure; and

--The procedure has comparatively high rates of non-confirmation upon examination by a second physician; there is substantial geographic variation in performance rates; there are or other reasons why per-procedure review would be cost-effective.

A PRO may also include procedures not identified by the Secretary in pre-procedure review if it would be cost-effective and consistent with these criteria.

The Secretary is required to ensure that appropriate notice is provided to physicians, hospitals, ambulatory surgical centers, and beneficiaries regarding the pre-procedure review program.

Section 9401 also allowed PROs to require second opinions as part of the pre-procedure review for certain surgical procedures if it is warranted (for a detailed description of these provisions, see the discussion of second surgical opinions in the "Other Relevant Issues" section of this paper).

The Secretary is required to report to Congress within 36 months of enactment on the results of the changes made in Section 9401.

Section 9402 specified that the aggregate reimbursement in any given fiscal year could not be less than the aggregate reimbursement in FY 1986.

Section 9403 authorized PROs to deny payment for care of substandard quality as identified through criteria developed under the guidelines established by the Secretary. Beneficiaries are protected under the waiver of liability

provision against being charged for services for which Medicare payment has been denied.

Before COBRA, the law provided that PROs could deny payment if the care was not medically necessary or not performed in an appropriate setting; however, PROs could not previously deny payment for care of substandard quality.

Section 9404 allowed PROs with more than one member affiliated with a health maintenance organization or competitive medical plan to qualify as a PRO on the same basis as other organizations.

Section 9405 required PRO review of Medicare services furnished by health maintenance organizations and competitive medical plans with Medicare risk-sharing contracts.

Section 9406 authorized the Secretary to assign review responsibilities to another PRO, intermediary, or carrier during the period after the Secretary has given notice of intent to terminate a PRO contract and prior to the time the Secretary enters into a contract with another PRO.

E. Omnibus Budget Reconciliation Act of 1986

The Omnibus Budget Reconciliation Act of 1986 (P.L. 99-509) contained the following four sections modifying the law regarding PROs:

Section 9343 required PRO contracts to include a review of all ambulatory surgical procedures (or, at the Secretary's discretion, a sample of selected procedures) performed in ambulatory surgical centers and hospital outpatient departments.

Section 9351 made a number of changes relating to PRO review of hospital denial notices (i.e., notices that further inpatient care is no longer medically necessary).

Section 9351 established the following procedures regarding PRO review of hospital denial notices:

--If the hospital determines and the attending physician agrees that continued stay is no longer necessary, the hospital may provide the patient with a coverage denial notice.

--If the attending physician does not agree with the hospital's determination, the hospital may request the PRO to review the validity of its determination.

--If a patient receives a coverage denial notice and requests a PRO review, the PRO must review the determination and provide notice to the patient, hospital, and attending physician, regardless of the patient's financial liability for continued stay.

--If a patient requests a PRO review of the hospital's determination no later than noon of the first working day after receipt of the hospital denial notice, the hospital must provide the PRO with the records required to review the determination by the close of that business day, and the PRO must provide notice of its review no later than one full working day after it has received the request and the records.

--If a patient has made a timely request and did not know or could not reasonably be expected to know that continued stay was unnecessary, the hospital may not charge the patient for hospital services before noon of the day after receipt of the PRO's decision.

--PROs must solicit the views of the patient in conducting its review.

Section 9352 required fiscal intermediaries to provide to PROs each month the data necessary to enable the PROs to initiate a timely review process. If the fiscal intermediary cannot furnish the data on a timely basis, the Secretary may require the hospitals to do so.

PROs are required to perform early readmission reviews to determine if the previous inpatient hospital services and post-hospital services meet professionally recognized standards of health care. The reviews may be done on a sample basis if the PRO and the Secretary determine it to be appropriate. An early readmission case is defined as a readmission occurring within 31 days of discharge. Review of services provided by physicians in an office setting is

excluded from the scope of review for early readmission cases until January 1, 1989.

Section 9353(a) required PROs to allocate a reasonable portion of their activities to review of quality of services among different cases and settings including inpatient hospital, post-acute, ambulatory, and health maintenance organization (HMO) and competitive medical plan (CMP) care. PROs, in allocating their activities, are required to consider the need for review based on previous problems, the cost and potential yield of the reviews, and the availability and adequacy of alternate quality review and assurance mechanisms.

Each PRO contract is required to include review of inpatient and out-patient services provided by HMOs and CMPs to determine the quality and appropriateness of services provided. The level of review activity is to equal the level of review activity, per beneficiary, in other settings.

The Secretary is authorized to contract for HMO review with organizations other than PROs in half of the States by April 1987, provided that these States collectively have 50 percent or less of the total number of HMO or CMP enrollees. The Secretary is required to identify methods available to assist PROs in identifying potential cases of substandard care.

The Secretary is required to provide at least 12 PROs with assistance in review and analysis of small area variations in utilization of hospital and other services for which Medicare reimbursement is made.

The requirement that PROs allocate a reasonable proportion of their review activities to reviewing different cases and settings would be delayed for two years as it pertains to review of services provided by physicians in an office setting. The requirement that PROs review HMOs and CMPs applies on or after April 1, 1987.

Section 9353(b) required at least one consumer representative to serve on each PRO board.

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Section 9353(c) required PROs to conduct appropriate review of all written complaints by beneficiaries about the quality of services provided. The PRO must inform the beneficiary or the beneficiary's representative of the final disposition of the complaint.

Section 9353(d) required PROs to share confidential information related to a specific case or possible pattern of substandard care upon request of the State licensing or State certification agency or of the national accreditation body, but only to the extent the information is required to carry out its official functions.

Section 9353(e) required hospitals, skilled nursing facilities and home health agencies to maintain an agreement with the PRO regarding review of services (other than inpatient hospital services) and review of beneficiary complaints regarding quality of care. PRO activities are to be considered a cost of providing services and are to be paid directly by the Secretary to the PRO. Payments are to be transferred from the Hospital Insurance (Part A) and the Supplementary Medical Insurance (Part B) Trust Funds and are not to be less in aggregate than the amount determined by the Secretary to be sufficient to cover the costs of specified review activities.

Similar provisions apply to HMOs and CMPs as of April 1, 1987.

III. MAJOR PROGRAM FEATURES 1/

A. General Overview

Hospitals are required to enter into agreements with Peer Review Organizations (PROs) as a condition for receiving payments under Medicare's prospective payment system for inpatient hospital services. PROs review the services provided to Medicare patients to assure that services are medically necessary, provided in the appropriate setting, and meet professionally-recognized standards of quality health care.

The Secretary of Health and Human Services is required to contract with PROs. Organizations eligible for PRO contracts include physician-sponsored organizations, physician-access organizations, and health benefit payer organizations. PROs are expected both to focus on curtailing unneccesary costs and assuring the quality of health care.

1/ Peer Review Organization program information in sections III and IV was obtained in March 1987 from published and unpublished Health Care Financing Administration documents and interviews and telephone conversations with officials from the Health Care Financing Administration Office of Medical Review. Other health care organizations were also contacted with respect to issues concerning the PRO program.

B. PRO Contracts

The Secretary of Health and Human Services contracts with private organizations (which then become peer review organizations) for the review of necessity, appropriateness, and quality, of health care services furnished under Medicare.

There are 54 such contracts. Each of the 50 States, the District of Columbia, Puerto Rico, and the Virgin Islands are designated as separate PRO areas. Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands are considered to be in a single PRO area. A directory of the PRO contractors for each area can be found in Appendix A.

The Secretary was required to enter into contracts with PROs for an initial period of 2 years, renewable every 2 years. The initial PRO contracts were signed for the FY 1984-1986 contract cycle. By November 15, 1984, the Secretary entered into 54 2-year contracts; subsequently, three were terminated and replaced by other organizations.

For the FY 1986-1988 contract cycle, six entities replaced existing (other than the three terminated) PROs. Only one fiscal intermediary contracted to perform PRO review (for two PRO areas). For more information on the status of current PRO contracts (including their effective dates), see Appendix B.

Each of the 54 contracts between the Secretary and the PROs must contain certain similar elements. All of the contracts must specify objectives which are to be achieved during the contract period. These contracts must also define the structure, scope, and process of Medicare review performed by the PROs. All are expected to comply with relevant regulations and manual instructions.

The PRO contracts, however, may also contain certain differences. These differences may include different objectives, levels of preadmission review,

and requirements for on-site or off-site review. Five PRO contracts are rather different because Medicare's prospective payment system (PPS) does not apply to their areas. Two of these contracts apply to States--Maryland and New Jersey--which currently have waivers from the Secretary to operate their own State cost control systems instead of PPS. Three contracts apply to hospitals outside the 50 States and the District of Columbia (i.e., one contract for Puerto Rico, one for the Virgin Islands, and one for Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands) which are currently exempt from PPS. Puerto Rico will be included within PPS effective October 1, 1987.

For more information on how the Health Care Financing Administration evaluates contract proposals (including the weights awarded for each factor), see Appendix C.

C. Eligible Organizations

Organizations eligible for PRO contracts include physician-sponsored organizations and physician-access organizations. In limited circumstances, payer organizations may also be eligible.

When the Secretary selects contractors for competitive (i.e., non-renewal) PRO contracts, priority consideration is given to physician-sponsored organizations. Physician-sponsored organizations must be composed of a substantial number of physicians in the review area and must be representative of these physicians. Forty-one contracts are currently held by physician-sponsored organizations.

Physician-access organizations may also be eligible to become PROs. These organizations must have available to them, by arrangement or otherwise, the

services of enough licensed physicians practicing medicine or surgery in the review area to assure adequate peer review of the services provided by the various medical specialties and subspecialties. Thirteen contracts are currently held by physician-access organizations.

Payer organizations (i.e., Medicare fiscal intermediaries) may become PROs in limited circumstances. These organizations are eligible for PRO contracts only if the Health Care Financing Administration determines that an eligible organization other than a payer organization is unavailable. Two contracts (the one for Hawaii and the one including Guam and American Samoa) are currently held by a payer organization.

A chart displaying which type of eligible organization has become the PRO in each State can be found in Appendix B.

D. Medical Review

PROs review the services rendered to Medicare beneficiaries to assure that they are medically necessary, provided in the most appropriate setting, and meet professionally recognized standards of quality. Some of the review provisions discussed below are required by legislation and by regulation; however, many of these provisions are specified in Health Care Financing Administration manual instructions.

1. Review Process and Denials

After the beneficiary is discharged from the hospital and payment is made to the hospital, paid bill data is sent to the PRO. The PRO selects a sample for review and requests the revelant medical records from the hospital. The PRO reviewers (usually nurses) then review the medical records either at the hospital or at the PRO office.

The PRO nurse reviewers use criteria developed by physicians to approve payment for cases which they determine to clearly meet acceptable standards. (PRO physicians in each State develop criteria, taking local practice patterns into account). Review criteria should contain the generally-recognized reasons justifying a patient's hospital admission or surgical procedure. The criteria should also contain the generally recognized services and care which should be provided for specific diagnoses or procedures. The PRO nurse reviewers refer questionable cases to PRO physician reviewers.

If the PRO physician reviewer determines that the care was not medically necessary or that it should have been provided in another setting (e.g., an outpatient setting), the PRO will issue a payment denial. Only a PRO physician may issue a payment denial. A payment denial may only be made after the attending physician has been given an opportunity to discuss the case with a PRO physician. Denial notices are sent to the beneficiary, physician, provider, and fiscal intermediary.

During FY 1986, PROs denied payment for 8,785 cases on the basis of inappropriate admissions and transfers. Of these, 4,279 were for readmissions following premature discharges; 2,779 were readmissions for care that could have been provided during the first admission; and 1,727 represented patients who had been inappropriately transferred between a unit of the hospital subject to PPS and a PPS-exempt unit of the same hospital.

The Consolidated Omnibus Budget Reconciliation Act of 1985 (P.L. 99-272, commonly referred as COBRA) authorized PROs to issue denial notices for substandard quality of care. Before COBRA, PROs did not have the authority to deny payment for cases involving only quality of care problems. Quality denials have not yet been implemented; HCFA officials state that they expect final regulations on quality denials to be published by October 1, 1987.

A beneficiary, practitioner, or provider dissatisfied with a denial may request a reconsideration. A request must be filed within 60 days after receipt of the initial denial notice, unless there is good cause for late filing of the request. A request for an expedited reconsideration may be filed within 3 days of the notice by a beneficiary who is awaiting admission or is still an inpatient.

A reconsideration must be conducted by a specialist in the type of services under review and may not be the same physician who made the initial denial determination. The PRO must issue a reconsideration determination within 3 working days of an expedited reconsideration request, within 10 working days if the beneficiary is still a patient in a skilled nursing facility, and within 30 working days for all other cases.

A beneficiary has further appeal rights, including an administrative hearing before an Administrative Law Judge (where the reconsideration determination is adverse and the amount in controversy is at least $200), and judicial review (where the decision in the administrative hearing is adverse and the amount in controversy is at least $2,000). The beneficiary must file within 60 days after the notice of reconsideration determination for a hearing with an Administrative Law Judge and within 1 year for an Appeals Council review.

A provider or practitioner may not ordinarily appeal a reconsideration. One exception allows provider or practitioner to appeal if, during a DRG validation (a review to ascertain that the diagnostic and procedural information that led to the DRG assignment is substantiated by the medical record), the PRO changes the diagnostic or procedural coding used on the claim and this results in a lower Medicare payment. Some providers and practitioners have expressed their belief that it is unfair that they cannot further appeal a PRO decision.

2. Quality Review and Interventions (Including Sanctions)

The PRO nurse reviewer uses generic quality screens and discharge criteria to determine if the sample cases meet acceptable standards of quality care and refers questionable cases to PRO physician reviewers. If a PRO physician reviewer identifies quality problems, and has given the attending physician an opportunity to discuss the case, the PRO must initiate corrective action.

Such actions may include the following: education, intensified review, alternate timing of review, and sanctions. In addition to reviewing for quality on a case-by-case basis, PROs use their data systems to identify patterns of inappropriate care; this is known as "profiling."

One corrective action available to PROs is that they may require a physician to participate in continuing medical education. The education may or may not be targeted toward a specific quality problem that has been identified by the PRO.

Another corrective action which PROs may use is intensified review. A PRO may review 100 percent of a physician's cases in a calender quarter to make certain that quality problems found in a previous quarter do not persist. The PRO may also target intensified review through profiling; for example, PRO data systems could idnetify physicians with quality problems particular diagnosis related groups (DRG). Intensified review would then apply only to cases within that particular DRG.

PROs may also initiate alternate timing review. For example, preadmission review may be required for a physician with a large number of medically unnecessary admissions predischarge review may be initiated for a physician with a high incidence of premature discharges.

If the other interventions do not correct the quality problem, the PRO can initiate the sanctions process, if there is a substantial violation or a gross and flagrant violation. The Secretary of Health and Human Services is authorized

to impose sanctions based on the PRO's recommendation; the Secretary may exclude from the Medicare program or impose a monetary penalty against practitioners or providers.

A substantial violation is a pattern of care over a substantial number of cases that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the documentation of care required by the PRO.

A gross and flagrant violation is a violation which has occurred in one or more instances and which presents an imminent danger to the health, safety, or well-being of a Medicare beneficiary, or unnecessarily places the beneficiary in high-risk situations (e.g., risk of substantial and permanent harm).

The provider or practitioner is then allowed to meet with or provide additional information to the PRO, before the case is sent to the Department of Health and Human Services Office of the Inspector General. For a substantial violation, the provider or practitioner has two opportunities--20 days after receipt of the first sanction notice and 30 days from receipt of the second sanction notice. For a gross and flagrant violation, the provider or practitioner has one opportunity--30 days from receipt of the only sanction notice.

The PRO and the provider or practitioner may agree to a corrective action plan after the first sanction notice. If the problem is corrected during the period of the plan, the sanction process stops. Corrective action plans are not usually used for gross and flagrant violations.

If the case has not yet been resolved, the PRO then sends a recommendation for a sanction to the Inspector General's regional office. The provider or practitioner must be sent a copy by the PRO and has 30 days to submit additional material to the Inspector General.

If the Office of the Inspector General agrees with the PRO sanction recommendation, the Office notifies the provider or practitioner that the sanction

will be effective 15 days from the date the notice is received, and that the provider or practitioner may request an appeal hearing from an Administrative Law Judge. The Office of the Inspector General also publishes a notice in the appropriate local newspaper and notifies other entitites of the sanction.

Sanctions activity increased during fiscal year 1986 following the issuance of April 1985 regulations. As of September 30, 1986, PROs had identified 3,812 cases in which they had detected a pattern of questionable care or a single gross and flagrant episode. First notices were sent to 1,024 providers or practitioners informing them of the possibility of sanctions. In some instances, corrective action was taken. Follow-up notices were sent to 126.

As of January 31, 1987, PROs have recommended sanction action in 93 cases. The Office of the Inspector General acted upon 67 of the 93 cases (the remaining 26 cases are pending in the Office of Inspector General). The 67 cases have been resolved in the following manner: one hospital and 34 physicians have been excluded from the Medicare program; 17 physicians have received a monetary penalty; two physicians are deceased; and 13 cases were overturned by the Office of Inspector General.

3. Scope of Work

a. Focus on the Prospective Payment System. Because the first PRO contract cycle corresponded to the beginning of Medicare's prospective payment system (PPS), Health Care Financing Administration (HCFA) officials state that PROs focused their review on those areas such as utilization where there were incentives to circumvent (or "game") the new system.

The major areas of PRO review, as detailed in the HCFA "scope of work" documentation, therefore included the following:

--Admissions (to assure that they were medically necessary and appropriate);

--Readmissions and transfers (to assure that patients are not discharged too soon or transferred unnecessarily);

--Accuracy of coding (to assure that payments are appropriate for the diagnoses and procedures associated with the stay);

--Day and cost outlier cases (to assure that they are medically necessary and appropriate and warrant additional payment); and

--Identification of quality problems with subsequent corrective action (including education of problem providers and physicians, intensified review, monetary penalties, and exclusion from Medicare payment).

b. Emphasis on Quality. PRO contracts for the 1986-1988 contract cycle continue to require that PROs review areas where PPS can be circumvented. HCFA officials state that the contracts in the second PRO contract cycle also include an increased emphasis on quality review. The new areas of PRO review include the following:

--Providing generic screens 2/ as a tool for identifying potential quality problems;

--Requiring each case selected by the PRO for retrospective review to be reviewed for the appropriateness of the discharge;

--Broadening the scope of the PRO objectives to better address quality issues by focusing on problems identified through generic screen review and statistically identified adverse outcomes such as mortality or premature discharge;

--Reducing the level of PRO review in acceptably performing hospitals, while increasing the level of review in unacceptably performing hospitals; and

--Requiring each PRO to have a community outreach program to educate beneficiaries about PRO review and Medicare rights.

2/ The following generic screens are included as indicators of appropriate care:

--adequacy of discharge planning;
--medical stability of patient at discharge;
--any case where the death of the patient may be an indication of poor quality of care;
--nosocomial infections;
--unscheduled return to the operating room; and
--any trauma suffered in the hospital.

Each PRO also has individual objectives, as approved by HCFA, to achieve. These objectives are tailored to specific problems in the PRO's local area.

For 1986-1988, PROs have the following five objective areas:

--Eliminate adverse outcomes, including premature discharges, by focusing on providers and/or practitioners (based on results of HCFA generic quality screens);

--Eliminate adverse outcomes, including premature discharges, by focusing on providers and/or practitioners (based on HCFA-identified outliers or PRO-identified problems);

--Eliminate adverse outcomes, including premature discharges, by focusing on DRGs (based upon HCFA-identified outliers or PRO-identified problems);

--Reduce unnecessary admissions and/or procedures by providers and/or practitioners (based upon HCFA-identified outliers or PRO-identified problems); and

--Reduce unnecessary admissions and/or procedures by DRGs (based upon HCFA-identified outliers or PRO-identified problems).

Table 1, a comparison of the 1984 Scope of Work to the 1986 Scope of Work, follows.

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TABLE 1. Comparison of 1984 Scope of Work To 1986 Scope of Work

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

TABLE 1. Comparison of 1984 Scope of Work To 1986 Scope of Work (continued)

Review Area	1984	1986
Validation of Objectives	Not in contracts.	Sample of one quarter's discharges to validate objective performance.
Hospital Notices	100 percent where patient or physician disagrees. 100 percent where patient is liable. 10 percent of remaining.	Same.
Speciality Hospital Review	Proposed by each PRO.	15 percent of discharges.
Admission Pattern Monitoring	Discontinued during contract.	Not in Scope of Work.
Intensified Review	Trigger: 2.5 percent or 3 cases (whichever is greater) of cases reviewed. Review increased to: 100 percent or subsets.	Trigger: 5 percent or 6 cases (whichever is greater) of cases reviewed Review increased to: 50 percent or subset (first quarter) or 100 percent or subsets (two or more consecutive quarters.
Community Outreach	Not in contracts.	All PROs to propose program.

Source: Health Care Financing Administration, Office of Medical Review

Representatives of PRO contractors have expressed their concern that the intended mission of PROs has not been clearly articulated by government officials. As a result, they believe there are varying expectations of the balance PROs should maintain between their cost containment and quality assurance activities.

E. Evaluation of PRO Performance

PROs are evaluated by the HCFA regional offices, the HCFA central office, and an independent contractor (known as the "SuperPRO"). The Office of Inspector General has performed audits and inspections of various aspects of the PRO program.

HCFA regional offices are responsible for onsite monitoring of all aspects of PRO performance. The HCFA central office has provided the regional offices with a PRO Monitoring Protocol and Tracking System (PROMPTS) which ties into the regional monitoring. PROMPTS monitoring will be conducted at the 9th month (for on-going assessment which may alert HCFA to situations where a PRO contract termination is appopriate) and at the 19th month (for use in the determination of PRO contract renewals). PROMPTS can also be used to review the performance of regional offices.

If any PRO is found by HCFA to be deficient, the PRO must develop and follow through on a corrective action plan. If corrections are not made, "contract action" may be initiated. Contract action taken in the past include withholding funds from seven PROs and terminating the contracts of three others.

SysteMetrics, Inc. was awarded the contract in June 1985 to become the first "SuperPRO." The SuperPRO is responsible for evaluating a sample of PRO determinations in admission review, DRG validation, and quality of care.

The Office of the Inspector General performs financial audits of PRO contracts in both the first and second contract cycles. The Office of Inspector General also inspects cases which have been reviewed by PROs (e.g., an inspection of cases identified as questionable readmissions or transfers).

IV. OTHER RELEVANT ISSUES

A. Out-of-State Review

The PRO contracts in 10 States are held by organizations based outside those States. 3/ As listed in Appendix B, contracts for the following States are currently held by out-of-State organizations (State in which the out-of-State PRO is based is in parentheses):

Alaska (Washington)

Delaware (West Virginia)

District of Columbia (Maryland)

Guam/American Samoa (Hawaii)

Idaho (Washington)

Kentucky (Indiana)

Maine (Rhode Island)

Nebraska (Iowa)

South Carolina (North Carolina)

Vermont (New Hampshire)

3/ In addition, the PRO contracts for Montana and Wyoming are held by a union of both the Montana and Wyoming medical societies.

HCFA officials say that they award out-of-State contracts in the following four situations:

(1) when States merge their plans voluntarily;

(2) when there is no bid from an organization within the State;

(3) when HCFA considers the bid from an in-State organization to be unacceptable; or

(4) when HCFA considers the bid from an in-State organization to be acceptable, but awards the bid to an organization in another State in the competitive bidding process.

Critics of out-of-State PROs say that they are concerned that these PROs may lose the support of local physicians. They argue that the acceptance of local physicians is critical to the success of PRO review, if PROs are to begin to affect physician behavior.

Others point out that even if a contract is awarded to an out-of-State organization, the actual review is often performed by in-State physicians. They say that administrative efficiencies may be achieved by having PROs review the activities of more than one State. They also argue that an out-of-State organization which performs well may be preferable to an in-State organization that is less acceptable or unacceptable.

B. Health Maintenance Organizations

Under section 1876 of the Social Security Act, qualifying health maintenance organizations (HMOs) and competitive medical plans (CMPs) may enroll Medicare beneficiaries on a so-called "risk-contracting" basis.

Plans contracting on a risk basis are paid a prospectively determined fixed monthly premium, or capitation amount, for each enrolled Medicare beneficiary. Plans are required to provide Medicare enrollees with, at minimum, the same scope of benefits as they would have received had they not enrolled in the plan. The cost of these benefits is, except for limited beneficiary cost-sharing,

financed by the plan. Thus, the plan is "at risk" for any losses if it costs exceed its capitation revenues. This risk is believed to provide plans with a financial incentive to contorl both utilization and costs of services. While this incentive may encourage HMOs and CMPs to reduce their costs by eliminating unnecessary or ineffective care, some analysts have expressed the concern that risk-contracting plans may reduce their utilization and costs such that the quality of care provided will decline. In order to qualify for a risk contract, the HMO or CMP must have an on-going internal quality assurance program.

Prior to the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), there was no specific legislation requirement for any independent, outside review of services provided to Medicare beneficiaries enrolled in risk-contracting HMOs and CMPs, such as the required review of inpatient hospital services conducted by PROs. The HMO and CMP industry argued that such review was unnecessary as all plans are required to have an internal quality assurance program in order to qualify for a risk-contract. In addition, the industry argued that if an external, independent quality review was considered necessary, it would be inappropriate to use the existing PROs for such reviews because PROs are staffed primarily by physicians experienced in the fee-for-service sector. HMOs and CMPs may have patterns of care that provide a high quality of care, but that differ from the traditional patterns of care in the fee-for-service sector. Thus, review by the PROs could force HMOs and CMPs to adopt fee-for-service patterns of care that would not necessarily improve quality but could prevent these plans from achieving their cost-saving objectives. Further, they note that PROs traditionally have focused their review activities on inpatient hospital services rather than to broad spectrum of services provided by HMOs and CMPs.

Others argue that while utilization patterns may differ from HMOs and CMPs to the fee-for-service sector, quality standards should be identical regardless

of the payment mechanism. They also maintain that many HMO and CMP physicians participate in the PRO process.

Based in part on the concern regarding the incentives for underutilization in the risk-contracting program, PRO review of services rendered by HMOs and CMPs was mandated by COBRA, effective for services after January 1, 1987. This provision was subsequently amended by the Omnibus Budget Reconciliation Act of 1986 to allow the Secretary to contract for reviews of HMO and CMP services with entities other than PROs on a competitive basis, but such contracts were limited to no more than half of the States, covering no more than half of the total population of Medicare beneficiaries enrolled in risk-contracting plans. See Appendix E for a list of the States selected for competitive bidding. In addition, the effective date of the mandated PRO review of HMO and CMP services was delayed to April 1, 1987.

HCFA recently issued a "Scope of Work" for implementing review of HMO and CMP services. This Scope of Work identifies three levels of potential review.

First, if an initial evaluation by the contracting review organization of the internal quality assurance program of a risk-contracting HMO and CMP suggests that this internal process is effective, the plan would be subject to a minimal level of external review. This review, referred to by HCFA as a "limited review," would examine inpatient, ambulatory and post-hospital care, focusing on issues of quality, appropriateness and underutilization. Cases would be selected for review if they: (1) met one of thirteen specified conditions based on a 50 percent random sample of 4 selected conditions; (2) were part of a 3 percent random sample of admissions; (3) were part of a 5 percent sample of all non-traumatic deaths; (4) were a hospital transfer case of (5) were part of a sample of readmissions within specified time periods. In addition, the reviewing organization would conduct a focused review of ambulatory services and review complaints by consumers.

Second, if the initial evaluation of the reviewing organization suggests that the internal quality assurance program is not effective, the HMO and CMP would be subject to a higher level of review, referred to as the "basic review" level. This second level of review would focus on similar areas and issues, but would use larger samples.

Third, If the ongoing reviews (at either the limited or basic levels) suggest problems in quality of care, the level of review could be increased to the third level, "intensified review." Under this level, the samples of cases reviewed would be increased even more; for example, 100 percent of all cases having any of 13 conditions, 6 percent of all admissions, and 100 percent of all readmissions.

HMOs and CMPs would move from one level of review to the next, depending on the outcome of on-going reviews and on whether the plan takes steps to address the quality issues identified. The review organization is responsible for notifying HMOs and CMPs when quality problems are identified and for negotiating with the providers on corrective plans. The review organization is also responsible for referring problems to the Office of the Inspector General or HCFA as appropriate, including initiating recommendations for civil money penalties and other sanctions such as termination of Medicare contracts.

Critics of the Scope of Work for review of HMO and CMP services say that the initial quality review (used to determine whether a limited, basic, or intensified review will be used for future review) should be based on a thorough assessment of patient quality outcomes, instead of on an examination of the HMO's and CMP's review process. The critics are concerned that unless a sufficient number of actual medical records are assessed, too large a number of HMOs or CMPs may be placed on limited review plans. Choosing limited review, they argue, without first conducting a more comprehensive review may make it

difficult to gather a valid enough sample to determine if the care rendered is of appropriate quality.

C. Rural Providers and Practitioners

1. Rural Practice Patterns

Some rural practitioners and providers have expressed their concern that urban standards of medical care are being inappropriately applied by PRO reviewers to rural practice.

PRO representatives say they must balance the need for sensitivity to rural conditions (e.g., lack of alternative community resources such as skilled nursing facilities) with the need to assure that minimum standards of care are provided to Medicare beneficiaries. These representatives argue in favor of including local peer physicians in the review process whenever possible.

According to HCFA officials, when they evaluate the performance of PROs, familiarity of the PRO physician reviewer with the practice setting is taken into account. They note that a memorandum was recently sent to the HCFA regional offices reminding them of this policy. HCFA officials also emphasize that PRO criteria are only used for screening purposes and that a denial can only be made by a PRO physician reviewer, and only after the physician reviewer has discussed the case with the attending physician.

2. Off-Site Review

In certain instances, some PRO representatives, particularly those in States with sparsely-populated rural areas, believe adequate resources to send personnel to perform on-site review of all facilities are not available. These PROs, in

order to complete their review functions, have required certain facilities to mail their records to PROs.

Some hospital representatives believe that this places an administrative and financial burden on rural facilities. In fact, the American Hospital Association has filed a suit to recover the photocopying and mailing expenses incurred during off-site review. PRO representatives state that off-site review detracts from the educational benefits that can occur during face-to-face peer review.

HCFA officials respond that during negotiations over the current PRO contracts, they required PROs to complete greater levels of on-site review.

3. The Review Trigger

During the first PRO contract cycle, if 2.5 percent or 3 cases (whichever was greater) of cases reviewed were found to be in error, this would "trigger" a more intensified review.

Hospital representatives say that given the smaller sample sizes taken from rural hospitals, a higher proportion of small and rural hospitals than their urban counterparts were subject to this intensified review.

HCFA officials say that the original threshold of 3 cases was added to the 2.5 percent requirement to handle the problems with small and rural hospitals. To decrease the overall volume of review and to allow PROs to focus on poor hospital performers, the triggers in the second contract cycle have been changed to 5 percent or 6 cases. In addition, the Scope of Work for the second contract cycle has decreased the level of the first quarter of intensified review from 100 percent to 50 percent.

D. Second Surgical Opinions

Section 9401 of The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) requires PROs to perform 100 percent pre-procedure review on at least 10 elective surgical procedures. PROs are authorized to require second opinions as part of the pre-procedure review process if it is warranted. The PRO may approve or disapprove a procedure as reasonable and necessary without requiring a second opinion. The PRO may require a second opinion and allow the beneficiary to decide. The Secretary is required to develop appropriate measures to ensure that second opinions are required only in situations where a second opinion is needed to resolve outstanding medical necessity questions. Payment may not be made if a second opinion was required but not obtained. The second opinion need not necessarily agree with the first opinion in order for payment to be made.

The Secretary is required to specify the type or types of specialists that may perform second opinions for each procedure. The patient may choose any physician of the requisite specialty to perform the second opinion--unless the physician is affiliated with or has a common financial interest with the physician, or if the physician has been disqualified (in accordance with guidelines established by the Secretary) from performing second opinions because of the gross unreliability of past second opinions.

A second opinion would not be required if (1) a delay in providing the procedure would result in a risk to the patient, (2) no physician is reasonably available who is both an appropriate specialist and a parcicipating physician or a physician who agrees to accept assignment for the second opinion, or (3) the procedure is to be performed on a patient who is a member of a health maintenance organization or competitive medical plan with a Medicare risk-sharing contract.

PROs are required to serve as referral centers for second opinions. PROs must maintain a list of physicians qualified to perform the second opinion, advise the patient as to which physicians are participating or who have agreed to accept assignment for second opinions, and assist patients in referral to a qualified physician. The PRO is required to obtain and forward the relevant medical records to the physician providing the second opinion, if requested to do so by the patient.

Beneficiary deductibles and copayments are waived for second opinions (and a third opinion, if the second is in disagreement with the first).

The Department of Health and Human Services (HHS) is developing regulations to implement the pre-procedure review provisions. HHS has assembled a physician panel (which included representatives from the American Medical Association and physician specialty organizations) to assist in identifying those elective procedures which could be subject to pre-procedure review. HHS has identified 13 procedures; 10 of these procedures were recommended by the physician panel.

COBRA required the second surgical opinion program to be implemented by January 1, 1987. HCFA officials say that they expect the proposed regulation to be issued by May 1987 and the final regulation to be published by October 1987.

The American Medical Association and the American Hospital Association have raised some concerns with regard to the second opinion program. One concern they have expressed is over the identification of specialists who could render second opinions for specific procedures. They have also expressed concern over the potential impact on quality if needed surgery is delayed.

Others argue that the law states that a second opinion would not be required if a delay in providing the procedure would result in a risk to the patient.

Some PRO officials say they are concerned that the objectives of the second opinion program are unclear. They say that they are not sure if the program's primary intent is to educate program beneficiaries (in which case they would give priority to second opinion referrals) or to reduce unnecessary surgery (in which case they would emphasize larger numbers of payment denials).

E. PRO Funding

Initially, PRO activities were funded from Medicare's Hospital Insurance Trust Fund. As PRO review activities expand from inpatient review to include outpatient review (as provided for in the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) and the Omnibus Budget Reconciliation Act of 1986), the Supplementary Medical Insurance Trust Fund will also fund a portion of the activities. Federal expenditures for PRO inpatient review activities were $151 million in FY 1986.

The PRO program is funded outside of the congressional appropriations process. The Social Security Amendments of 1983 provided that there would be a funding floor for PRO review of inpatient hospital care--expenditures in a given fiscal year (for both direct and administrative costs) were not permitted to be lower than expenditures for the program in FY 1982, adjusted for inflation. COBRA changed the funding floor to the level of expenditures for the program in FY 1986, adjusted for inflation. The Omnibus Budget Reconciliation Act of 1986 provided that PRO review for certain outpatient activities shall be funded at an amount determined by the Secretary to be sufficient to cover the costs of specified review activities.

The President's Budget proposes to fund the PRO program at $176 million in FY 1988. In a recent hearing of the Senate Committee on Finance, Secretary of

Health and Human Services Otis Bowen said additional funding would be made available to the PRO program if required.

Some PRO representatives argue that the Administration is not sufficiently funding the PROs. They say that even though the scope of their reviews has been modified and expanded (e.g., COBRA requires additional review of assistants-at-surgery for cataract surgery), the resources available to carry out their new functions have not been renegotiated.

F. Variations in Medical Practice Patterns

Several studies have observed that there are large geographic variations in patterns of care. For example, Wennberg showed that the likelihood that a woman in Maine would have a hysterectomy by the time she reached 70 years of age ranged from a low of 20 percent in one community to a high of 70 percent in another. 4/

There may be justifiable medical explanations for such variation, but some observers have interpreted these variations as indications of inefficiencies in patterns of care. It has also been suggested that these variations exist due to the lack of definition as to what the most appropriate care is; that is, when there is disagreement among physicians as to the best approach for treating a particular problem, there will be large variations in practice patterns.

According to some, these variations identify opportunities for the Medicare program to the quality of care and to the number of unnecessary procedures. The PRO program is seen by some as one way to reduce unnecessary variation. Because the program is organized on a statewide basis, PRO decisions often reflect medical practice differences from State-to-State.

4/ Wennberg, J. E. Dealing with medical practice variations a proposal for action. Health Affairs. v. 3, no. 2. Summer, 1984. pp. 6-32.

In addition to interstate variations, Congress has also paid attention to intrastate variations. The Omnibus Budget Reconciliation Act of 1986 required the Secretary of Health and Human Services to provide at least 12 PROs with assistance in review and analysis of small area variations in utilization of hospital and other services for which Medicare reimbursement is made. Congress intended that the PROs would use the small area variation information in establishing priorities for review activities and in conducting educational programs for community physicians.

Senator MITCHELL. Good morning, ladies and gentlemen. I welcome you all to this hearing, and look forward to the testimony that will be presented by the scheduled witnesses today.

The purpose of this hearing is to examine the Peer Review Program under Medicare, which is directed by Congress to assure quality of care and utilization review for most services provided to Medicare patients.

The committee is interested in learning how well the Health Care Financing Administration is implementing the Peer Review Program, and how the PROs are carrying out their responsibilities to insure that quality care is being provided to Medicare beneficiaries.

The mandate that the Peer Review Program assure quality of care is the central focus of this hearing. I and others are well aware of the record of utilization control by the PROs, but I must say that I am skeptical of the quality of care aspect of the PRO processes implemented to date.

Have Medicare beneficiaries been denied necessary care in the name of cost containment? If so, is the practice widespread? We hope to learn the answers to those and other questions today.

Members of this committee recently expressed their concern to Secretary Bowen and the Office of Management and Budget about the apparent lack of funding for the expanded responsibilities assigned to Peer Review Program, as mandated by COBRA. We want to hear from the PROs themselves on this subject and look forward to testimony from the American Medical Peer Review Association.

I share the concern of a number of senators on this subcommittee about the performance of PROs in rural areas. Rural doctors from Maine to Texas have expressed serious concern about the sanctioning process under PRO review. This issue has been the subject of national attention in recent weeks, and we look forward to the testimony of Congressman Stenholm on that matter.

I support the concept of peer review. It is a necessary and valuable check on the delivery of health care services to the elderly Medicare beneficiaries. I also believe, however, that there are some problems with implementation of the program. We want to learn what those problems are and how we can best correct them.

I want to assure the physicians and providers sanctioned by the PRO that if that happens, it is done for a justifiable cause and that they have the right of due process in the sanctioning procedure.

We all want a budget for the PRO program that is adequate to do the job that the law mandates. And an adequate budget for the PRO program will not serve program or the Medicare beneficiaries.

Quality of care for Medicare beneficiaries must remain our highest priority. While we, of course, must control the enormous and rising cost of the Medicare program and reduce unnecessary hospital admissions and other medical procedures, we must place the health of elderly Americans—whom this program is supposed to serve—at the top of our agenda.

I am encouraged by the amount of interest in this hearing, and look forward to working with my colleagues to make improvements in the PRO program that will continue to control utilization, but will also assure quality care for Medicare beneficiaries.

I am pleased to be joined today by my colleague, the former Chairman of this subcommittee who served as Chairman with great distinction and is responsible for a good deal of the health care legislation in this country, Senator Durenberger. Senator, welcome.

Senator DURENBERGER. Thank you very much, Mr. Chairman. I applaud you for holding this hearing, and you have well stated the concerns that we have all had since the beginning of this program.

There is no responsibility more important for this committee than its oversight of the program, which Congress set up to insure the beneficiaries are protected and given high-quality medical care.

The PRO also makes certain that the government purchases quality care, not mediocre or second-class or bad care, and appropriate care, not inappropriate or less than appropriate care.

And finally, the PRO program helps Congress keep faith with the working generation of taxpayers of America, who finance 92 percent of the Medicare program, by guaranteeing that the Medicare program is a wide and prudent purchaser of medical services.

But with the economic incentives turned around, the role of the PROs is paramount in making certain that beneficiaries are given the best quality care and that there is no underservice.

The PROs have a tough job. But the job is more important today than ever before. We count on them to help us see what midcourse corrections are needed as we undergo this revolution in health care. We undertake to add services, encourage better use of outpatient care, and live with changes in clinical practice that affect all of us. We must look out for the frail elderly.

I have been holding special meetings throughout Minnesota, and I've heard from hundreds of seniors, disabled beneficiaries, physicians, nurses, allied health personnel, administrators, and citizens groups. The best summary that I heard of the concerns that the medical profession has for frail elderly was given in very impressive testimony by Dr. Ann Vogel of New Ulm, Minnesota. I'm submitting her statement. It is not only an excellent description of what she and her colleagues are experiencing today, but it brings together articulately and humanely what many are experiencing throughout America.

I hope you all will have a chance to read her testimony. It comes from the head and the heart of an impressive physician in rural America.

[The statement of Dr. Ann Vogel follows:]

Concerns Regarding the Medical Needs of
The Elderly in Brown County and Surrounding Area

January 17, 1987

Ann C. Vogel, M.D.,
Practicing Physician,
New Ulm, Minnesota,
Sioux Valley Hospital and
Surrounding Nursing Homes

I have been involved in the Minnesota PRO (PSRO before these) for the past 10 + years. Presently, I am a physician reviewer and board member of the Foundation for Health Care Evaluation located in Minneapolis and Burnsville.

The comments which follow come from my listening to a wide range of providers (health care) and particularly physicians in the state of Minnesota, as well as physicians who are members of the American Medical Directors Association (AMDA) - which is a national organization of over 600 physician Medical Directors of LTC facilities in this country, as well as my personal experience taking care of Medicare patients before and after the 1984 change in the reimbursement mechanism and introduction of the new rules and regulations and policy implementation regarding the review of admission criteria, length of stay, etc.

Let me preface my comments by saying: The new PRO review process initiated in 1984 has helped to cut down unnecessary medical expenses in many areas and I welcome that. However, there are some vulnerable Medicare patients who are definitely being harmed by it. Most often those frail elderly and acutely ill who have had, for example - strokes, terminal cancer, or developed slow organ failure (heart, lung, kidney), and eventual shutdown - and who may not be able to receive optimal or even reasonably compassionate care in a nursing home or home care setting. These are the individuals I will largely be referring to in the comments that follow.

The walking well, and fairly mentally alert elderly in this country - who become acutely ill, often have a good chance of a reasonable recovery and they fare much better under our present Medicare system.

Rehabilitation Reimbursement (Level II)

We need to allow Medicare coverage for stroke patients who require more intensive rehabilitative therapy than they often receive before being transferred to a nursing home. Right now some stroke patients who have feeding difficulties or bladder/bowel problems are having feeding tubes and catheters inserted to facilitate their transfer to a nursing home - when under some of those circumstances, a transfer to a Medicare covered rehabilitation bed would have very possibly prevented using either in the first place.

The present metro versus rural reimbursement rate is not equitable and places rural providers at a financial disadvantage. Care often can involve use of the more expensive medical technology.

Admission criteria (hospital) for Medicare patients need to be modified for the frail elderly. Examples of modifiers which would work include: psycho social, medical, functional.

Social: The widowed or others living alone with no immediate relatives or friends available - who could serve as a temporary primary care giver for the patient - usually these individuals live in a very small community or outside the city limits and have no transportation.

Psychological: Psychological impairment that is due most often to some degree of cognitive impairment (i.e. dementia) which prevents an individual from following directions accurately or prevents them from understanding directions aimed at self care. Reportedly, this was vetoed by HCFA's Chicago office.

Medical: The frail elderly who become acutely ill are often those who were chronically ill. They have multiple and often complex medical problems which cause a minor acute illness to become a major acute illness - to manage. And this often requires hospitalization in order not to place them at medical risk in recommending their treatment plan. If it was attempted

to carry out treatment outside the hospital - other preventable medical complications would be likely to occur. Example: an elderly individual with early pneumonia who also has heart disease, diabetes and kidney failure (if it were a younger patient without other medical problems - outpatient treatment would work).

Functional: An individual who can not ambulate safely without ambulatory aids or who has perceptual deficits. Example: a wheelchair confined elderly individual falls and sprains an arm and thus can no longer transfer from wheelchair to bed safely or an individual with flu and poor vision can't read the syringe to make exchanges in an insulin dose. Perceptual deficits such as loss of hearing, vision, or sensation (seen with deafness associated with aging, or cataracts) and loss of manual dexterity (often arthritis in the elderly) - causes elderly who are acutely ill to lose their ability to look after themselves and attend to their personal hygiene and nutrition needs especially where ill or injured. Bladder/bowel incontinence of varying degrees makes outpatient treatment of an acutely ill and frail elderly patient much more problematic and often impossible to do outside the hospital.

More Medicare covered transitional care or swing beds are needed in the patients "home" hospitals. Presently hospitals with bed capacities of 50 or more can not provide this necessary and less expensive care for the frail, acutely injured or ill patients they admit and treat.

For example, presently Sioux Valley Hospital (SVH) is faced with moving "stabilized" acutely ill patients to a nursing home for this care even if it is for a relatively brief period. There is only 1 Medicare approved nursing home in Brown County, which is outside New Ulm. And designated Medicare nursing home beds in Sleepy Eye - west of New Ulm, are almost always filled. Meeting the criteria for admission to these few Medicare nursing home beds in the county can be a headache, impractical, and at times too rigid an interpretation of "allowable reimbursable services.

Stabilized elderly acutely ill, but recovering, patients in SVH must be admitted frequently to a nursing home without Medicare coverage - this results in cost shifting for the patient - i.e. the Medicare age patient must then find the money to pay for his/her own care in these nursing homes. These people were relying on having some Medicare insurance available to take care of their medical expenses in their "hours of need" and are distressed when they find their needed extended care at the nursing home won't be covered. This problem will only increase in years to come - as the demographer's predictions of the rise in frail elderly population comes true.

Smaller community hospitals can only do so much "charity work" and continue to care for the "prolonged recovery or prolonged death" of Medicare patients - before their cash flow suffers and ability to serve suffers.

The criteria which needs to be met for home health care (Medicare) eligibility is too rigid at times - especially as it pertains to the patient who has terminal cancer. One can't predict then, that these patients will die - and sometimes it takes longer than "Medicare coverage will allow". Thus the frail elderly patient, again with very limited resources, must agonize over whether he/she has enough money to pay for the care they need while struggling on with a hopeless (often it is cancerous) illness. I use the latter as an example because it can be the most emotionally and physically draining on all concerned.

The last example of the present cost shifting from Medicare payment to out-of-pocket payment which is occurring, lies in the arena of Home Health Care (HHC). Here "special category" patients such as the terminally ill (again, especially cancer patients) for eligibility of covered services is often too restrictive. Example: Oxygen use, tube feeding use or nutritional supplements, IV tubing, IV medications and extra supplies such as section equipment - under many circumstances is not covered. Often, around the clock nursing in the home may become necessary if no nursing home bed was available and home care was then a consideration for the terminal care and these services are also not reimburseable. The result of this scenario? The remaining survivors - i.e. the elderly spouse, or elderly relatives or responsible family members, if there are any - are faced with potential financial ruin at times if asked to reimburse the providers for that costly labor intensive and at times rather long term - terminal care.

I hope some of these comments help the congressional LTC committee in gaining a clearer, truer picture of the effects of the present cut backs in our Medicare program and the need to protect the benficiaries. If you wish any further information or have additional questions or comments I would be happy to attempt to help in suggesting perhaps other physicians who could add more light on our present dilemma of trying to give needed care to the elderly - especially the vulnerable, frail, ill or injured in this country.

Thank you for your time and assistance.

Senator MITCHELL. Thank you very much, Senator Durenberger. Our first witness today is Representative Charles Stenholm, a Member of the United States House of Representatives from Texas.

Welcome, Mr. Stenholm. We look forward to hearing from you.

STATEMENT OF THE HONORABLE CHARLES W. STENHOLM, MEMBER, U.S. HOUSE OF REPRESENTATIVES, FROM TEXAS

Congressman STENHOLM. Thank you, Mr. Chairman and Senator Durenberger.

Let me say, I appreciate very much the opportunity to appear before you today to discuss an issue of, I know, mutual concern. And I share the opening comments that both of you have made.

As I walked out of my office this morning, I noticed a little plaque that I have in my office. A quotation attributed to President Eisenhower observed that farming is very easy when your plow is a pencil and you are a thousand miles from the corn field. I think this morning my message that I will bring to you in a few brief minutes is that medical care looks mighty easy when your scalpel is a pencil, and you are a thousand miles from the hospital.

I think that's the message that has been coming through as we have been conducting hearings and listening to the people of the 17th District. In the past month and a half, three of us in West Texas, Congressmen representing a good part of the rural areas of Texas that have been affected by some of the problems associated with PROs, have heard from nearly 1,000 individuals.

And I might say to you today, I am very proud of the fact that the Texas Medical Association has been very diligent now in being helpful to us as we attempt to address what possible legislative, as well as regulatory, changes are needed. And I also would say that the Texas Medical Foundation should be handed some commendation for showing some flexibility and willingness to respond to concerns which have been brought to them.

Just this past Saturday, the Texas Medical Foundation—which is the PRO entity in Texas—again voted to make some changes in the protocol reflecting that more and more folks are beginning to recognize that some of the things we have been doing in the past are just not working.

I would like to begin now by telling the committee a little bit about the 35 counties that I represent in West Texas. In that expanse of land, I have four counties which have no hospital in the entire county. Eight of my hospitals have 25 or fewer beds and an additional 22 have 50 or fewer beds. Two counties in my District not only are without a hospital, but additionally, have no physicians, dentists, nursing facilities, or pharmacies. It is not difficult to deduce from this information that health care providers are a rare and treasured commodity in the 17th District of Texas.

Historically, we have not had the easiest time securing those health care providers in the District for obvious reasons. As with so many other rural regions of the country, we must fight to attract and keep physicians and nurses, and to keep the doors of our hospitals open. West Texans are accustomed to fighting hard for their survival and they are willing to make the sacrifices which naturally come as a part of their chosen rural lifestyle. They are not will-

ing, however, to be forced to do battle with their own federal government. And it is precisely the federal government which they see as the greatest threat to the survival of rural health care today.

Let me preface my comments with a strong affirmation of my belief in federal oversight in a program which currently requires a budget of $75 billion for 30 million beneficiaries. Runaway health costs of the past decade, along with the imperative of protecting the public safety, argue convincingly for both utilization and quality reviews of the Medicare program. I refuse to be a defender of either wasteful spending or bad medicine in rural Texas or anywhere else in the country. Furthermore, I too, Mr. Chairman, believe strongly in the concept of peer review. Since I am not medically trained, I certainly do not want to be in a position of determining who can and who can't be reimbursed for treating Medicare patients, nor do I want some group of equally ill-equipped bureaucrats fulfilling that duty. Physician peers are the best qualified individuals to make those determinations.

But while the concept of peer review is sound, I feel there is plenty of room for improvement in the way the PRO law is written, the way the Health Care Financing Administration is administering the program, and the way the various PROs are implementing the process.

Just two weeks ago I conducted a day-long hearing to address rural health concerns in my District. Numerous issues were considered, and I would be happy to provide this committee with a transcript of the comments made on matters such as hospital reimbursement and home health care concerns when it's available to me.

But the session which revealed the greatest sense of anger and fear was that portion which is the most relevant to today's hearing—and that is activities of the peer review organization. It is those concerns, so intensely presented to me, that I wish to pass along to this committee today. And I might add that we listened for seven hours, and we had to turn some people away, because the facility had to be used that night for another purpose.

Now, I've met with angry farmers, I've met with angry educators, I've met with a lot of people mad at me and mad at the federal government and mad at everybody that moves at different times. But nothing compares with the intensity of the feelings that were expressed by well-meaning citizens, doctors, nurses, but also the citizenry as a whole.

One doctor introduced himself as "Dr. so and so, living here in paranoid rural Texas." My own physician in my home town explained that "I have practiced medicine in the United Kingdom for seven years, and now in the United States for seven years. And I have never felt so humiliated, harassed, and afraid to treat patients. I used to feel satisfaction and pride when I treated extremely sick people and they felt better. We did a lot of unnecessary tests to protect from malpractice suits. Now we do them to protect from TMF and HCFA. I'm more afraid of TMF and their sanctions than I am of my own patients suing me."

One of the paradoxes which is an unacceptable inconsistency for my health care providers is that the federal government indicates its acceptance of a difference between urban and rural areas when

it comes to matters such as Medicare reimbursement. And that's a subject for another day, Mr. Chairman. But, then the government denies there is a difference when it comes to expectations, requirements, and regulations as they pertain to those same rural health care givers.

Several weeks ago, a representative from HHS' Inspector General's office addressed Congressional staffers, right here in Washington, on their part in the PRO process. Perhaps the most disturbing thing said during that briefing came in response to an inquiry about the need to account for differences in medical practice between urban and rural areas and to consider the effect on the rural area when a sanction is applied. The panelist's response was, "In the opinion of the Inspector General, no care is better than bad care." Beyond showing a gross insentitivity to the hundreds of thousands of people living in my district, the respondent erroneously equated different care with bad care.

An official of the TMF recently was quoted as saying that if the closing of a few rural hospitals meant that people had to drive 24 miles for care, it was no big deal. Well, for many of my people, the loss of a doctor or the closing of a hospital means travelling a lot further than 24 miles for health care, including emergency health care. Both the fields of medicine and psychology recognize that such transport, however much needed, is a big deal and have named the resulting effect "transfer trauma". This shock to the individual arises from abrupt and involuntary relocation, and has been shown to have its severest impact on the health of an elderly person in involuntary transfers.

Is there really a bias, or at least an insentitivity to rural concerns in the peer review process? At the beginning of this year, sanctions had been recommended against 20 Texas doctors and 16 more sanction cases were pending. Of those 36 cases, 32 involved rural physicians. It's difficult for me to believe that 88 percent of all the questionable physicians in the State of Texas reside in rural America.

When I held my meeting on March 14, I gave strict instructions that I didn't just want to hear complaints; I wanted some recommended solutions. I feel that I should hold myself to that same standard before you today, Mr. Chairman, so I am giving you 10 suggestions—and I won't go into those in the interest of time and brevity today—concerning due process, appeals process, required Inspector General action, administrative and judicial review, retroactivity, public notice, notice on the pre-admission reviews, incentives for education, etc.

We put these together with the best of our ability to this time, based on the recommendations that have come to us. We will be looking at the transcripts of those other suggestions that have come to us. The Texas Hospital Association, and, as I've already mentioned, the TMA and others are looking at this very, very serious problem and are coming forward with concrete solutions of how to make it work better.

In conclusion, Mr. Chairman, again I commend you for holding these hearings today, for bringing the proper focus of your committee—as I know my counterparts on the House side will also be doing—at how we best deliver health care to all of America, and do

it in the most efficient and expeditious and human way that we possibly can.

With those remarks, Mr. Chairman, I thank you very much for allowing me the privilege of being before you today, and would say to you I look forward to working with you in coming up with some concrete solutions to the problem before us.

Thank you.

Senator MITCHELL. Thank you very much, Congressman, for a very fine statement. I gather that your recommendations are directed toward improving the process to providing some due process for those involved in it. You don't recommend that we just totally abolish that process.

Congressman STENHOLM. Absolutely. As I said, I agree with your opening statement and I made it very clear in my statement: the peer review process is a good one. I think that where we have fallen down—and so often we fall down—is in the area of our federal government. We try to superimpose certain conditions on the entire United States when we have to recognize differences in different areas. At the same time, I believe these have been honest mistakes. I don't choose to throw rocks at some of the individuals here today.

As far as some of the quality assurance protocols, and the manner in which we, in Texas—and I judge it's not just a problem for us—have chosen to go about it, I know it's a new program. I think we have been very derelict in our educational processes, and I think mistakes have been made. But I don't want to throw the baby out with the bath water—I want to build on our mistakes and make something that will truly serve the needs of the country.

Senator MITCHELL. Thank you very much, and we look forward to working with you on this matter in the coming months.

Congressman STENHOLM. Thank you, sir.

Senator MITCHELL. Thank you, Congressman.

[The prepared written statement of the Honorable Charles W. Stenholm follows:]

Statement by
Congressman Charles Stenholm

Concerning **Peer Review Organizations**

before the
Finance Subcommittee on Health
March 27, 1987

Mr. Chairman and Members of the Committee, I appreciate having the opportunity to come before you today to discuss what has become one of the most serious concerns in my District: Peer Review Organizations (PROs). I commend the chairman for his wisdom in seeking opinions on this subject and I particularly appreciate the stated emphasis on the effects of PRO actions in rural communities.

Although I have been hearing about the problems of rural health care essentially since coming to the House of Representatives eight years ago, I am encouraged by the expanded attention these issues have been receiving recently. In the past weeks and months, the peer review situation has begun to be examined on many fronts. I am certain that this committee noticed the article which appeared on Tuesday of this week on the front page of that rural town newspaper, the New York Times. During the past month and a half, three West Texas Congressmen have met with nearly 1,000 individuals interested in rural health. Also within the state, I have been very proud of the work being accomplished during the past two months by the Texas Medical Association in addressing peer review issues. Likewise, I have been pleased with our peer review organization, the Texas Medical Foundation (TMF) for showing some flexibility and willingness to respond to concerns which are brought to them. I understand that just this past Saturday the TMF once again voted for some changes in protocol which will allow greater face-to-face contact between reviewers and physicians in the early stages of the process.

Nonetheless, the residents of the 17th District of Texas and I feel we still have considerable ground to cover in improving the peer review system. For this reason I appreciate the committee's attention to the issue.

I would like to begin by telling the committee a little about the 35 counties in West Central Texas which I have the privilege of representing. In that expanse of land, I have four counties which have no hospital in the entire county. Eight of my hospitals have 25 or fewer beds and an additional 22 have 50 or fewer beds. Two counties in my District not only are without a hospital, but additionally, have no physicians, dentists, nursing facilities or pharmacies. It is not difficult to deduce from this information that health care providers are a rare and treasured commodity in the 17th District of Texas.

Historically, we have not had the easiest time securing those health care providers in the District. As with so many other rural regions of the Country, we must fight to attract and keep physicians and nurses, and to keep the doors of our hospitals open. **West Texans are accustomed to fighting hard for their survival and they are willing to make the sacrifices which naturally come as a part of their chosen rural lifestyle. They are not willing, however, to be forced to do battle with their own federal government. And it is precisely the federal government which they see as the greatest threat to the survival of rural health care today.**

Let me preface my comments with a strong affirmation of my belief in federal oversight in a program which currently requires a budget of $75 billion for 30 million beneficiaries. Runaway health costs of the past decade, along with the imperative of protecting the public safety, argue convincingly for both utilization and quality reviews of the Medicare program. I refuse to be a defender of either wasteful spending or bad medicine in rural Texas or anywhere else in the Country. Furthermore, I believe in the concept of peer review. Since I am not medically trained, I certainly do not want to be in the position of determining who can and who can't be reimbursed for treating Medicare patients, nor do I want some group of equally ill-equipped bureaucrats fulfilling that duty. Physician peers are the best qualified individuals to make those determinations.

But while the concept of peer review is sound, I feel there is plenty of room for improvement in the way the PRO law is written, the way the Health Care Financing Administration (HCFA) is administering the program, and the way the various PROs are implementing the process.

Just two weeks ago I conducted a day-long hearing to address rural health concerns in my District. Numerous issues were considered, and I would be happy to provide this committee with a transcript of the comments made there on matters

such as hospital reimbursement and home health care concerns. But the session which revealed the greatest sense of anger and fear was that portion which is most relevant to today's issue: activities of the peer review organization. It is those concerns, so intensely presented to me, that I wish to pass along to this Committee today.

I have met before with angry farmers and I have dealt with angry educators, but I have never heard more anger from my people than I heard that Saturday. The sad thing is that what lies behind their anger is a great deal of fear. One physician from my home county explained, "I have practiced medicine in the United Kingdom for seven years and here for seven years, and I have never felt so humiliated and harassed and afraid to treat patients. I used to feel satisfaction and pride when I treated extremely sick people and they felt better. . .We did a lot of unnecessary tests to protect from malpractice [suits]. Now, we do them to protect from TMF and HCFA. I am more afraid of the TMF and their sanctions than I am of my own patient suing me."

Another doctor introduced himself as "Dr. _____, living here in paranoid rural Texas." People don't just suspect there is a hidden agenda within HCFA to close rural hospitals--they are convinced of it. Well, I don't agree that there is an intentional policy to punish rural hospitals, but I do believe that existing within many federal programs, and especially here with PROs, there is a gross insensitivity to rural realities. Health strategies devised in New Haven, Connecticut or optimal technology formulas based on populations in the Minnesota home of the Mayo clinic may serve those areas well, but they may not be the best medicine for Stamford, Texas. The arbitrary "3 percent per hospital rule" used by TMF in reviewing charts gives the impression of neat uniformity but, in reality, grossly over-examines physicians practicing in rural hospitals and under-examines physicians in urban hospitals.

One of the paradoxes which is an unacceptable inconsistency for my health care providers is that the federal government indicates its acceptance of a difference between urban and rural areas when it comes to matters such as Medicare reimbursement, but denies there is a difference when it comes to expectations, requirements and regulations.

Several weeks ago, a representative from HHS' Inspector General's office addressed Congressional staffers on their part in the PRO process. Perhaps the most disturbing thing said during that briefing came in response to an inquiry about the need to account for differences in medical practice between urban and

rural areas and to consider the effect on the rural area when a sanction is applied. The panelist's response was, "In the opinion of the IG, no care is better than bad care." Beyond showing a gross insensitivity to the hundreds of thousands of people living in my district, the respondent erroneously equated different care with bad care.

An official of the TMF recently was quoted as saying that if the closing of a few rural hospitals meant that people had to drive 24 miles for care, it was no big deal. Well, for many of my people, the loss of a doctor or the closing of a hospital means travelling a lot farther than 24 miles for health care, including emergency health care. Both the fields of medicine and psychology recognize that such transport, however much needed, is a big deal and have named the resulting effect "transfer trauma." This shock to the individual arises from abrupt and involuntary relocation, and has been shown to have its severest impact on the health of an elderly person in involuntary transfers.

Is there really a bias, or at least an insensitivity to rural concerns in the peer review process? **At the beginning of this year, sanctions had been recommended against 20 Texas doctors and 16 more sanction cases were pending. Of those 36 cases, 32 involved rural physicians. It's difficult for me to believe that 88% of all the questionable physicians in Texas practice in rural areas.**

When I held my meeting on March 14, I gave strict instructions that I didn't just want to hear complaints; I wanted some recommended solutions. I feel that I should hold myself to that same standard here today so please let me share a few of those suggestions for improvement with you. I am indebted to all of the participants in my recent hearing for these recommendations, and I especially appreciate our state Medical Association, as well as the American Medical Association for articulating in concrete and specific ways many of the concerns and issues my constituents have raised.

1. DUE PROCESS

In a country where due process is a treasured right, the lack of it stands out starkly in the peer review process. Currently, the PRO law simply requires that reasonable notice and an opportunity for "discussion" be provided to a physician undergoing a possible sanction procedure. Physicians do not have a right to an attorney, a right to present witnesses, nor a right to cross-examine witnesses. While some PROs have attempted to allow the opportunity for meaningful review, such a "privilege" is entirely at their prerogative. The law should be amended to specify appropriate due process requirements which all PROs must follow before recommending sanctions.

2. APPEALS PROCESS

The PRO law should be amended to provide that administative hearings and review be available in sanction proceedings prior to the imposition of any sanctions. Currently, the sanctions come first and then the appeal follows, implying a "guilty until proven innocent" attitude. [Reference: Section 1156(b)(4) of 42 U.S.C. §1320c] My colleague, Ralph Hall, and I have introduced H.R. 1445 (a copy of which is attached) to correct this timing in the application of sanctions. Because there are situations which may arise where a physician would present an "imminent hazard" to the health and welfare of Medicare beneficiaries, I believe that the bill as it currently stands needs to be amended. In these cases of severe and immediate danger, a special expedited hearing process should be provided so that due process isn't ignored, but meanwhile, the safety of senior citizens is protected.

3. REQUIRED IG ACTION

The law permits certain sanction recommendations from the PRO to go into effect automatically if the Office of Inspector General does not act within 120 days of the recommendation. While it is fortunate that up to this time the IGs have acted within a timely fashion, this laxity in the law should not be permitted. [Reference: Section 1156(b)(1)]

4. ADMINISTRATIVE & JUDICIAL REVIEW

Currently, Medicare beneficiaries have access to administrative and judicial review when adverse utilization determinations are made. (When $200 ore more is involved, an administrative hearing is available; when $2,000 or more is involved, a judicial review is available). The same access should be provided to providers and physicians. [Reference: Section 1155]

5. RETROACTIVITY

Many of my physicians are claiming that new standards are being applied to treatment rendered prior to the standards being adopted. This retroactive application of utilization review and quality assurance standards and requirements should be prohibited. Written notice of new requirements should be provided 30 days in advance of implementation to all providers and physicians, and the new requirements should not be applied to treatment records documenting medical care rendered prior to the implementation date of new standards and requirements. [Reference: Section 1154]

6. PUBLIC NOTICE

The public notice procedures of the Administrative Procedures Act are required for good reason and have served the country well in keeping the public

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informed of potential and actual government action. HCFA, however, has issued many transmittals to the PROs involving significant program policies simply through manual letters. As was held by a District Court last year in American Hospital Association v. Bowen, HCFA should be required to submit for public review all rules that impose "a new procedure or obligation which is not directly derived from the language of a statute or regulation."

7. NOTICE ON PRE-ADMISSION REVIEWS

One of the recurring themes throughout my district meeting was echoed numerous times in the comment, "If the government would just tell us what the rules are, we could figure out how to play the game." Along with the just mentioned recommendations, changes need to be made to the current law to require PROs to provide regular written notice to all physicians concerning the services that are subject to pre-admission review. [Reference: Section 1154(a)]

8. INCENTIVES FOR EDUCATION

Evaluating the effectiveness and efficiency of public sector programs is never an easy task. Often goals and objectives are established more because they are quantifiable than because they are desirable. During HCFA's recent contract renewal process, it became apparent that the administration seems to value and reward aggressive denial and sanction activity. Sanctions may be easy to count, but they certainly are not necessarily the best way to improve the health care provided Medicare beneficiaries. If we are truly concerned about providing access to quality care, shouldn't a PRO receive greater reward for improving physician performance through educational activities? Obviously, HCFA's policy of bonus awards for sanction actions but not for educational activities reveals a dangerous bias on their part. Such a policy should be amended to emphasize educational activities.

9. SENSITIVITY to the NATURE OF RURAL CARE

Numerous physician witnesses at my March 14 hearing raised questions of reviewer competence, appropriateness and representativeness. If reviews are truly meant to be peer reviews, such qualities are vital and imperative. Particularly unsettling to me has been the fact that very few of the top level members of our Texas Medical Foundation represent rural areas. Especially in cases where a rural physician is being considered for santioning, rural reviewers should be involved.

Furthermore, the PRO law refers to national and regional norms of practice for a PRO to use in evaluating services. I believe that PROs should develop guidelines which also reflect local practice patterns, taking into account

that substantive differences between urban and rural care do not necessarily imply qualitative differences in the care delivered. [Reference: Section 1153(c)(7)].

10. SUPPLY OF PHYSICIANS

My final concern, one relating to a chronic rural health problem, involves the ability of rural areas to attract new physicians. With so many of the communities in my district being served by just one to three physicians, cases could easily arise where all of the town's doctors would be sanctioned. In fact, one of my communities is on the brink of facing just such a scenario. Not only does such a situation create tragic consequences for the area's senior citizens, but it threatens health care for the entire community. An already struggling rural hospital which no longer has available physicians to treat more than 50% of its patients (those who are Medicare beneficiaries) will quickly be forced to close its doors altogether.

While I do not have a specific recommendation in this regard, I would appreciate the committee's consideration of what emergency measures and incentives might be possible for encouraging the supply of physicians to a community in such circumstances.

CONCLUSION

Let me conclude by reiterating that I believe in federal oversight of the Medicare program, I believe in the concept of peer review, and I believe in the right of rural citizens to receive quality health care. I am not defending the practice of bad medicine, but I am defending the right of rural physicians who provide invaluable services to their communities to have a system which deals them a fair hand.

Again, I appreciate the committee conducting this hearing and allowing me the opportunity to pass along these grave concerns which have been presented to me by the citizens of rural West Texas.

I

100TH CONGRESS
1ST SESSION

H. R. 1445

To amend title XI of the Social Security Act to ensure physicians hearing and judicial review rights before exclusion from the medicare program.

IN THE HOUSE OF REPRESENTATIVES

MARCH 5, 1987

Mr. HALL of Texas (for himself, Mr. STENHOLM, and Mr. BOULTER) introduced the following bill; which was referred jointly to the Committees on Ways and Means and Energy and Commerce

Mr. Chapman

A BILL

To amend title XI of the Social Security Act to ensure physicians hearing and judicial review rights before exclusion from the medicare program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. PROVIDING PRE-EXCLUSION HEARING FOR PHYSICIANS UNDER THE MEDICARE PROGRAM.

(a) IN GENERAL.—Section 1156(b) of the Social Security Act (42 U.S.C. 1320c-5(b)) is amended by adding at the end the following new paragraph:

"(5) Notwithstanding paragraph (2), a determination under this subsection to exclude a physician shall not become

effective and notice to the public respecting such exclusion may not be furnished—

"(A) before the expiration of 30 days after the date of the notice of such proposed exclusion to the physician, and

"(B) if the physician requests a hearing thereon (under paragraph (4) and section 205(b)) within such 30-day period, until the physician has been provided the opportunity to exhaust the administrative and judicial remedies available under paragraph (4) for review of the determination, including the right for the physician to seek judicial review in the appropriate district court under section 205(g).".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to determinations made under section 1156(b) of the Social Security Act for which a notice has not been provided before the date of the enactment of this Act.

(c) TRANSITION FOR CURRENT EXCLUSIONS.—

(1) PHYSICIANS IN ADMINISTRATIVE AND JUDICIAL PROCEEDINGS.—In the case of a physician—

(A) for whom a notice of determination under section 1156(b) of the Social Security Act has been provided before the date of the enactment of this Act,

(B) who has requested a hearing thereon (under sections 1156(b)(4) and 205(b) of the Social Security Act) on a timely basis before the date of the enactment of this Act, and

(C) who has not exhausted the administrative and judicial remedies available under section 1156(b)(4) of the Social Security Act for review of the determination,

the Secretary of Health and Human Services shall—

(i) suspend the exclusion of the physician under section 1156(b) of the Social Security Act beginning on the date of the enactment of this Act and ending on the date the physician has exhausted the administrative and judicial remedies available under paragraph (4) of such section, and

(ii) provide notice to the public, within 14 days after the date of the enactment of this Act, of the suspension of the physician's exclusion.

(2) PHYSICIANS WHO MAY STILL REQUEST AN ADMINISTRATIVE HEARING.—In the case of a physician—

(A) for whom a notice of determination under section 1156(b) of the Social Security Act has been provided within 365 days before the date of the enactment of this Act,

(B) who has not requested a hearing thereon (under sections 1156(b)(4) and 205(b) of the Social Security Act) on a timely basis before the date of the enactment of this Act, but

(C) who requests such a hearing on such a timely basis and by not later than 30 days after the date of the enactment of this Act,

the Secretary of Health and Human Services shall—

(i) suspend the exclusion of the physician under section 1156(b) of the Social Security Act beginning on the date the physician requests such a hearing and ending on the date the physician has exhausted the administrative and judicial remedies available under paragraph (4) of such section, and

(ii) provide notice to the public, within 14 days after date of such request for a hearing, of the suspension of the physician's exclusion.

The next witness is Dr. William Roper, the Administrator of the Health Care Financing Administration. Dr. Roper.

(No response)

Senator MITCHELL. Kind of a central witness to the process.

Good morning, Dr. Roper. Welcome, and we look forward to hearing from you.

STATEMENT OF WILLIAM L. ROPER, M.D., ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. ROPER. Thank you, Senator. Mr. Chairman and members of the committee.

Senator MITCHELL. Dr. Roper, before you begin, I did want to say that Senator Bentsen had intended to be here today, particularly to hear Congressman Stenholm, but was unavoidably called out of town. Senator Bentsen has a statement which will be inserted in the record, and has a series of questions for other witnesses, which will be submitted in writing. Thank you, doctor, and please proceed.

[The questions from Senators Bentsen and Heinz follow:]

TEXAS PRO REVIEW

Q. Chairman Bentsen. In recent weeks, I've heard a great deal from rural physicians in Texas about the PRO program. The allegation has been made that the review processes used by PROs may subject rural physicians to a level of scrutiny more rigorous than that of their urban colleagues. As I understand it, this situation may occur because rural doctors must, of necessity, practice more conservatively. For example, facing a choice between asking a patient in pain to drive 60 miles home and back the next day, or admitting him to the hospital, the physician may admit him, even if not all the medical indications are certain.

What can you tell me about how the PRO review process takes into account the unique circumstances of rural health care delivery? How do you assure that the decisions of rural physicians are reviewed by those of their peers who understand the realities of rural health care? Are "rural" peer reviewers those from truly isolated communities, or is the definition of "rural" fairly broad?

A. Dr. Roper. The concept of peer review, and the PRO statute, require that PROs use typical patterns of practice within the geographic area as principal points of evaluation and review. Therefore, PROs apply local standards of medical practice to the cases they review. This includes the use of peer physician reviewers who are familiar with local standards of medical care. We recently issued a reminder to all PROs emphasizing the importance of using physician reviewers who practice in a like setting to that in which the physician whose services are under review practices. This includes, for example, using a PRO physician reviewer who practices in a rural setting to review services provided in a rural setting. We have intentionally not defined "like setting" or "rural versus urban" to provide PROs with greater flexibility in using physician reviewers who are truly peers of the physician whose services are under review.

We assure that PROs use appropriate physician reviewers through monitoring performed by the HCFA regional offices. In addition, the regional offices and "SuperPRO" (SysteMetrics, Inc.) review samples of PRO determinations to assure that PRO determinations are appropriate.

The PRO review process has flexibility regarding review determinations in that all factors which impact the patient's need for hospitalization are considered (i.e., medical, environmental, etc.), regardless of the urban or rural setting. Therefore, the PRO physician reviewer may consider, for example, either travel distance or environmental factors when determining the need for hospitalization under Medicare.

Questions from Senator John Heinz

Q. Senator Heinz. I believe that it was more than a year ago that HCFA contracted with 7 PROs (including California, Alabama, and Florida) to do a study of premature discharges. What is the status of these studies? When will the results be provided to Congress? What have you learned from this study?

A. Dr. Roper. Six PROs were selected to participate in the pilot study to determine the extent of premature discharge occurring under the PPS. The selected PROs and types of study are:

Alabama, Arkasas, Iowa:	Concurrent and retrospective review of discharges to a SNF.
California:	Discharges with a readmission occurring within 8-20 days and discharges where the patient expired within 20 days.
Florida:	Retrospective review of discharges to a HHA or SNF.
Oregon:	Retrospective and concurrent review of specific hospital discharges by DRG and development of a discharge readiness scale.

All of these studies have recently been completed. In addition to confirming that there is no systemic problem with premature discharge, our review findings include:

- Very few patients are being transferred to SNFs prematurely.
- The rate of inappropriate transfers to swing beds is higher than inappropriate transfers to SNFs.
- There is frequently a lack of adequate documentation in medical records for discharge planning.
- There is a need to increase documentation of patient psycho-social environment and caregiver status in the medical record.
- The incident of premature discharges related to the PPS could not be assessed due to lack of data prior to PPS implementation.

The individual PRO reports have been made public and are available. No specific report to Congress is planned.

Q. Senator Heinz. Would you favor the AHA's proposal to allow providers to appeal PRO decisions to an administrative law judge and judicial review?

A. Dr. Roper. In our view, The PRO review process assures adequate due process for providers and physicians. Hospitals and physicians are provided an opportunity to discuss a proposed denial determination with the PRO physician before it it issued. Also, after the issuance of a denial, the hospital and/or physician again have the opportunity to discuss all aspects of the PRO denial and may present all relevant information during the reconsideration.

We have recently strengthened our PRO sanctions process and will soon be sending out instructions to implement the modifications. Under this improved process, physicians will have the right to be represented by an attorney at meetings held by the PRO to consider a sanction. The attorney may assist the physician in the presentation of evidence and testimony by witnesses. Such meetings will be held by the PRO within 30 days of a request by the physician in question and verbatim records of meetings will be made available to the physician. Additional information relevant to the possible sanction can be submitted by the physician within five working days following the meeting, if the PRO agrees. Any PRO physician who may reasonably be expected to be personally biased with respect to the physician in question will not be party to the PRO's judgment.

In addition, the HHS Inspector General has agreed to seek a regulatory alternative to the current process of publishing local newspaper notices regarding physicians excluded from Medicare. The change would permit such physicians to personally inform their Medicare patients that Medicare would no longer pay for the physicians' services.

Finally, while a provider is not entitled to an appeal of the medical necessity of the care, it is entitled to appeal a determination (under Section 1879 of the Act) that it knew or should have known that care was noncovered. Section 1879 entitles a provider to an ALJ hearing when it is found to be financially liable for a furnished service and the amount in dispute is $100 or more. Adverse determinations under section 1879 by an ALJ involving $1000 or more entitle a provider to an appeal to a Federal court.

Q. Senator Heinz. You have indicated in your testimony that you plan to release hospital data by the end of the year. I assume that they will focus on individual hospital mortality and morbidity rates, as they did in March 1986. What did HCFA learn from last year's experience, and what changes do you plan to make this time around, either with respect to the analyses themselves, or how the data are to be released?

A. Dr. Roper. HCFA found that a provider might appear on the mortality list for factors not linked to quality of care problems. We have already changed parts of our analytic methodology. We will be seeking the advice of nationally recognized experts on both the nature of the data to be released as well as the methodology. In addition, we will be seeking public comment on the data and methodology. Finally, we will take measures to allow the affected hospitals opportunity to comment on the reason they are or should not be on an outlier list; and we will have their comments published.

#1 Follow-up: Did those list of outlier hospitals help PROs to identify quality of care problems? Can you give me any examples?

The mortality outlier lists were instrumental in the PRO's identification of quality of care problems. When identified, these quality of care problems were included as part of their contract in one of the PROs objectives. Below are a few examples:

- The Connecticut PRO found seven DRG or DRG-pairs which represented 38 percent of a hospital's deaths. A reduction of 118 deaths over the 2-year contract is proposed by the PRO.

- The Illinois PRO has identified seven hospitals with quality of care problems. The PRO will focus review in those hospitals to determine if the high mortality rate was caused by incomplete, inadequate treatment or premature discharge.

- The Kansas PRO has three of the four hospitals on the mortality outlier list linked to DRG 089 (pneumonia) objectives.

#2 Follow-up: To what extent did PROs find that the hospitals on that list of high mortality rates could explain the cause of those rates to be other than quality of care problems?

Since this is HCFA's first attempt to identify quality problems using this statistical model, no aggregate count has been compiled. Contract objectives submitted to date indicate a significant number of problems identified as a result of the list. HCFA has determined a number of factors, not related to quality of care, which explain a hospital's appearance on the list, including:

- o teaching hospitals
- o severity of illness
- o patient mix
- o standard of care
- o morbidity rates.

Q. Senator Heinz. It has now been almost a year since COBRA mandated that PROs deny payment for poor quality care. When will HCFA issue the regulations to implement this provision? What has been the reason for the long delay?

A. Dr. Roper. The current schedule for implementing this provision requires that the regulations be published in final to be effective on October 1, 1987. We are very aware of the sensitivity of this provision and have taken steps to assure a broad range of input on our implementation plans. On June 24-25, 1986, we convened a panel of physicians from 16 medical societies, specialty societies, and PROs to advise us.

Since that time, we have drafted the regulation to implement this COBRA provision. The draft regulation includes the mandated guidelines by which the PROs will develop their review criteria, model denial letters, and levels of severity for which denials will take place.

We have continued to involve the industry in the many issues surrounding implementation of the quality denial provision and will provide the general public with an opportunity to comment on proposed rules.

We are proceeding to implement this provision as expeditiously, but as carefully, as possible. We believe that the consultation with PROs, and medical and specialty societies, as well as the opportunity for public comment, will promote a quality denial process which is effective and equitable for all concerned.

Q. Senator Heinz. What are HCFA's plans for implementing the sections of OBRA requiring that the PROs review quality of services in all health care settings, including post acute and ambulatory care settings?

A. Dr. Roper. I believe that the implementation of the OBRA provisions for review of SNF, home health, hospital outpatient, and ambulatory surgical center services will fulfill the requirement, set forth by OBRA, to assure that PROs review the quality of care provided in all settings. Specifically, plans are underway to implement OBRA provisions for review of:

- a sample of hospital readmissions within 31 days of discharge including a review of the SNF, home health, and hospital outpatient posthospital services to assure that services meet professionally recognized standards of quality;
- beneficiary complaints about the quality of hospital, SNF, and home health care;
- a sample of ambulatory surgical procedures; and
- quality of care provided by health maintenance organizations and competitive medical plans.

Q. Senator Heinz. How many sanctions for poor quality of care have been recommended by the to PROs to HHS?

A. Dr. Roper. 112.

Q. Senator Heinz. How many physicians and providers have actually been sanctioned?

A. Dr. Roper. 61 physicians
1 provider

Q. Senator Heinz. Provide a State-by-State breakdown of sanctioning activity.

A. Dr. Roper. There have been a total of 34 PROs which have submitted sanctions:

Arkansas	6
Arizona	1
California	19
Colorado	2
District of Columbia	1
Florida	2
Georgia	1
Iowa	9
Idaho	1
Illinois	2
Indiana	1
Kansas	4
Kentucky	3
Louisiana	1
Maryland	1
Maine	1
Michigan	2
Missouri	3
Mississippi	1
North Carolina	3
New Hampshire	1
New Jersey	3
Nevada	1
New York	2
Ohio	4
Oklahoma	1
Oregon	1
Pennsylvania	1
South Dakota	1
Texas	17
Virginia	5
Washington	5
Wisconsin	4
West Virginia	2
	112

Q. Senator Heinz. Why is it taking so long to implement the COBRA provisions requiring second surgical opinions? They were supposed to be in place January 1, 1987. When do you anticipate that program will actually begin?

A. Dr. Roper. We are working toward implementation of this requirement of COBRA.

o We plan to publish this summer in the Federal Register, a Notice of Proposed Rulemaking (NPRM). This will allow the medical community, interest groups and the general public to comment on the content of the NPRM, and for HCFA to consider those comments before publication of a final regulation. Our schedule is to publish a final regulation in the fall of 1987. Implementation will follow shortly thereafter. The draft regulations were developed through a series of progressive steps, including:

+ Gathering data on the frequency with which certain procedures were performed.

+ Convening a team of physicians who represented the major medical specialties to assist in identifying the surgical procedures.

+ Developing a draft list of specialists, whose specialized training and experience with particular procedures qualified them to perform a second opinion in one or more of the identified procedures, and;

+ Circulating the list of procedures and types of physicians qualified to render second opinions, as well as an implementation strategy to numerous interest groups including the American Hospital Association, the American Medical Association, the American College of Osteopathic Surgeons, the American College of Surgeons, the Federated Ambulatory Surgery Association, and the Society of Office Based Surgery.

Q. Senator Heinz. Who is reviewing the care of Medicare HMO patients that are currently in the hospital? Has there ever been a time when that was not the case in any State? Who is reviewing the care of those patients in ambulatory care settings?

A. Dr. Roper. PROs are responsible for reviewing the care provided to Medicare HMO patients in the hospital. PROs have had this responsibility since the beginning of their first contracts. The only instances in which PROs have had to relinquish this responsibility involves several terminations of PRO contracts for poor performance. In each instance, the Medicare fiscal intermediary performed the review until a new PRO contract was awarded.

Except for preadmission review on risk HMO patients, the review is identical to PRO review performed on PPS cases. PROs were notified in December 1985 to discontinue preadmission review because, in contrast to the PPS system, risk HMOs lack incentive for unnecessary hospital admissions.

By June 1, in response to requirements under OBRA of 1986, review of risk HMO cases will entail quality review of inpatient and outpatient services, including services in the ambulatory care setting.

Dr. ROPER. Thank you, Senator. I am pleased to be here this morning to outline our efforts to assure quality health care in the Medicare program.

Before I get into the specifics of the PRO program, I want to assure the committee that Secretary Bowen and I have no higher priority than quality health care. We are pleased with our progress to date in improving the PRO program. We're not satisfied that it's a perfect system, or even an almost perfect system. But it's one that we're making improvements on, and we feel it is very, very important to Medicare.

The full title of the PROs in the law is Utilization and Quality Control Peer Review Organizations. In the first contract period—1984-1986—we initially oriented these organizations towards utilization control to be sure there was no gaming of the new prospective payment system. Our experience with the first contract period taught us many things and we have taken deliberate action to improve the PRO program during the second contract period.

We have intensified PRO efforts on quality and revised the PRO scope of work to focus on quality. Now, every case a PRO reviews, whether it is part of a random sample or for a specific purpose such as DRG validation, is subjected to a series of generic quality screens. This ensures the broadest possible quality review.

Every case a PRO reviews is subjected to a review to be sure the discharge is appropriate and not premature. Every PRO must develop objectives which focus on eliminating adverse outcomes. All related readmissions within 15 days, and soon to be 31 days, are reviewed.

We are targeting reviews to benefit hospitals that are performing well. We have reduced the overall national average for hospital review from about 42 percent to about 26 percent, and targeted this review to areas in which we will get the most possible benefit from it.

We have added an important requirement to PRO contracts to assure that beneficiary concerns and problems are sufficiently addressed.

We have implemented significant management initiatives to improve our administration of the program. In this regard, last summer, at Secretary Bowen's request, I undertook a thorough review of the PRO program, meeting with representatives of physician groups, the hospital groups, consumers, and the PROs themselves to listen to their problems and to hear their suggestions. We developed a "PRO Action Plan" to address these concerns. More specifically, we sought to improve our management of the program, as well as the performance and effectiveness of PROs.

For example, we have improved communication between our central office and our regional offices. We have established new, improved procedures for responding to questions and clarifying policy. We have improved our policymaking by seeking advice from a wide range of advisers. And we have developed a new PRO monitoring protocol and methodology.

We have implemented most of these recommended actions already. We held a follow-up meeting in December to report on progress and to hear further suggestions.

In addition to the major program improvements, we are moving to implement the PRO provisions of COBRA and OBRA. These Acts significantly broaden the duties of PROs in assuring quality. Let me highlight our progress in that regard.

PROs were given the authority to deny Medicare payment when they find care to be of substandard quality. They were also given the mandate to review elective surgical procedures before surgery occurs and provide for a second surgical opinion in certain cases. These are important matters, raising sensitive and complex issues, and we are going to go through the public comment process to shape these changes, to put them in place appropriately. We plan to publish proposed regulations in May.

In December, we issued instructions to implement the requirement that PROs review all requests for using assistants at cataract surgery, effective March 1. In addition, last month we issued our scope of work for quality review of health maintenance organizations and competitive medical plans. We expect that program to be in place by June.

Besides making program changes and working to implement new provisions, we have reemphasized our enforcement philosophy. It is our intention to ensure rational action based on facts. We will attempt to identify problems, change practice patterns, and educate. By the same token, we will move aggressively to correct problems as quickly as possible and, if circumstances merit, we will not hesitate to invoke the most severe penalties available.

In all cases where a PRO finds quality problems, corrective action will be taken, ranging from education of the individual physician or hospital, to intensified review, to payment denials, and if appropriate, to exclusion from the Medicare program.

In cases where PRO educational efforts have failed or where a PRO identifies a gross and flagrant threat to quality, PROs will recommend sanctions, which may ultimately result in the exclusion from the program.

We take these sanctions very seriously, Mr. Chairman. We are not anxious to impose sanctions. We are anxious to educate and change behavior where necessary. But we do have a responsibility to protect beneficiaries.

Finally before I conclude, I want to mention several important activities we are engaged in to deal with possible problems in the future. One is, we are investing substantially in research on measuring quality and quality outcomes. Also, we are beginning a major effort to develop appropriate information to release to the public on the performance of hospitals. The purpose of this effort is to provide important data to consumers on which they can make decisions; and also to provide PROs with some statistical indicators of potential problems.

This is a somewhat controversial matter. We are proceeding carefully with the full advice and input from consumers, hospital organizations and others. But, it is something we are committed to do, and to do this year.

Let me conclude by saying that we think we have an effective PRO program, but I assure you we are not completely satisfied with it. We will continue to work with consumer advocates and

representatives of the health care community to refine and improve our efforts.

I would be happy to answer your questions.

Senator MITCHELL. Thank you very much, Dr. Roper. Before we begin the questioning, I would like to recognize the presence of two Senators who have joined us during your testimony. Senator Rockefeller, do you have an opening statement you wish to make?

Senator ROCKEFELLER. I do not, Mr. Chairman.

Senator MITCHELL. Senator Pryor?

Senator PRYOR. Mr. Chairman, I do have, but I don't want to delay you and the committee. I would just ask that my statement be submitted into the record.

Senator MITCHELL. That's fine. That will be done.

Dr. Roper, in testimony before this committee earlier this year, Secretary Bowen said that additional funding, above the amount requested in the President's budget, would be made available for PROs, if required. Do you believe that additional funding is required? Do you intend to request additional funding for the PROs, particularly in light of the additional responsibilities placed on PROs in recent legislation?

Dr. ROPER. Yes sir. I do believe additional funding is required, particularly, as you say, in light of the new responsibilities. We have developed a request for additional apportionment of funds. That has now been given to the Office of Management and Budget, and we're in discussions with them about those matters. I expect them to be concluded shortly.

Senator MITCHELL. How much have you asked them for?

Dr. ROPER. Over two years, COBRA and OBRA will require about $130 million.

Senator MITCHELL. Over two years.

Dr. ROPER. Yes sir.

Senator MITCHELL. Equally divided among the years?

Dr. ROPER. It's more in the second of the years, because we're already into Fiscal 1987.

Senator MITCHELL. All right. Could you provide us with a breakdown of that? How much the first year and how much the second year?

Dr. ROPER. Yes sir.

Senator MITCHELL. If you don't have the figures right in mind.

Dr. ROPER. Yes sir.

[The information follows:]

PRO REQUIREMENTS TO IMPLEMENT COBRA/OBRA

[Dollars in thousands]

	FY 1987	FY 1988	Total
COBRA	$17,509	$73,401	$90,910
OBRA	18,242	786	19,028
Total	35,751	74,187	109,938

In addition, to complete the second funding cycle, we have requested support ($19.2 million) to cover the cost of photocopying of provider medical records required for the accurate review of care.

Senator MITCHELL. And would you also notify the committee as soon as you can what the results of your discussions with OMB are.

Dr. ROPER. I'd be pleased to do that.

Senator MITCHELL. We'd like to be kept abreast of that.

Dr. ROPER. Yes sir.

Senator MITCHELL. Right. And as soon as you complete your discussions with OMB, I assume you're going to make the additional request to the Congress?

Dr. ROPER. The funding of the PROs is done through an apportionment process and not an appropriation. We request the money to be apportioned to us from OMB. It's not something that we need to come forward and request an appropriation for.

Senator MITCHELL. I see. So that will get it done once you complete that?

Dr. ROPER. Yes sir.

Senator MITCHELL. All right. Good. In your testimony, you refer to corrective action, such as education, which PROs may order when they find a quality problem with a particular physician or other provider. Would you explain in what detail what actions you have in mind there, and tell us whether you believe the PROs are adequately staffed and funded to successfully implement other corrective actions?

Dr. ROPER. The process always emphasizes education, because what we found out in our discussions this summer that I mentioned in my testimony is all the parties with an interest in this matter—the physicians themselves, the PROs, the hospitals, and the consumer groups—want to have physicians continuing in the program practicing good medicine.

And so at the first instance of a deficiency and throughout the program, we will have the PROs stress corrective action, pointing out to physicians and others what problems they see in their performance, and urging that they seek continuing medical education and other kinds of corrective action.

When that fails is when the other steps in the process come into play. You asked if the PROs have the resources to do those things. Yes sir, they do.

Senator MITCHELL. You've explained that the emphasis in the second round of contracts has shifted from utilization control to quality assurance. In evaluating PRO performance, how much emphasis will be placed on the number of admissions denied, which means money saved, as opposed to the quality of care provided? And a related question, are there denial quotas that PROs must meet in order to show that they're being cost effective?

Dr. ROPER. The second point first. We manage the PROs and much of the rest of what HCFA does using performance criteria that we use in a management by objectives format. We do have expectations for the PROs, but these are not hard and fast guidelines that they have to issue so many traffic tickets, if you will, or they are judged to be not performing satisfactorily. If they do not issue a certain number of denials, then we expect an explanation of why the work that they are overseeing is so much better than the rest of the country, for example.

Senator MITCHELL. How do you decide how many, in advance, how many denials should be made by a PRO?

Dr. ROPER. It's a judgment that our staff comes up with. It's purely an arbitrary judgment, but it's based on the past two years of experience with the PRO program.

Senator MITCHELL. Well, you know the criticism is that it's an arbitrary judgment based on cost objectives and unrelated to the reality of the care being provided. And it's kind of hard for me to see how what you've described would be interpreted by the PROs themselves as anything other than a quota.

Dr. ROPER. It's not a quota though, Senator. It's one of many criteria that we evaluate them by. Denials are not the important matter. The question is, "Are the PROs fully reviewing the utilization and quality process?" If no denials are issued, provided that they have done their work, we're satisfied. These are not quotas.

Senator MITCHELL. Well, I'll come back to that. We now proceed to questioning by the members in the order of their appearance this morning. Senator Baucus?

Senator BAUCUS. Thank you, Mr. Chairman. Dr. Roper, you in your statement acknowledge the differences that face rural physicians compared with urban. What, in your view, should PROs do to acknowledge that difference, that is to be sure that there aren't urban doctors reviewing rural practices, and therefore their view would be unfair, inaccurate or just not the quality review that would otherwise be the case? What, in your view, should PROs do? What changes should they make to be sure that rural physicians get a fair review?

Dr. ROPER. Throughout the program, Senator, we are stressing that this be really "peer" review. And as your question implies, for that to be the case, a rural physician needs to be reviewed by another rural physician.

Senator BAUCUS. Would that be on site?

Dr. ROPER. In some cases it means on site, in other cases not necessarily. But rural physicians ought to be reviewed by rural physicians. And we've instructed the PROs firmly that that's the case.

Senator BAUCUS. When should it be on site and when not?

Dr. ROPER. On-site review is something that is useful in some occasions. On-site review means the reviewer goes into the hospital record room and sits down and reviews the record there. He does not review on the ward with the doctor standing at the patient's bedside. We believe that on-site review has its place, and would rather do more of that than less of that. But, it's a question of reviewing the charts in the hospital record room versus reviewing them at the PROs office and sending the charts back and forth in the mail. On-site review is not to be all to end all, is what I'm trying to say.

Senator BAUCUS. I know the difference. I'm just asking again, when should there be on site and when not?

Dr. ROPER. I don't have a hard and fast rule for you. We like to do it when there is real occasion to educate the physician and to help shape behavior.

Senator BAUCUS. What does HCFA intend to do if PROs do not pay adequate attention to the rural nature of the review? That is, either do not have sufficient on site reviews, or do not have physi-

cians who are familiar with rural practices so that there is a real problem. What will HCFA do if PROs do not have an adequate rural review procedure?

Dr. ROPER. That will be something that they'll be judged on in a negative fashion. We'll give them bad marks. We are evaluating their performance continually, and we expect them to do a good job in this area like all the others. If they perform so inadequately, we can terminate their contract or put their contract up for competitive bid next time around.

Senator BAUCUS. I understand that HCFA is in the process of coming up with regulations requiring second opinions for certain elective surgery. What criteria are you going to use as to when a second opinion should be necessary?

Dr. ROPER. The specifics are that for certain diagnoses second opinions will be required. For other diagnoses they may be required. We're working out the details of that and will publish our plans in a notice of proposed rule making shortly, seeking comment from all interested parties on this matter.

Senator BAUCUS. The debate then is for certain procedures it will be required and for other diagnoses it may be required?

Dr. ROPER. Yes.

Senator BAUCUS. When do you expect to come out with that?

Dr. ROPER. May is our proposed publication date for the NPRM.

Senator BAUCUS. Is there any thought to not requiring second opinions in remote areas, rural areas, where it's very difficult to get a second opinion?

Dr. ROPER. I'd be glad to take that suggestion, Senator.

Senator BAUCUS. You have just been given a note on that.

Dr. ROPER. Yes.

Senator BAUCUS. What's it say? [Laughter.]

Dr. ROPER. We'll certainly take your suggestion seriously. [Laughter.]

Senator BAUCUS. I appreciate that and I urge you to do it. You said you would do it, and that's good, because it's clear that many, many parts of the country, the very remote areas have a set of circumstances that are much different than urban areas. It's very difficult to get a second opinion on surgery in rural areas of the country.

Dr. ROPER. I certainly understand. Yes sir.

Senator BAUCUS. Thank you very much.

Senator MITCHELL. Thank you, Senator Baucus. Senator Rockefeller?

Senator ROCKEFELLER. Thank you, Mr. Chairman. Dr. Roper, Senator Baucus raises a question of differences between rural hospitals and urban hospitals. Also, I might note there has not been, in the state that I come from, overwhelming complaints with respect to our PRO's treatment of either category—although there have been some complaints. But, could you argue that a rural hospital should not be held to the same standard as imposed on the urban hospital? Because, a hospital in a rural area simply doesn't have the resources to meet that standard?

But then, you could also turn right around and say from a health care and quality point of view, that proper health care is proper health care, regardless of the problems of rural hospitals. Just as

there is consolidation of schools, these may have to be consolidation of hospitals? That is of course an idea which would be highly undistinguished politically.

How do you, in fact, address that problem?

Dr. ROPER. Well, throughout the PRO program, Senator, judgment is required. The essence of the judgment of a physician's peers is paramount in the program. Where there are things that can be done to take into account the unique circumstances in rural areas, we want to do that. But finally, as I believe your question implies, Medicare beneficiaries in rural areas are entitled to quality care, high quality care. And we will manage this program to see that that's the case. We are not going to have second-class Medicare beneficiaries in rural areas or urban areas or anywhere else.

Senator ROCKEFELLER. But you are, in fact, aren't you, almost by definition of the financial constraints on rural areas?

Dr. ROPER. Well, the prospective payment system for hospitals and the methodology we currently use for physicians have a differential payment for urban and rural areas. That's built into the system, at least in the first instance, because of different costs of doing business, cost of living in urban and rural areas.

I'm convinced that at times in the past we have overcompensated urban areas as opposed to rural areas. But I think OBRA 1986, the bill you all passed last October, went a long way towards remedying the disadvantaged position of rural hospitals.

Senator ROCKEFELLER. This is a new subject to me in terms of looking at it from the federal point of view. The scope of work for PROs grows. And if one considers the public's instinct and Congress's instinct, it will continue to grow. We are asking the PROs to do more things—review of quality of care, second opinions, all kinds of things.

Now there are fewer people who want to become nurses. It's harder to get doctors to serve in rural areas. The Administration doesn't want to continue the national health service corps. One wonders—about all of the review, the paperwork, and the accounting entailed in this PRO system. There is this tremendous amount of paperwork that's involved. Doctors whom I have talked with are enormously discouraged by that, not because it represents some vast federal intrusion—although many of them would look at it that way—but just because it's a pain. Paperwork is a pain. Paperwork is a pain for me. I despise it. I suspect you despise it. We do it because we have to do it. Then at some point we just sort of go nuts, and paperwork, like a house of cards, just comes tumbling down.

Do you think that at some point in the future this is a problem with this program?

Dr. ROPER. We've certainly been given a lot of ambitious new responsibilities.

Senator ROCKEFELLER. I don't want you just to be positive, upbeat about this.

Dr. ROPER. We are doing our darnedest to comply with the additional duties you gave us in COBRA and OBRA. But, if I can respond to your paperwork burden question, just implementing the new responsibilities you've given us is a formidable task. But, we're determined to do it and do it well.

Senator ROCKEFELLER. All right. Mr. Chairman, one final point. HCFA has a growing tendency of issuing new policies and mandates to the PROs which result in new rules. The healthcare providers are finding out about these new rules through manual letters and transmittals, rather than through a formal rule-making process. Now that is one area where I hear a lot of criticism from my state. People are very unhappy about that. The same pattern is being alleged by home health care agencies.

There is, in fact, I believe a law suit against HHS this issue in the home health area. Do you have comments on that?

Dr. ROPER. We are anxious to make policy in an informed fashion. We don't desire to make policy in a vacuum. At times we decide to issue manual instructions, which is a somewhat more informal way of doing business than through the formal rule-making process.

I'm determined, even when we issue manual instructions, to do so after thorough consultation with all the interested parties. But finally, I'm convinced that on some increasingly important matters, we are just going to have to swallow hard and realize it's going to take longer, and go through formal rule making.

PRO denial for substandard care—a provision that was put in the COBRA statute—is such an important matter, with such far-reaching implications, that I'm determined we've got to use rule making rather than the manual instructions, although we understand from our counsel that we could do it without going through rule making. But, although it may make us late in implementing your provisions, I think rule making is the prudent course on matters of such overwhelming importance.

Senator ROCKEFELLER. Thank you, Mr. Chairman.

Senator MITCHELL. Senator Durenberger had been here earlier, Senator, and returned. So he is next in line. Senator Durenberger?

Senator DURENBERGER. Just one question, Mr. Chairman. Dr. Roper, we have heard a lot about—I have, I think we all nave—since the institution of this program that a lot of hospitals, and it's particularly painful in small rural hospitals, have been providing a lot of information by way of record copy. Photocopying costs are—they may not look like much around here where the government ends up paying for it—but out there, where the government doesn't pay for it, hasn't paid it, it's a very, very substantial burden on small hospitals.

I understood that you had made a commitment to some of us that—after you lost your court case—that we, the government, would start paying for the photocopying costs. And the last I heard about where all this was at was "It was somewhere in OMB."

Dr. ROPER. Last week I sent a letter to Carol McCarthy, the President of the American Hospital Association, telling her that we will pay for photocopying under these circumstances.

Senator DURENBERGER. Starting when?

Dr. ROPER. Immediately. It has taken us much longer to implement than I thought it would—several months to get the i's dotted and t's crossed—but we're doing it.

Senator DURENBERGER. Can you be specific?

Dr. ROPER. Specific about how much we're going to pay, or what?

Senator DURENBERGER. No, can you be specific—two issues. One, can you pin it down to like May 1, June 1, something like that? And then second, what can you say about payment retroactively for costs already incurred?

Dr. ROPER. We plan to begin paying for photocopying now. The issue of retroactivity is one that we've not addressed. But, I think it is important that we undertake paying for the cost from here on.

Senator DURENBERGER. Well, as of today is what, March 26th?

Senator BAUCUS. 27th.

Senator DURENBERGER. 27th. You mean that hospital costs incurred as of March 27th or as of the date of your letter to Carol McCarthy will be paid for for sure?

Dr. ROPER. April 1st. [Laughter.]

Senator DURENBERGER. April what year? [Laughter.]

Dr. ROPER. 1987.

Senator DURENBERGER. April 1st, 1987. The issue of retroactivity was not addressed.

Dr. ROPER. No sir.

Senator DURENBERGER. Do you need help from us to address it? Maybe a reconciliation or something?

Dr. ROPER. I think what is important is doing the right thing in the future. We'd be glad to continue discussions about what to do in the past.

Senator DURENBERGER. Thank you.

Senator MITCHELL. Thank you, Senator Durenberger. Senator Pryor?

Senator PRYOR. Thank you, Mr. Chairman. Dr. Roper, a couple of questions about the appeal process. I've been looking at some way to try to achieve some balance in the system of providing equivalent appeal rights to providers and beneficiaries alike.

It is my understanding that currently providers may only appeal to the PRO on claim denials and they cannot appeal through the Administrative Law Judge level. Is that correct?

Dr. ROPER. If the process goes to referral of a potential sanction to the Inspector General, then the Administrative Law Judge process kicks in. But, within the PRO itself there is not a provision for an ALJ hearing.

Senator PRYOR. So the provider and the beneficiary have separate appeal processes, I guess you would say?

Dr. ROPER. Yes sir.

Senator PRYOR. I wonder if you would comment on any proposal that we might seek to offer that would give the provider the same rights as the beneficiary.

Dr. ROPER. The process of considering and issuing denials, considering and referring for sanctions is one that we're studying very carefully right now. I have met with leadership of physician groups, including the AMA, and we are studying whether we ought to make administrative changes in our process. I'm not sure the administrative process needs to be exactly the same for beneficiaries and providers. But, I think we need to consider whether making changes and improvements in the process is merited, and we are, as I said, studying that carefully. I am doing that in concert with the Inspector General.

Senator PRYOR. Is there any inherent or philosophical reason why the provider and the beneficiary should not have the same process to utilize?

Dr. ROPER. I don't have a philosophical difference, no sir.

Senator PRYOR. Let's go then, is there a bureaucratic reason?

Dr. ROPER. What we are surely going to do is consider denials of payment for quality of care, and the consideration is already there for potential sanctions for quality of care. And I can see that there is a difference, as far as protection of beneficiaries' need, from the way we deal with providers, especially in matters of quality. That's a philosophical difference, not a bureaucratic difference.

We need to protect beneficiaries, and at times that requires more expeditious action than is available if you go through the Administrative Law Judge process every step of the way.

Senator PRYOR. In the last two sessions of the Congress, I have introduced legislation to create a separate HHS review commission, which would contain all HHS Administrative Law Judges. Now, Senator Heflin of Alabama has a similar proposal, but his would even extend this concept further. It would create a unified ALJ corps, with separate divisions for different benefit areas.

I wonder if you might comment on Senator Heflin's proposal, or maybe you might like to comment on my concept? Are you familiar with these proposals?

Dr. ROPER. Yes sir, I am. We seem, Senator, to be groping for what is the right degree of due process to grant, especially to doctors and hospitals, to ensure their legitimate rights without burdening the system. And, frankly, I understand, and I have heard from providers about their concerns. But, I have a concern that we might well go so far as to set up a process that would have us embroiled in so much due process that years and years and years will pass before we make any determinations.

Again, in the area of quality assurance, there are times when poor quality care is what has happened, and we need to be able to act, and act expeditiously. I would be concerned about adding further levels of review that impeded our ability to act quickly where necessary.

As to whether the ALJs ought to be grouped together in a single unit in or out of the Department, I'd defer to your judgment. I'm not a lawyer and don't have a strong view one way or another on those kinds of administrative matters.

Senator PRYOR. I think our time is about up, Dr. Roper.

Dr. ROPER. Yes sir.

Senator PRYOR. Thank you.

Senator MITCHELL. Dr. Roper, I have to say that I am still troubled by the question of denial quotas. Without in the slightest questioning your good faith, over two years ago, Mrs. Davis sat right where you are sitting and assured us, unequivocally, that there were no quotas, there was no pressure on the PROs to deny, that quality of care was to be a prime consideration as the law required.

We've gotten a lot of information suggesting that not to have been the case over the past two years. You, yourself, have just said here this morning, you've acknowledged that the denial, the expected denial rate is an arbitrary figure. You simply make up a

number that you tell someone you expect them to deny. And if they don't deny that many, they must explain it to you.

It is a very troubling thing. I just don't see how that can have any affect on the PROs—the people operating the system—at least subconsciously of feeling they must meet those targets, whatever the realities of the cases that they review or they are going to be in trouble. And you have hanging over their heads the prospect of the renewal of the contract coming up periodically.

I just don't know. There is no way the law can be written to ensure that will be executed as intended. It requires people who implement the law to, in good faith, do so in the manner intended. All I can do is reaffirm to you that the law is very clear—that quality of care is to be, is a principle objective of the process. It is not to be subordinated to utilization. There are not to be quotas or whatever you called them, that have the effect of emphasizing one factor and subordinating the other, which appears to have been the case over the past couple of years, and indeed seems to me is implicitly acknowledged by you when you say that you're going to emphasize quality of care in the next round of PRO contracts.

I guess I can't answer anything more than your words of reassurance. That's about all you can do. But, do the best you can to reassure us, will you?

Dr. ROPER. May I enlarge on my earlier comments?

Senator MITCHELL. Yes. Fine.

Dr. ROPER. I think the point you raise has been one of the real misfortunes of the first contract period. My predecessors and I have said what we're trying to do and people have come back and said, "But, that's not what is playing out in the field."

One of the things I learned this summer, as we went through this process of reviewing the PRO program and how it was operating, was that we've not always done a good job in communicating the message from Washington and Baltimore through our regional offices to the PROs themselves.

There are several levels of communication there. And while I'm convinced that the senior leadership of the agency has been saying and meaning what I have been relating to you, I don't put all the blame on our observers. I think perhaps down where the rubber meets the road, people have interpreted these suggestions as stronger points than that.

I just reiterate to you the points I made in my opening statement, though. We have taken several steps and plan to take more to ensure that we do communicate much more clearly, and that people understand what we're saying.

And on this point, we are not setting up arbitrary quotas.

Senator MITCHELL. Why do you need any figures at all? The law says you are to review and to keep those two objectives in mind—utilization and quality of care.

Dr. ROPER. Sure.

Senator MITCHELL. Why do you need to then say, here is a suggested or, in whatever form you've stated, here is a suggested number that you have to reach in denials. Why do you need that? How does that do anything other than distort the process in favor of that criteria as opposed to the other?

Dr. ROPER. I understand your point, Senator. And I'm not certain that it is absolutely necessary. I'll go back and think about that. The point I would further make, though, is we have a whole series of criteria on which we evaluate the PROs. This is only one of them. In this day and age of competitive bidding, we try to make our evaluation of the PROs as quantitative as possible so that when we're called to task on why we gave a contract to somebody and not to somebody else, we can point to the numerical score and say your contract bidder was here and the other one was there.

The reason, throughout this particular aspect of the evaluation, we have put numbers in is so we could quantify things. Maybe this one has been so misunderstood and misperceived, we ought to re-evaluate it. I'll pledge to you that we will.

Senator MITCHELL. Thank you very much, doctor. Senator Baucus?

Senator BAUCUS. Thank you, Mr. Chairman. Dr. Roper, when we last spoke about rural PRO reviews, and particularly on-site reviews, you stated that on site reviews are when the documents in a rural hospital are looked at. Wouldn't it make more sense for on-site to mean also interviewing the hospital administrator or medical staff to get a much better sense of the realities and situations, rather than a cold sterile document?

Dr Roper. Sure. If we had unlimited resources, it would be best in every instance to talk to all parties involved personally. My point, though, Senator, is at the first instance when you are looking for potential problems that will then be followed up on more vigorously—a few of them will be followed up on more vigorously—it is a paper review at that level. And it doesn't seem to me to be an essential point whether that paper review is undertaken in the hospital record room or some miles away.

Senator BAUCUS. Well, let me tell you. There is a big difference between rural and urban hospitals. Big difference.

Dr. ROPER. I understand. You've told me that several times.

Senator BAUCUS. Well your answer somewhat disturbs me. And as you say, I've told you that. Do you have any direct experience of that?

Dr. ROPER. I grew up in a rural state and have worked in rural hospitals. Yes sir.

Senator BAUCUS. How recently have you been to a rural hospital?

Dr. ROPER. How recently?

Senator BAUCUS. What was the size of that hospital? How many beds?

Dr. ROPER. I'd have to reflect on it. It's been a few years.

Senator BAUCUS. It's been a long time, hasn't it? I suggest you get back to a rural hospital and see what they are all about.

Dr. ROPER. I'd welcome that.

Senator BAUCUS. They're different. They're much different than urban hospitals. When you do, you will realize that on site reviews, the nature of interviewing staff and administrators, etcetera, are critical.

Second, does HCFA have any records that show whether there is a difference in payment denials, comparing on site with off site reviews?

Dr. ROPER. I'm not aware of that, but would be glad to provide you an answer for the record. I don't know.

Senator BAUCUS. Could you, please? I would appreciate that if you could so I can see if there is any correlation.

Dr. ROPER. Certainly.

Senator BAUCUS. I suspect there might be more payment denials when reviews are not done on site. And I'm just curious whether your data would support that or not.

Dr. ROPER. I'd be glad to.

Senator BAUCUS. Thank you.

[The information follows:]

We have no data on this issue. However, we do not believe the location (onsite, offsite) of the review has an impact on the denial rate. Most PRO review is retrospective and the services being reviewed have already been performed at the time the review is completed.

Senator MITCHELL. Senator Rockefeller?

Senator ROCKEFELLER. Mr. Chairman, this is more amusing than a musing. Not necessarily amusing.

Again, it is sort of philosophical. I'm trying to struggle with this, Dr. Roper. The purposes of PROs are to protect beneficiaries from bad care and to protect Medicare from paying for unnecessary or inadequate care and to weed out incompetent providers. Now, again I want to say that the PRO in my state of West Virginia is well respected. It is considered to be fair. Dr. Harry Weeks runs it, as you know, and he's well regarded.

I guess what I'm trying to get at—and I know how important this is to the country—but is the system really working—saving money and weeding out incompetent people? I'm concerned about the so-called misery index involved in trying to make it work.

I have some data here from one of our hospitals—an urban hospital in West Virginia. Of the 451 cases in a certain DRG category which were reviewed by the PRO, 185 of those cases were questioned, which is 41 percent, and it goes on like that.

What comes out of it which is so beneficial? In other words, is it helping seniors, weeding out incompetence, preventing Medicare overpayments, and so on? The cost and misery involved, and with Congress adding on more responsibility, concerns me. How do you justify that it's working? I know that's kind of a dumb question.

Dr. ROPER. It's not dumb at all. It's probably the most important question of all. My conviction—and it's a strong conviction, Senator—is that this is a very worthwhile program. It's a program fraught with judgment, as I have said earlier, but I think the people who are involved in this process—from the doctors in practice and the hospitals themselves, the people who work for the PROs, the people who work for HCFA—are hard-working people who are trying their darnedest to do a good job.

And I think the benefits are substantial. We have figures to show that the number of cases denied and the economic value of those cases are well in excess of the cost of operating the program.

But I surely would not try to justify this program on economic grounds. I think the importance is in providing assurance, first of all to beneficiaries, but also to family members and leaders like yourselves, that this is a program that is operated in the best interest of the people who are depending on it—the beneficiaries.

And I think despite the frustrations and the hassles of a lot of people involved in the process, it is doing that. We could surely do a better job, but I think it's something that if we didn't have, we would have to create something that looked very much like this.

Back in July, as I mentioned earlier, Secretary Bowen and I spent several days talking with the leaders of the various groups who have an interest in this matter. And we came out of those meetings with the firm conviction that this is a program that is very worthwhile and ought to be continued.

If I can just conclude, the program depends on the good faith effort by everybody involved. One of my concerns is that we maintain the good faith, particularly of the doctors of America, because if that hassle factor that you describe gets so high that we can't get good doctors willing to serve on the boards of PROs and be involved in the review process, then we're going to have real problems.

And I have a continuing concern that we not go so far as to cause those kinds of problems.

Senator ROCKEFELLER. Do you want more tasks from Congress?

Dr. ROPER. Frankly, I'd like a little while to implement the tasks that I've already been given. I'd like a breathing spell here.

Senator ROCKEFELLER. Thank you, Mr. Chairman.

Senator MITCHELL. Senator Durenberger?

Senator DURENBERGER. Bill, one question on the photocopying. Are you going to ask OMB for the money for the next six months?

Dr. ROPER. Yes. We have already asked for the money, and, as I said, we're in discussions about the 1987 budget. I hope for a decision shortly on that. But we've reached agreement that we are going to pay for the photocopying.

Senator DURENBERGER. We just don't want the PROs to have to work that out of the small amount of money they already have granted.

Dr. ROPER. I agree. This is a new cost.

Senator MITCHELL. Senator Pryor?

Senator PRYOR. Mr. Chairman, I don't have a question, but I would like to associate myself with your remarks and your line of questioning relating to quotas. And I'm very glad that you raised this issue because we sat in this room about three years ago and heard the Social Security Administration come before us and testify that there were no quotas in disability determination cases for the Social Security recipients.

They stated 50 times, I guess, to committees of Congress that there was no quota system. Yet, everyone, everyone knew that there was a quota system. ALJs had a quota system that they were mandated to—nothing in writing, but everyone knew it. And, I think Senator Mitchell has touched on a very, very serious problem here, and I associate myself with his remarks and hope that you will take his remarks and ours seriously about the quota system process.

Thank you, Mr. Chairman.

Senator MITCHELL. Thank you, Senator. Dr. Roper, thank you very much for being with us today.

Dr. ROPER. Thank you, sir.

Senator MITCHELL. And we look forward to working with you on this and other matters.

The next witness is Dr. Thomas Dehn, the President of the American Medical Peer Review Association.

Dr. Dehn, welcome. We look forward to hearing from you.

[The prepared written statement of William L. Roper, M.D. follows:]

STATEMENT OF

WILLIAM L. ROPER, M.D.

ADMINISTRATOR

HEALTH CARE FINANCING ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON FINANCE

UNITED STATES SENATE

MARCH 27, 1987

Mr. Chairman and Members of the Committee, I am pleased to be here to outline our efforts in assuring quality health care to our Medicare beneficiaries.

Before I get into the specifics of our Peer Review Organization (PRO) Program, I want to assure this Committee that Secretary Bowen and I have no higher priority than quality of care. I would also tell you that we ~~are not satisfied~~ that we have a perfect system of quality assurance or, frankly, even an almost perfect system. Rather, we are pleased with our progress and the course we have set for continued improvement.

The full title of PROs in the law is Utilization and Quality Control Peer Review Organizations. In fact, during the first contract period (1984-1986) we initially oriented PROs toward utilization control to be sure there was no gaming of the new prospective payment system. Our experience with the first contract period taught us many things and we have taken deliberate action to improve the PRO program during the second contract period.

- o We have intensified PRO efforts on quality and revised the PRO scope of work to focus on quality.
  - Every case a PRO reviews, whether it is part of a random sample or for a specific purpose such as DRG validation, is subjected to a set of generic

quality screens. This ensures the broadest possible quality review.

- Every case a PRO reviews is subjected to a review to be sure the discharge is appropriate and not premature.

- Every PRO must develop objectives which focus on eliminating adverse outcomes, including premature discharge.

- All related readmissions within 15 days are reviewed and we will be expanding the provision to 31 days as required by Omnibus Budget Reconciliation Act of 1986 (OBRA). If a premature discharge caused the readmission, PROs will deny payment for the readmission.

o We are targeting reviews to benefit hospitals that perform well, and are increasing our efforts in problems areas.

- We reduced the overall national average for hospital review from about 42 percent to about 26 percent of all Medicare admissions. Our analysis indicated that with proper targeting we could reduce the overall level of review to be just as

effective in ensuring quality while reducing burden, especially on small, rural hospitals. As a result, a good performing hospital gets a minimal review while a hospital with identified problems is subjected to intensified review of identified problem areas, up to 100 percent.

- We added an important requirement to PRO contracts to assure that beneficiary concerns and problems are sufficiently addressed.

  - PROs must develop community outreach programs. For example, in Maine the PRO has a consumer representative on the Board of Directors and a toll-free hot line. The PRO also published a brochure explaining Medicare and the PRO's role.

- We have implemented significant management initiatives to improve our administration of the PRO program. We have taken action that is improving communications and consistency in policy development and implementation.

  - Last summer Secretary Bowen and I met with representatives of physicians, hospitals, consumers and PROs to listen to their problems and suggestions. We developed a "PRO Action Plan" to

address these concerns. More specifically, we sought to improve our management of the program, as well as the performance and effectiveness of PROs. For example, we

+ improved communication between our central and our regional offices;

+ established new, improved procedures for responding to questions and clarifying policy;

+ improved our policy making by seeking a range of opinion on major issues from consumers and health care professionals; and

+ developed a new PRO monitoring protocol and methodology.

- We have already implemented most of the recommended actions. At a subsequent meeting with the Secretary in December, consumer and industry representatives gave us considerable praise for our quick action to resolve many of their problems and implement many of their suggestions.

In addition to the major program improvements, we are moving to implement the PRO provisions of the Consolidated Omnibus Reconciliation Act of 1985 (COBRA) and the Omnibus Budget Reconciliation Act of 1986 (OBRA). These acts significantly broaden the duties of PROs in assuring quality. I would like to highlight briefly our activities to implement key provisions.

PROs were given the authority to deny Medicare payments when they find care of substandard quality. They were also given the mandate to review elective surgical procedures before surgery occurs and provide for a second surgical opinion in certain cases. These are sensitive and complex issues. We have already obtained a wide range of expert input and we will be asking for public comment on proposed regulations which we plan to publish in May.

In December we issued instructions to implement the requirement that PROs review all requests for using assistants at cataract surgery, effective March 1. In addition, on March 9 we issued our scope of work for quality review of health maintenance organizations (HMOs) and competitive medical plans (CMPs). After review and award of the contracts, we expect the program to be in place by June. This review will address both hospital and outpatient services furnished under these private health plans. The review process will assess the extent to which appropriate services are provided, including whether

underutilization of care and premature discharge of patients have occurred, and whether the setting in which the care takes place is appropriate.

Besides making program changes and working to implement new provisions, we have reemphasized our enforcement philosophy. It is our intention to ensure rational action based on facts. We will attempt to identify problems, change practice patterns, and educate. By the same token, we will move aggressively to correct problems as quickly as possible and, if circumstances merit, we will not hesitate to invoke the most severe penalties available.

In all cases where a PRO finds quality problems corrective action will be taken, ranging from education of the individual physician or hospital, to intensified review, payment denials, and if appropriate, exclusion from the Medicare program.

In cases where PRO educational efforts have failed or where a PRO identifies a "gross and flagrant" threat to quality, PROs will recommend sanctions, which may ultimately result in the exclusion of a physician or provider from participation in the Medicare program.

Mr. Chairman, I want to emphasize that decisions to impose sanctions are not made lightly. Physicians and providers are given several opportunities to rebut or correct any

deficiencies identified by the PRO. And when I say PRO, I want to point out that the PRO physician reviewer is a peer, knowledgeable about the standards of medical practice in the area. We have recently reminded all PROs that rural practice must be reviewed by PRO physicians who practice in a like setting.

Just as PROs monitor the performance of physicians and providers, we monitor the performance of PROs to assure that they are meeting their contractual obligations. We do this on an ongoing basis through our regional offices and through data and reports that PROs submit. If a PRO failed to fulfill its contractual obligations, we would terminate its contract.

Prior to the end of their contract cycle, PROs will be assessed using an objective evaluation process to determine how well they accomplished their overall contract requirements. PROs demonstrating poor performance will not have their contracts renewed. In such cases the contract for the State will be awarded through the competitive bidding process.

Before I conclude, I want to mention several important activities we have initiated to improve the measurement of quality, to use our data to help consumers, and to correct problems in hospitals.

A significant part of our research agenda is being devoted to

improving our ability to assess quality outcomes in specific, measureable terms. We will be bringing the talents of a wide range of experts to bear on the problem, and we are optimistic that these efforts will result in an improvement in the state-of-the-art of quality measurement.

We are beginning a major effort to develop appropriate information to release to the public on the performance of hospitals. The purpose of this effort is twofold:

- It would provide consumers with some important data which will help them make decisions.

- It will provide PROs with some statistical indicators of potential problems. We will require that PROs follow up to determine whether quality problems indeed exist; and, if they do, to take appropriate measures to resolve them.

We recognize that the release of such data is controversial and sensitive both for consumers and the hospital industry. Consequently, although we are proceeding deliberately, we are also proceeding carefully. We intend to obtain the best expert opinion available on our statistical methodology for analyzing data.

Similarly, we intend to get the best possible input from

consumer and industry representatives on the exact type of data we can release and how best to explain its limits and uses. We intend to publish a notice in the Federal Register announcing our intent and soliciting general comment. Finally, we will provide affected hospitals an opportunity to explain why they are (or should not be) on our statistical lists, and we would publish these comments with the lists.

This is a dramatic enhancement in our approach to quality and consumer information. I want to emphasize my complete commitment to this effort. I fully intend to have this major data release completed by the end of this year.

Let me conclude by saying that we think we have an effective PRO program, but I assure you that we are not satisfied. We will continue to work with consumer advocates and representatives of the health care community to refine and improve our efforts.

I would be happy to answer any questions you may have.

STATEMENT OF THOMAS G. DEHN, M.D., PRESIDENT, AMERICAN MEDICAL PEER REVIEW ASSOCIATION, MILWAUKEE, WI, ACCOMPANIED BY ANDREW WEBBER, EXECUTIVE VICE PRESIDENT

Dr. DEHN. Thank you very much, Mr. Chairman. I appreciate the opportunity to address you this morning.

My name is Tom Dehn. I am the President of the American Medical Peer Review Association. And with me is Mr. Andrew Webber, who is our Executive Vice President.

I take note of the fact that on previous occasions I have had the opportunity to appear before this committee where questions were raised regarding whether the PRO program was doing anything. And while I understand that the temperature in the room is rising a bit, it is somewhat refreshing to respond to allegations that perhaps the PRO is doing too much. Someone leaned over to me a few moments ago and suggested that we support your candidacy for Secretary of Health and Human Services in a future Administration. Perhaps you might consider that.

Senator MITCHELL. I'll tell you, Senator Durenberger and I went down and had breakfast with Secretary Bowen the other day, and by gosh, that's a heck of an office he's got there. [Laughter.]

Dr. DEHN. Well, you know, it's a corner office, good view. Not bad.

Senator MITCHELL. Califano spared no horses when he put that in. And I told Bowen that if he gets elected President, it's going to be downhill from his office to the Oval Office. [Laughter.]

Dr. DEHN. I have submitted a written statement, and would appreciate the opportunity to enter that into the record.

Prior to some of my less formal remarks, before Senator Baucus gets too far out of the door, I would like to respond to a question that may not be asked of me. And that is one with regard of on site review, and it deviates a little bit from my prepared comments. But, let me say that the PRO program supports 100 percent on site review—not some, not a little bit, not once in awhile, but 100 percent on site review.

The State of Wisconsin, from where I come, engaged in 100 percent on site review up until approximately a year ago when it appeared that because of limitations on our budget we were nearly bankrupt. And, in fact, it was our state that required copying of medical records, which has become a critical issue. And it was our state PRO that in conjunction with Health Care Financing Administration lost the case. Actually the solution to the problem of photocopying might be adequate funding to do on site review and eliminate the need for photocopying.

Senator BAUCUS. I appreciate how quick you caught me before I got out of the door. But unfortunately, you weren't quite quick enough—you didn't catch Dr. Roper.

Dr. DEHN. We'll get to him on another day.

I have several comments to make, Senator Mitchell and members of the committee, regarding the PRO program with my perspective from the trenches. But, I think that because over the last several weeks the rural-urban issue has become such a hot issue, I'd like to begin with direct comments about that.

In the written testimony that we have submitted as an organization, I would reference page number 5. And if you would indulge me a moment to simply read a short anecdote. A physician practices alone in a community that is about 100 miles away from the nearest tertiary center. The closest physician is in a community that is 15 miles away. In mid-1985—and this is an actual instance—reviews raised some general quality concerns that were forwarded to the regional reviewers in this particular state, in the central office. The twenty most recent Medicare admissions were then copied, all identifiers were removed from the charts, and three individual physicians reviewed those medical records for quality. The resultant review was collected by staff, etcetera, and went through a reasonable due process, and a decision was made to send a 20-day notice to the physician and allow him to meet with the PRO leadership. Upon receipt of the notice, the physician retained an attorney, which seemed appropriate, and met with the Organization's leadership. The meeting resulted in the design of an education program agreeable to both parties that was constituted as follows.

And I need not get into the detail, but what it involved was essentially mini-residencies. This physician was, frankly, practicing, by all reasonable standards, at a significant deviation from what was considered to be norm in that state—and the state, incidentally, is not Texas.

The physician agreed to four. one-week mini-residencies. There was one day a month when he would attend the teaching rounds in the particular hospitals.

The bottom line of the comment is that we pursued,—or that particular PRO pursued, rather than a sanctioning process an educational role. That is to be preferred in all cases. We feel, more than colloquially, that when we sanction a physician we have failed.

The thrust is therefore, and we hope, much more educational than punitive. We understand the concerns that Representative Stenholm raised earlier about due process. It is our understanding that he has introduced a bill and our organization would like to work with him on what he himself acknowledges as some somewhat hazy language in that bill that would probably improve the due process for both the beneficiaries and the providers.

The issues that we are talking about today have arisen because of a re-focus from simply utilization review to quality. And we applaude that. I think that the Health Care Financing Administration does—even though they appeared to get beaten up on a little bit a few minutes ago—deserve some credit for striking a reasonable balance between quality and utilization. We are satisfied with that.

The fact is, however, that quality review is very costly, and it may sound again like a broken record, but there is simply not enough money to do it and do it right. Currently, Senator, in the budget of the PROs there is zero money for education of physicians. We would rather educate the physicians in those—that are single and sole-source providers in these communities, than put them out of business. We would rather educate them. There is zero money in the PRO program for education. And only 6 percent of the pro-

posed budgets for beneficiary education were actually funded by HCFA.

Now, in that regard we would ask you to give us a hand to require first of all a 1 or 2 percent allocation related to the PRO budget, but over and above the PRO budget, to establish some sort of a technical assistance center whereas we can further define how to do quality review. I think we all have to admit it is sort of ethereal and it is probably more judgmental than any of us are really, really comfortable with.

And I think the second aspect is, does it seem reasonable to allocate $150 million a year to review a program where the overall expenditure is $75 billion. That by my calculation comes out to be 1/5 of 1 percent for quality review. The industrial norm is 5 percent, and our industry isn't doing that good in quality assessment in the U.S. And I think we know that.

So we simply ask for money to do the job and to do the job right. And we don't think that that's an unreasonable amount. Perhaps even doubling the budget—$150 million more a year compared to $75 billion is relatively a small amount.

I think equally important, and questions that have arisen by other members of your committee, is the administration of the program. All the money in the world will not ensure a good program if it's not managed appropriately. We would ask for statutory language that the Health Care Financing Administration be required to complete all contract modifications, including the negotiation of additional funding, prior to the implementation of any new directives. My written statement is replete with examples of the kind of time bombs within the PRO program that have been referred to of late as scope of work creep.

Finally, and one of extreme importance to beneficiaries, is the issue of external review of HMOs/CMPs and it's an issue that has not come up yet today. The current scope of work we consider to be moderately deplorable.

Let me explain to you that under the current scope of work there are two levels of review for these organizations where all the fiscal incentives are to undertreat—not just in the hospital, but in the pre-hospital and the post-hospital setting. The current scope of work issued by the Health Care Financing Administration suggests a 60-day review of the paper within an HMO or a prepaid plan, and on the basis of that paper review to determine whether this prepaid plan or risk contract should undergo intensive review or undergo somewhat less intensive review called limited review.

We feel that a more reasonable way to do it is to take a look at the outcomes, the product that the risk contracts are delivering, for six months, maybe a year. And after we get some experience as an external reviewing organization—not necessarily the PRO, but whoever gets that contract—after experience, real hands-on experience with that prepaid plan to then make a determination, yes, you're doing a good job—we'll back off on review; no, you're not doing a job that is up to the standards, and we would like to intensify your review.

I challenge you, if you think that we've had problems under PPS related primarily to hospitals where the fiscal incentives in the hospitals are simply to undertreat, in the prepaid plans there are

broader fiscal incentives to undertreat. We would hope that this would not happen—but the incentives are there to undertreat in the pre-hospital setting, in the hospital setting, and in the post-hospital setting, and they deserve good, thorough external review.

Let me summarize. I would like for our organization and whoever in this room—who as either testifiers or hearing examiners—to work together to identify problems with due process. There are problems. Let's try to clean up those problems.

Again I say, it sounds like a broken record. But if we are truly concerned about quality review, then we're going to have to say it with money.

And finally, let's take another look at the quality review of the risk contracts to assure the beneficiaries that there is adequate accountability in these plans where the fiscal incentives are to limit care, to undertreat. I would be happy to answer any questions. I realize that my testimony was somewhat intense, and I am prepared to offer some specific information with regard to the rural-urban problem in Texas.

Senator MITCHELL. Thank you very much, Doctor, for very informative testimony. You heard my exchange with Dr. Roper.

Dr. DEHN. Yes sir, I did.

Senator MITCHELL. Do the PROs feel that they must meet quotas of some kind? What is the view, the perspective from the PROs on that issue?

Dr. DEHN. Well I appreciate that question. I think it's a question and it's a feeling that the PROs share a concern that at the end of the year, at the end of the two-year contracting period—which we would hope would be extended incidentally—that we may be looked at on the basis of how many scalps we have on the door. But, my feeling is that when the rubber meets the road, I don't believe that any reasonable physician will make a denial on the expectation that the PRO either will or will not get a contract renewal.

To my knowledge, no physician that is engaged in this process makes any money. So they have little interest from a financial basis in whether the contract is renewed. On a philosophical basis we would like to remain in control of the review process as physicians.

Senator MITCHELL. For those PROs which are not physician owned or operated, does it create an internal problem?

Dr. DEHN. It would be difficult for me to speak to that. I think that there are some profit motives in some of the non-physician run PROs. It may in fact determine activity with regard to denials and sanctions.

Senator MITCHELL. Do you know whether any PROs are penalized in performance evaluation for a low denial rate, and if so, are denials which are later overturned counted against them?

Dr. DEHN. I think that all the PROs feel perhaps subtle pressure, but to my knowledge, Senator, no PROs have buckled to that pressure.

Senator MITCHELL. On the question of rural hospitals. In your testimony you said that PRO review must be sensitive to prevailing local conditions, that a minimum standard of care must be upheld irrespective of geographic location.

Dr. DEHN. Yes sir.

Senator MITCHELL. I think that's a statement on which we all could agree. What changes would you recommend in the PRO law or HCFA's rules that would allow necessary flexibility in judgment medical practice in rural areas?

Dr. DEHN. Actually, I believe that the existing rules are in place. A reasonable approach would be to define, with the help perhaps of Representative Stenholm's suggestions, a relatively uniform due process activity which would speak to both the beneficiary and to the provider.

Let me say that the situation that occurred in Texas was one that was fully expected. Texas in unique insofar as they have not had a statewide review organization up until approximately two years ago. And what happens, and with all respect to the physicians who practice in the rural community, many of these physicians are overworked, they practice in isolation, and very frankly, their practice patterns in some cases have evolved in ways that have been somewhat deviant from normal practice patterns that are noted throughout the rest of the country.

In Texas those standards have only recently been applied. And, it is not unusual to see, in the beginning of the maturation process of a PRO or PRO review program, that those physicians that practice in isolation will be sanctioned in inordinate numbers. States as Senator Rockefeller referred to earlier, West Virginia, California, and some of the other states that have been in the business for a long time, show a relatively even split between the sanction process of rural and urban physicians.

Senator MITCHELL. Thank you very much, Doctor. I have several other questions that I would like to submit to you in writing.

Dr. DEHN. Thank you.

Senator MITCHELL. Unfortunately, I have to leave for a few minutes to tend to some other business. I will now ask Senator Pryor if he has any questions. And Senator Durenberger will be returning to chair the meeting. I understand you have to leave as well?

Senator PRYOR. I'm afraid I do.

Senator MITCHELL. Yes. All right.

Senator PRYOR. I would like to ask one question.

Senator MITCHELL. You go right ahead, and then Senator Heinz and Senator Durenberger will be right back.

Senator PRYOR. Fine.

[The questions and answers follow:]

AMPRA TESTIMONY
Dr. Thomas Dehn, M.D.

ANSWER TO QUESTION FROM SENATOR JOHN HEINZ (R-PA)

QUESTION

Would you elaborate on your concerns about HCFA's plans for HMO review. Are you saying that it will provide very little guarantee that the HMOs are delivering high quality, accessible care? How would you improve on HCFA's quality assurance design?

ANSWER

The American Medical Peer Review Association (AMPRA) is concerned that the plan for external review of HMOs/CMPs is flawed. The measure of a plan's performance is not the existence of an operational internal quality assurance process but whether the plan did in fact deliver high quality health care as measured by final patient outcomes. AMPRA is opposed to the requirement of the RFP that quality review organization conduct an initial assessment of plan's performance in only sixty days and that the basis for deciding whether a plan receives a "limited" or "basic" review is the presence of an internal quality assurance mechanism.

AMPRA is in favor of a simple modification of the RFP that would require all Medicare risk contract plans to come under a "basic"

review for the first six to twelve months of the program. At the end of this period, and with the benefit of more reliable data on a plan's performance, the quality review organization would then make a decision to relax or intensify review for each individual plan. Such a program design would conform with congressional intent to emphasize outcome oriented review while still realizing that any system should reward the good performers with reduced oversight.

Senator PRYOR. Doctor, I'm concerned about the process of sanctioning. Let's take a physician who may or may not have done something wrong. I think the system now allows for that sanctioning against the physician—for the sanction to take place and then for the sanction to be actually published before a hearing is held and before that provider, or that physician, has an opportunity to respond or to let's say give his side of the issue. Is that true? Does the system provide for this? I mean, does it allow this, let me say?

Dr. DEHN. I think in some situations it does, Senator. I would like to very quickly——

Senator PRYOR. That's wrong.

Dr. DEHN. That's wrong.

Senator PRYOR. Very wrong.

Dr. DEHN. I would like to quickly take you through the controversial situation, which in fact came up earlier, the typical example that would occur in Texas.

During the performance of a routine review of medical records, a physician and/or hospital may be questioned with regard to the quality of care. Nothing would be done unless, in the judgment of the reviewing physicians, some present danger occurred. At this point, there is no publication of any of this activity.

In Texas, upon that initial review, the quality concerns would go to an 11-member board of medical review made up of not only rural physicians and urban physicians, but also of osteopaths and of M.D.s. Again, the process is still not public knowledge. It still is guarded by confidentiality.

Upon review by that next 11-member board, if that 11-member board finds significant quality problems they appoint a subcommittee to look and to meet with the physician and request in depth an explanation for his or her behavior. Still not published, the physician is still practicing medicine.

At that point if there is significant deviation from good standards of practice—and believe me, that does occur; Dr. Sammons from the AMA says 5 percent of my colleagues practice poorly—we still have an opportunity to negotiate with the physician and seek an educational solution to his problem. It's still not in the papers; it's still not published.

But if that physician is either uneducable or is recalcitrant, then it is by a contract, by law, the PRO must initiate the formal sanction process which then becomes publishable. I think that in all fairness to the system, the system does afford the physician, prior to publication, an opportunity to work with his peers or her peers to improve the practice of medicine, to negotiate out a solution to the problem before it becomes a thermonuclear war. It does, and it has in Texas.

Senator PRYOR. I'd just caution, because I think you are talking about really a very basic right in our system. And I'm just hopeful that your organization will be very, very sensitive to this issue, because I think it could be abused. And I'm hopeful that you are aware of it and sense it.

Dr. DEHN. Senator, we are aware of it, and as you can appreciate, we must strike a balance between providers and beneficiaries. And that is to say that while we need to—and we must—provide due process to the provider, we also when we see a situation where

there is some and flagrant violations, we must protect the beneficiary from practice of medicine that is of substandard quality.

Senator PRYOR. I understand. I understand.

Dr. DEHN. It's a heck of a tightrope to walk, but we are willing.

Senator PRYOR. I understand that there is a balance you have to achieve. I just wanted you to know of my concern and I think some others here.

Dr. DEHN. Thank you. I appreciate that.

Senator DURENBERGER. Tom, I don't have any questions, but I remind my colleague from Arkansas that I can recall that the first time you appeared here you were angry, and you were angry about what was happening in the initial implementation of the peer review process. And you talked to us about people who had died because of the way this process was being operated. And so I think, unlike many witnesses who may claim to see the balance, this one has a record of seeing it and doing it.

And that's because—I'll correct one more part of the record—you're really not from Wisconsin.

Senator PRYOR. I bet he is from Minnesota somewhere.

Senator DURENBERGER. Dr. Dehn is from Sterns County, Minnesota——

Senator PRYOR. All right.

Senator DURENBERGER [continuing]. Which is the home of Lake Wobagon and Minnesota's Senior Senator.

Dr. DEHN. And most all truth.

Senator DURENBERGER. Yes, and it's also the home of the Sterns County syndrome, which is a problem that the predominantly German population got into in the last century by intermarriage, an intellectual problem that neither of us hopefully has been afflicted with.

Tom, I'm going to be, I think I am the, unless Dave takes this over, I am the——

Senator PRYOR. Senator Durenberger, you are the presiding elder as of this moment.

Senator DURENBERGER. I thank you both very much. It was a pleasure to have you.

Dr. DEHN. Thank you very much, Senator. Thank you, Senator Pryor.

Senator DURENBERGER. Our next witness is Lovola Burgess, the Board Member of the American Association of Retired Persons from Albuquerque, New Mexico.

[The prepared written statement of Thomas G. Dehn, M.D. follows:]

PRESENTED BY: THOMAS G. DEHN, M.D.
PRESIDENT

AMERICAN MEDICAL PEER REVIEW ASSOCIATION

Mr. Chairman, I am Thomas G. Dehn, M.D., President of the American Medical Peer Review Association (AMPRA) and President of Samaritan Physician's Association, an IPA/HMO in Milwaukee, Wisconsin. With me is Andrew Webber, Executive Vice President of AMPRA. AMPRA is the national association of physician-based medical review organizations and of the Peer Review Organizations (PROs) under contract to the Medicare program. We appreciate your invitation to participate in these oversight hearings, and we are gratified by this Committee's continuing interest in and support of the PRO program.

We would like to begin our testimony with several general comments about the PRO program and the experiences of our members as they approach the mid-point in the second series of Medicare contracts. As this Subcommittee knows well, there have been a number of new congressional mandates affecting PRO activities over the last year. These statutory provisions for the most part are responses to recommendations we have made to this Subcommittee during prior hearings on the PRO program, and we want to express again our appreciation for your support.

QUALITY OF CARE UNDER PPS

Mr. Chairman, I am often asked as President of AMPRA, "How is quality of care under the Medicare prospective payment system?" This question has always been difficult for Peer Review Organizations (PROs) to answer. Definitions of quality in medical care are, at best, problemmatic. PRO review has not been in place for very long. Review is presently confined to hospital based care. Most importantly, the emphasis leading up to the second round of PRO contracts has been on controlling rates of hospital utilization and not quality of care.

I am pleased to report to this Committee that AMPRA is now satisfied that an appropriate balance between cost containment and quality monitoring has been struck in the second round of PRO contracts. The new contracts place a heavy emphasis on the identification of quality concerns for every case under PRO review. We are now in a better position to comment substantively on the state of quality of care in our nation's hospitals.

In a recent survey of the AMPRA membership, the PRO community was all but unanimous in stating that quality of care has not declined as a result of the Medicare prospective payment system. Many insist, in fact, that quality of care has improved. The incidence of premature discharges from hospitals - a concern PROs monitor for every case under their review - is infrequent and isolated. PROs, in the same AMPRA survey, state that the identified quality concerns cannot be traced to the new economic incentives of prospective payment but rather are characterized by problems of clinical mismanagement present in any delivery system.

The PRO community's confidence in the present state of quality is tempered by our concern for the future of hospital based care and the present pressure PPS incentives and an increasingly competitive marketplace are putting on the ambulatory and post acute care settings. Does anyone doubt that the inevitable ratcheting down of PPS payments will run the risk of compromising quality at some future point? "Fat" in hospitals has been effectively reduced and additional trimming of internal costs may well threaten patient care.

AMPRA reiterates its earlier testimony to the Committee that the major quality of care concern for the Medicare program is the absence of an effective post acute and long term care benefit for beneficiaries. At a time when PPS has

intensified demand for non-acute care services, benefits have been curtailed and no external quality of care monitoring system has been imposed on that sector of the medical care industry that is expanding so rapidly.

FINANCING OF PEER REVIEW

Mr. Chairman, it is clear to AMPRA by now that the PRO program has been driven, like other federal health care programs, by overriding budget considerations. We applaud both the shift of PRO focus to quality of care and the expansion of PRO review, but we ask if these vital efforts will be supported by additional program funding.

In each year since the inception of the program there have been serious disagreements between our members and the Administration with respect to the funds necessary to carry out our review responsibilities. Congress set forth minimum funding levels which the Administration has viewed as maximums. In the first cycle of PRO contracts (1984-86) aggregate expenditures were $300 million. Thus far, the budgeted total for the 1986-88 cycle is only $292 million, despite the fact that additional PRO responsibilities have been mandated by the Congress.

We have supported these expanded review mandates and asked for appropriate funding. Congress in the Omnibus Budget Reconciliation Act of 1986 (OBRA) included explicit language giving the Secretary discretion to budget for these new review functions separately from the budgets prepared for the conduct of inpatient hospital reviews.

The Administration's budget for FY 1988 includes only a modest increase for PRO activities with n reference to a separate budget for HMO review, scheduled to now begin June 1, or for skilled nursing facility and home health agency reviews scheduled to come on line during the next fiscal year. At this point it is unclear how the Administration intends to finance these additional activities. THEREFORE, WE URGE THIS COMMITTEE TO CALL ON THE ADMINISTRATION TO BUDGET IN COMPLIANCE WITH THE STATUTORY MANDATES SO THAT WE MAY PROPERLY DISCHARGE OUR ADDED RESPONSIBILITIES.

An adequate PRO budget will help to answer many of the present criticisms aimed at the PRO program. How often have you heard Mr. Chairman, "Why isn't the PRO program more educational?", "Why isn't there more on-site review?", "Why can't there be better communications with Medicare beneficiaries?" The simple answer is lack of funding. For example, in our recent survey, we asked PROs what percentage of their proposed budget for beneficiary outreach was actually funded by HCFA. The answer: a mere 6 percent. If we want more education in the program, more on-site review, better communications with all interested parties, we must be willing to pay for it. Saying we have a beneficiary outreach program on paper does not mean we have one in fact.

PEER REVIEWERS OR POLICEMEN?

Mr. Chairman, I cannot leave the subject of the PRO program without responding to the frequent charge that PROs are only interested in "policing" doctors. In some physician circles, PROs are even perceived to be "doctor bashers". AMPRA notes the irony of this charge, after years of being told, even in the last evaluation of PROs, that we were not "aggressive" enough. It is time for the PRO community to respond.

I would like to state for the record that, in philosophy and in practice, all PROs support improvement in practice behavior through education and peer pressure rather than punitive action. Our AMPRA survey reveals that very few quality concerns indentified by PROs actually result in sanctionable actions being taken. Data from one PRO is characteristic of what we collected:

> One PRO has sent notifications on the identification of potential quality problems to 540 physicians and 259 hospitals. Through intensified review, educational activities and the development of corrective action plans, most of the problems were resolved without any subsequent formal action being taken. Of the 25 first notices sent (first level of sanction proceedings), 12 were resolved at this level. Of the 9 gross and flagrant notices issued, 6 have been resolved to date. Of all problems identified to date by the PRO, only 4 sanction recommendations have been forwarded to the Office of Inspector General.

The untold story of success in the PRO program is further reflected by the anecdotes that we have collected from PROs that describe positive changes in practice behavior that need not be recorded in the Inspector General's log of sanctioned cases. Following is an example:

> A physician practices alone in a community that is about 100 miles away from the nearest tertiary center. The closest physician is in a community that is 15 miles away. In mid-1985, reviews raised some general quality concerns that were forwarded by regional reviewers to the PRO's central office. The twenty most recent Medicare admissions were then copied, all identifiers were removed from the charts, and three peer physicians independently reviewed each of the charts. The resultant review was then collected by the staff and a Medical Director summarized the findings and presented the information to the Medical Leadership. A decision was made to send a 20 day notice to this physician and an invitation was made to meet with the PRO leadership. Upon receipt of the notice, this physician retained an attorney, and met with the Organization's leadership. This meeting resulted in the design of an educationable program agreeable to both parties that was constituted as follows:

1. Four, one-week mini-residences would be held over the next year at the state University of Medicine.

2. One day a month (in months when the aforementioned mini-residency was not underway) Dr. A would attend teaching sessions at the medical school.

The PRO agreed to this program and did not pursue the formal sanction process further. This program commenced a year ago and is to be completed this month. The PROs reviews have revealed a vast improvement in documentation, no further quality concerns have been identified, and the physician who practices in the neighboring community has commented that the practice appears to be much improved. Final evaluation will be completed sometime in the next quarter; it is not anticipated that the PRO will need to pursue sanction proceedings further.

The great majority of quality concerns, as our example indicates, are resolved through dialogue with the physician and non-punitive corrective action plans. Unfortunately, sanctions and sanctioned physicians are visible and vocal but in no way reflect the true nature of PRO efforts. Sanctions have always been viewed by the AMPRA membership as failures in the peer review program. We will continue to abide by that principle.

CONTRACT ADMINISTRATION AND MANAGEMENT OF THE PRO PROGRAM

I would like to turn now to a number of issues associated with the administration and management of the PRO program. We would like to state that our relationship with the Health Care Financing Administration (HCFA) and its Health Standards and Quality Bureau (HSQB) has been open. Nevertheless, we would like to focus your attention on several unresolved administrative problems.

First, the two year, fixed price contracts between PROs and Medicare have been administered in a very rigid manner. Beginning with the negotiation process during which most PROs were essentially provided HCFA contracts for ratification, we have found that many of the features of federal contracting policy have not been applied to the PRO program.

Probably the most serious contract management issue for us has been the failure of HCFA to make contract modifications when the scope of work has been changed either by congressional mandate or by administrative policy. A good case in point has been implementation of the new provision for review of the use of assistants at surgery for cataract extractions. Last December PROs were directed to submit plans for this review by the end of January. Review began March 1. To date no contract modifications have been made, and PROs are financing this new activity from budgets that do not include funds for this purpose.

Another related example of problematic program management concerns the implementation of review of Physician Assistants (OBRA extended Medicare coverage to PAs) under the Assistants at Cateract Surgery provision of COBRA. Instructions received from HCFA outlined implementation of review of Assistant Surgeons (and clearly stated surgeons only) and failed to mention the Physician Assitants component. Thus directed, PROs proposed budgets, developed criteria and communicated with the provider community on implementation of the Assistant Surgeons review requirement. Days before implementation of this new review requirement, PROs were verbally contacted and instructed to review for Physician Assistants as well. While PROs are not adverse to changes in program policy, modifications must be accompanied by clear, rationale instructions and adequate timeframes for implementation and contract renegotiation.

While we do not advocate rigid adherence to the federal contracting procedures, we believe that PROs should be able to negotiate contract modifications prior to significant changes in their scope of work. AMPRA RECOMMENDS THAT LEGLISATION BE DEVELOPED MANDATING HCFA TO NEGOIATE FORMAL CONTRACT MODIFICATIONS AND ADJUSTMENTS TO PRO FINANCING PRIOR TO IMPLEMENTATION OF PROGRAMMATIC CHANGES.

The application of generic quality screens under HFCA guidance is another example of PRO difficulty with program management. Under 1986-88 contracts, PROs are now applying generic quality screens to all cases under review. This is an approach long supported by AMPRA and one used widely in hospital quality assurance programs. As we gain experience with this approach we have been able to identify a number of refinements that could result in more efficient use of this technique. Specifically, the number of cases that fail to pass the screens has been very much higher than was initially forecast. On review by our physician advisors we have determined that many of these cases are "false positives" -- that is, they present no evidence of a quality problem upon review of the record.

Under the procedures currently associated with application of the generic screens, HCFA requires that virtually <u>all</u> cases failing the screens must be referred to a physician reviewer for disposition. Experts involved in the early development of generic quality screens have never agreed with this approach, arguing that instructions and exceptions must accompany quality screens. AMPRA has also recommended the development of instructions for initial reviewers, including appropriate exception criteria, so that the volume of false positive cases referred to physicians could be reduced. We have given this recommendation to HCFA and we have been informed that some modifications will be made. As yet there has been no formal notification of any HCFA action. Generic quality screens are a valuable and reliable tool, but some flexibility in their use is both appropriate and cost-effective. Given limited programmatic resources, we must work to focus our energies on areas that will yield the greatest results.

The final administrative issue we would like to raise concerns the evaluation of PROs. Since the outset of the program there has been something of a tension between the assurance of quality and cost containment. With the change in payment incentives there has been considerable concern over the potential for unnecessary hospital admissions, leading to an early emphasis on admission reviews. Over time all of us have begun to focus on the potential for under-care and limitations on access to appropriate care.

The significance of these competing objectives in the evaluation process is that PROs have been uncertain or confused as to the expectations of HCFA and the Congress. We were initially led to believe that the evaluation process would rely heavily on outcome measures, when in fact most credit was given for strict adherence to procedures and timely reporting. AMPRA's cursory glance at the new PROMPTS document, that will be used to evaluate PRO performance in the second round, reveals a continued HCFA reliance on measuring a PRO's adherence to process requirements as the yardstick for performance. Yet the PRO statute was clearly developed to move the government away from dictating the process of review towards negotiated outcomes and defined expectations.

Without a clear articulation of the evaluation criteria, it is impossible to have a fair and objective assessment of performance. Furthermore, with delays in data and the time required to identify problems in order that intensifed review and sanction recommendations might be initiated, PROs are evaluated on two year contracts on the basis of nineteen months worth of work. AMPRA RECOMMENDS THAT PRO CONTRACTS BE EXTENDED BEYOND TWO YEARS TO THREE YEAR CYCLES. The constantly changing nature of the PRO program and the administrative savings to HCFA in terms of staff time and resources expended in the evalution and recontracting processes must also be considered.

HMO/CMP REVIEW

Mr. Chairman, we would like to share with the Subcommittee our concerns about the plans for expanded review activities that are being developed by HCFA. The recent solicitation for proposals for the review of HMO care includes a plan that requires review organizations to make a decision about the intensity of review efforts following a two month analysis of the HMO's internal program. AMPRA believes that any plan evaluation must be based more on patient outcome assessments rather than the existence of an internal quality assurance process. Sixty days is insufficient time to conduct any evaluation.

AMPRA STRONGLY RECOMMENDS THAT ALL HMOs INITIALLY BE SUBJECT TO A SIX MONTH BASIC REVIEW PROGRAM, AFTER WHICH JUDGEMENTS CAN BE MADE RESPECTING THE LEVEL OF INTENSITY NEEDED FOR REVIEW IN THE FUTURE. We support review based on peformance indicators and believe that the review organization should have the discretion to relax or intensify review based on objective performance indicators. If review organizations are forced to make premature decisions regarding HMO quality assurance programs, then the public's confidence in an external review program will be seriously undermined.

In a related matter, we want to call your attention to the plans under consideration at HCFA for the review of services provided by skilled nursing facilities (SNF) and home health agencies (HHA). It is our understanding that such reviews will only be limited to the review of early readmissions to acute care hospitals. Specifically, PROs will examine SNF or HHA services only when they are provided to patients readmitted to a hospital within thirty days. The provisions in OBRA requiring PROs to allocate a reasonable proportion of their review activity to care provided in all Medicare covered settings appears to us to demand a more comprehensive review program.

RURAL MEDICAL CARE

Finally, Mr. Chairman, a great deal of attention has been devoted to the impact of the PRO program on rural hospitals. We are very much concerned about the perception that PRO review activities have intentionally singled out rural facilities or practitioners for punitive action. At the same time we are very much aware of the need to provide the greatest degree of contact between our reviewers and the hospitals and physicians in rural areas.

Mr. Chairman, we are very much in favor of increasing the amount of on-site medical review for all hospitals, including rural hospitals. The obstacle we face is that the funds awarded in our contracts actually finance only limited on-site review. The costs associated with review in facilities widely scattered about a state are substantial, and yet we believe the cost-benefit of such expenditures to be quite high. Likewise, we support the addition of funds to enable PROs to conduct educational programs and technical assistance for hospitals and their physicians.

We recognize that rural hospitals face some burdens from the PRO program, and we are anxious to work with them to minimize problems wherever we can. We supported the increased flexibility in the thresholds for intensified review that has been implemented by HCFA, and we believe that there are additional modifications to our review protocols that would take more complete account of the circumstances and limitations of providing medical services in isolated communities. PROs must always be sensitive to local conditions and ensure involvement of local rural peers in the review process. AMPRA believes, however, in a minimum standard of care for all physicians, irrespective of geographic location.

SUMMARY OF LEGISLATIVE RECOMMENDATIONS

Mr. Chairman, I would like to summarize our legislative recommendations at this time. First, we believe it will be necessary to include in the statute more explicit language requiring the Administration to include in their budget each year specific amounts for the new review functions as required by last year's reconciliation bill.

Second, we recommend that HCFA be required to make contract modifications or adjustments prior to the effective date for new review functions. Such modifications should also include appropriate adjustments to PRO funding.

Third, we believe that as the program matures, it is reasonable to extend the PRO contracts to a three year period.

Fourth, we recommend that 1% of the PRO budget be added to each year's allocation for the purpose of creating a Research and Education Center to support technical assistance to PROs and to underwrite field testing of new review methodologies. At present, neither HCFA nor PROs have the resources for such activities which are vital for the success and effectiveness of our quality assurance objectives.

In closing, Mr. Chairman, we want to thank you for this opportunity to participate in these hearings. If you or other members of the Subcommittee have any questions, we will be glad to respond at this time.

STATEMENT OF MS. LAVOLA BURGESS, BOARD MEMBER, AMERICAN ASSOCIATION OF RETIRED PERSONS, ALBUQUERQUE, NM, ACCOMPANIED BY MS. STEPHANIE KENNAN, LEGISLATIVE REPRESENTATIVE

Ms. BURGESS. Thank you, Mr. Chairman. My name is Lavola Burgess and I am from Albuquerque, New Mexico as you mentioned, and I am a member of the Board of Directors and the National Legislative Council of AARP. Stephanie Kennan of the Legislative Staff of AARP is with me. On behalf of our 24 million members, I thank you for the opportunity to talk with you today and to give our support for a strong peer review program—one that will focus on monitoring and maintaining quality health care services.

Until PPS, quality of care was not an issue in Medicare. It is startling to discover that the word "quality" is not even mentioned in the Medicare statute, Title 18 of the Social Security Act.

Authority for the PRO program is found in Title 11. Prior to PPS, the apparent abundance of resources helped camouflage issues concerning the quality of services under Medicare—indeed fiscal intermediaries and carriers. The administrators of Medicare claims had no designated functions concerning the quality of care.

In contrast, however, PROs are mandated to be concerned about the quality of Medicare services. PROs are subject, however, to conflicting pressures and dynamics, as we have heard this morning.

PROs are government contractors, and as such must implement federal policies. By their nature, PROs represent and reflect professional and provider perspectives.

Ultimately, however, PRO success will depend upon putting patients' interests first. And while we acknowledge and support the effort to slow health cost inflation, the health care monitoring system must emanate primarily from a commitment to quality assurance, and not merely to cost containment.

By the same token, high quality care is not necessarily more expensive care. Insuring good outcomes by delivering all necessary and appropriate services can, in the long run, save health care dollars. I would like to highlight several essential elements contained in our vision of a PRO program operating in the public's best interest.

First, a basic quality assurance program must assure quality from one setting to another. Peer review must not be limited to the inpatient setting. Reductions in the length of stay, increases in patient transfers and greater use of outpatient services all point to the need for studying quality and the outcomes of care after discharge.

Adequate funds must be made available to meet the Congressional mandates for expanded review and monitoring. AARP believes that the PROs' current funding level is wholly inadequate to the job at hand.

Second, AARP calls for a major review of the criteria by which admissions to hospitals are being monitored and permitted. Our members are reporting many difficulties and hardships connected with the shift in the site of services. In many instances, same day surgery is simply too onerous for elderly patients. Similarly, over-

night inpatient evaluation should be available for Medicare patients presenting serious symptoms considering all relevant facts.

Third, AARP favors committing a portion of the trust fund to help services research, including analysis of physician practice pattern variations. In addition, there is an overriding need for analyzed comparative data and information about the outcomes and implications of PRO review activity.

Overall, the Association is dissatisfied with the data disclosure performance of the PROs. PROs must take a larger role in getting the data system on line and information out to the public.

Fourth, since the inception of the federal peer review program, there has been a debate over whether peer review should emphasize a policing function involving the imposition of sanctions or a strategy utilizing peer pressure and education to improve problem performance.

Everyone will agree that there are some doctors and some institutions whose performance in delivering care is so far below acceptable standards that the only appropriate response is to interrupt that performance. No area of the state—urban, surburban, or rural—should be immune from such scrutiny and such interruption where warranted by the application of peer review to compelling factual circumstances.

At the same time, AARP does not seek a body count approach to quality of care review. The educational feedback model can work to improve quality performance, but for such a model to work it must be based on data of sufficient quality to win the confidence of the professional medical community. Thus, for the foreseeable future we will have to live with the unresolved tension between PROs as policemen and PROs as educators. An important factor in easing that tension will be the PROs' public accountability through communication of the results of their peer review activity.

The PROs' almost complete failure to document and share with the public the nature and results of their review efforts, whether punitive or educational, contributes to the public's impatience and misunderstanding of PROs' function and role.

Fifth, HCFA's scope of work for quality review of Health Maintenance Organizations and competitive medical plans falls well short of AARP's minimum expectations for such review plans. Mr. Chairman, here we are concerned that the scope of work does not require uniform and comprehensive data collection for a reasonable period. That means, the decisions to expand or contract reviews will be made in the absence of a necessary base line.

The flaws in HCFA's plan include, one, it places unwarranted reliance——

Senator DURENBERGER. Are you near the end of your statement, Ms. Burgess?

Ms. BURGESS. Yes.

Senator DURENBERGER. Because it is going to be part of the record. And now that somebody else is in charge around here we can go to the 5-minute rule.

Ms. BURGESS. Okay, fine. I'll just get quickly to the conclusion.

PROs certainly have been thrust into a pivotal role, and it is not surprising you are being asked to do many things for many people. And the challenge is certainly to find the proper balance so that

they can be an educator, a community educator and protector, sanctioner, medical practitioner or arbiter, and the like.

And Mr. Chairman, thank you very much for allowing us to testify.

Senator DURENBERGER. Let me thank you, too, on behalf of everyone on this committee. And you know what happens when we get close to noon on a Friday and everybody gets very busy. And so it isn't because you didn't have an excellent presentation. I thought, and I want to compliment both you and Ms. Kennan for the scope and the grasp of that statement. As somebody who is involved in helping to create the legislation, I think you've captured, right from the beginning when you talked about nobody said anything about quality until PPS came along, and we should have been saying something about quality from 1965 on—well, from the beginning of time on. But we took it for granted. We took it for granted.

And I think one of the things that both the PPS system and the peer review process now are helping us learn—plus the providers themselves—are helping us learn that we can improve the quality of health care substantially by this process that we are going through. And so we are recognizing that which most people don't recognize. And I compliment an organization of which I am one of the 24 million members. [Laughter.]

Senator DURENBERGER. One of the points that Dr. Dehn made on behalf of the American Peer Review Association, etcetera, had to do with education. And one of the things we're all extremely sensitive to and very, feel deep regret about is that we didn't educate anybody in 1983 as to what we were doing.

Not only is that hard on the providers—they can adjust a little bit more quickly—but it's particularly difficult for the beneficiary to understand what is going on. And as I recall hearing his testimony, he was endorsing an improvement in the funding for educating the physicians and educating the beneficiaries to this whole process. Do you, would you endorse that as an important improvement in the process?

Ms. BURGESS. It's very, very important. We are doing some work in that already in AARP. We have a booklet out called, "Knowing Your Rights", and it has been widely distributed, and is very popular. We can't keep it in stock. We are trying very hard to let people know their rights in the PPS set-up.

Senator DURENBERGER. Thank you again very much. I appreciate your being here and particularly appreciate, I'm sure we all do, that statement.

Our next witnesses will appear as a panel: Warren Kessler, President of the Kennebec Valley Medical Center in Augusta, Maine, on behalf of the American Hospital Association; Dr. John Ring, Vice Chairman of the Board of Trustees of the AMA; Dr. John Ludden, Medical Director of Harvard Community Health Plan in Boston, on behalf of the Group Health Association of America and American Medical Care and Review Association; and Peter Reibold, Vice President of Providence Hospital, Columbia, South Carolina.

All of your statements will be made part of the record. You may abbreviate them in 5 minutes or less. And we will begin with Mr.

Kessler. I'm sure the chairman of this committee will be back to tell us what a terrific guy you are, Mr. Kessler. He is at a, fortunately as he may have told you, is at a very important press conference right now on the highway bill, which I take it is also important to Maine. So you may proceed.

[The prepared written statement of Ms. Lavola Burgess and responses to Senator Heinz's questions follows:]

STATEMENT OF

AMERICAN ASSOCIATION OF RETIRED PERSONS

Thank you Mr. Chairman. My name is Lavola Burgess. I am from Albuquerque, New Mexico and I am a member of the Board of Directors and the National Legislative Council of the American Association of Retired Persons. On behalf of our 24 million members, I thank you for this opportunity to state the Association's support for a strong peer review program focused on monitoring and maintaining quality health care services.

My testimony develops the theme of this hearing - PROs and Quality - by outlining three related issue areas:

1. The emergence of quality of care problems in Medicare;
2. Improving the quality of Medicare;
3. A closer look at PROs; including:
    - o increasing PRO emphasis on quality assurance;
    - o need for research;
    - o hospital admission criteria;
    - o need for data;
    - o PROs: educators or cops?
    - o HMO/CMP scope of work.

THE EMERGENCE OF QUALITY OF CARE PROBLEMS IN MEDICARE

Medicare's hospital prospective payment system dramatically shifted the way in which hospitals are paid for the provision of care to the elderly and disabled. By paying a set amount for each beneficiary in a particular diagnostic category, regardless

of the treatment actually provided, hospitals now face strong incentives to limit both the length of stay and intensity of care for their Medicare patients. In theory, such a system should discourage the use of unnecessary tests and treatment and should shift patients who need less than acute care services into less intensive settings at the end of their hospital stay. Care would thus be delivered in the most efficient manner while patients would still receive needed services. In practice, however, problems arise. In some cases the quality of care delivered in the hospital suffers. Some hospitals may discharge their patients prematurely in a strictly medical sense, sending patients home or to other facilities while they are still in need of hospital care. These are serious problems that need to be carefully monitored. Good quality control mechanisms are needed to ensure that quality is not allowed to deteriorate.

A second, and probably more common, set of problems can also arise, however, that fall outside the bounds of traditional measures of quality of care. When patients who need post-hospital care are discharged although no further treatment is available, the health of the patients suffers in much the same way as if the discharge had been medically premature. In such cases, patients may be sent home only a few days after surgery with no one to provide support, to administer medications, or to help change dressings. Patients recovering from hip replacement surgery may not receive needed rehabilitation treatments. If they do not get needed care, their recoveries may take longer, or

they may need to be readmitted to a hospital. In extreme cases, the patient may die.

These then are certainly problems affecting the overall quality of care. Before the advent of PPS, such patients might have stayed longer in the hospital. Now that option is less likely to be available. These patients do not need expensive hospital care and have not been inappropriately discharged in a medical sense. Rather, they suffer from the lack of a reasonable continuum of care that would offer skilled nursing services in another institutional setting or at home.

How large is this problem? While good information is still hard to find, the early results certainly suggest that the problem is potentially severe. The average length of an inpatient hospital stay fell by more than 10 percent between 1983 and 1984, the first year in which PPS was in effect. In fiscal year 1984 the average stay was 9 days--or more than 11 million hospital days less than if lengths of stay had remained unchanged from their 1983 levels. Not all of this decline can be attributed to PPS since there has been a long-term trend toward shorter hospital stays. Nonetheless, the 1984 decline occurred at a rate three times as high as in the recent past.

Moreover, the drops in the length of stays in hospitals have not just occurred for the simple cases; some of the largest declines have come in the diagnostic categories where the sickest patients are found. For example, the diagnostic category that covers hip procedures for persons age 70 or above includes many

frail elderly who are likely to need further care after discharge. Between 1981 and 1984, the average length of a hospital stay for such Medicare patients fell by 18 percent as compared to a drop of just over 14 percent for all Medicare hospital stays over that period. Thus, many of the 11 million fewer hospital days affected the oldest, sickest patients.

Although on paper, the Medicare program offers home health care and skilled nursing facility services for such persons needing post-hospital care, these services are often not available. Early trends indicate that use of these two services, which together account for less than 3 percent of all Medicare spending, has not grown in response to earlier hospital discharges. The increases in Medicare expenditures on home health and SNF care between 1983 and 1984 were at or below their recent average rates of growth. Many Medicare patients continue to lack access to these services.

Patients needing further care thus may not be able to count on Medicare. As a result, patients will have to purchase such care on their own, rely on other public programs such as Medicaid, turn to relatives and friends for informal care, or do without.

IMPROVING THE QUALITY OF MEDICARE

Our nation's ability to better assure high quality medical care is directly related to our understanding of what a quality medical outcome is and our capability to promptly detect and

correct unacceptable deviations from quality care. The fact of the matter is, however, that the country lacks adequate information about medical outcomes and the quality monitoring system necessary to promptly alert providers and policymakers to unacceptable care.

Until peer review organizations (PROs), quality of care was not an issue in Medicare. It is startling to discover that the word quality is not even mentioned in Medicare, Title 18 of the Social Security Act; PRO authority is found in Title 11.

Prior to PPS, the apparent abundance of resources helped camouflage issues concerning the quality of services under Medicare. Indeed, fiscal intermediaries and carriers, the administrators of Medicare claims, have no designated functions concerning the quality of care. In addition, neither fiscal intermediaries (FIs) or carriers collect data in a uniform way and thus have only marginal capabilities to compare and contrast data and trends.

In contrast, PROs are mandated to be concerned about the quality of Medicare services. PROs are subject, however, to conflicting pressures and dynamics.

A CLOSER LOOK AT PROs

PROs are government contractors, and, as such, must implement Federal policies. By their nature, PROs reflect and represent professional and provider perspectives. At the same time, notwithstanding all these pressures and dynamics, Medicare

beneficiaries look to PROs to act as the allies and the advocates for the patient community if the quality of care all of us hold dear is to survive. PROs function as arbiters, judges, protectors of beneficiary interests and overseers of providers of care. They are physicians and managers performing governmentally mandated work in an environment of intense pressure to contain health care costs. Ultimately, however, their success will depend upon putting patients' interests first.

Putting patients' interests first includes implementing a review strategy that truly improves health outcomes while respecting the physician-patient bonds that attend the healing process, bonds that have come under severe stress in recent years. Our interests lie in maintaining an efficient, cost effective health care system that at the same time remains humane, caring, and capable of renewing the trust and mutual respect between doctor and patient critical to patients' recovery from illness.

The jury remains out on whether such a strategy is feasible - but the hope of developing a PRO-beneficiary alliance has guided our basic support for peer review since the inception of the prospective payment system. Our message to Congress and the Department of Health and Human Services has been unequivocal: AARP seeks implementation of a national, federally sponsored, publicly accountable health care monitoring system involving physician peer review.

And, while we acknowledge and support the effort to contain health cost inflation, the health care monitoring system must

emanate primarily from a commitment to quality assurance and not merely to cost containment. Tied strictly to a payment system that already constrains spending, utilization review can too easily become simply the means by which the end of less spending is achieved.

Having said that, Mr. Chairman, AARP has long held the view that shorter lengths of stay do not necessarily imply inappropriate care. By the same token, high quality care is not necessarily more expensive care. Insuring good outcomes by delivering all necessary and appropriate services can, in the long run, save precious health care dollars. With that said, what essential elements are contained in our vision of a PRO program operating in the public's best interest?

o PRO Review: Towards Quality Assurance

A basic quality assurance program must assure quality from one setting to another. The 1986 budget act added significant authority to PROs' mandate in the direction of a comprehensive review system. In addition, the new law's requirements for discharge planning, coupled with PROs' increasing application of generic quality screens, give promise of added protections against one of the great problems induced by PPS, namely, the incentive to discharge hospital patients too soon during their recovery period.

Peer review must not be limited to the inpatient setting. Reductions in the length of stay, increases in patient transfers

and greater use of outpatient services all point to the need for studying quality and the outcomes of care after discharge.

Beyond requiring PROs to review care in the ambulatory and post-acute care settings, understanding the broader effects of PPS will require studies of an entire episode of illness from diagnosis and treatment through recovery, regardless of the site of care.

AARP calls for full implementation of PROs' new authority and new requirements. At the same time, in keeping with the statute's call for efficient implementation of these OBRA sections, we seek to work with HCFA, PROs and the quality assurance research community to build consensus on the best approach to implementing these important initiatives.

A funding level adequate to meet expanded review and monitoring needs would still constitute a very justifiable percentage of Medicare outlays - and thus we will seek its allocation. At the same time we would expect to keep a close watch on how this money is being spent to assure an optimum return for this investment of public funds.

Even if all these improvements were on line tomorrow, the best discharge planning in the world and the best needs assessment in the world cannot protect the continuum of care, and thus the quality of care to discharged patients, if the needed post-acute care services are not available. Failure to accomodate patients requiring post-acute care services is a major deficiency in Medicare's scheme of care. AARP is determined to do all it can -- legislatively and otherwise -- to improve the

delivery of needed services.

o The Need for Research

Our interest in an expanded review program leads to support for research activity designed to turn review information into a force for positive changes in physician and institutional performance. Thus, we favor the proposal to commit a portion of the Medicare Trust Fund to health services research, including analysis of practice pattern variations. In this regard, the Association favors the development of PRO related research, analytical, and technical assistance capabilities. AARP looks forward to working cooperatively with the American Medical Review Research Center (AMRRC), the promising and evolving PRO research entity.

o Hospital Admission Criteria

As the PRO program proceeds to implement the second scope of work, AARP calls for a major review of the criteria by which admissions to hospitals are being monitored and permitted. Our members are reporting many difficulties and hardships connected with the shift in the site of service. In many instances, same day surgery is simply too onerous for elderly patients. Similarly, overnight inpatient evaluation should be available for patients presenting serious symptoms considering all relevant facts.

When we look at the review objectives for the second round of PRO contracts, we don't see any suggestion that PROs will analyze the patient-specific characteristics and the outcomes of denied cases, and then communicate the results of those analyses so that the public can determine whether PROs' hospital admission criteria and denial rates are reasonable.

In this connection, we are pleased to note that the Prospective Payment Assessment Commission (ProPAC) is similarly calling for a study of PRO hospital admission criteria, in the Commission's current recommendations to DHHS.

o The Need for Data

There is an overriding need for analyzed, comparative data and information about the outcomes and implications of PRO review responsibilities. The debate about data disclosure has shifted from a focus on whether information should be published at all, to how to release data so consumers can use it effectively. We must rise to the challenge of turning raw statistics into a picture patients can understand. Toward that end, the Association believes the PROs' role as analyzer and disseminator of data will become ever more crucial to their future success.

The Association was pleased to see the California PRO (California Medical Review Inc. [CMRI]), become the first PRO to initiate, under its discretionary authority, a disclosure of data regarding hospital care in its state. CMRI's action was a commendable step in the direction of providing access to detailed

performance data on a provider and procedure-specific basis. As part of the PRO regulatory framework, CMRI solicited and published the comments of the hospitals covered by the report. The result--a combination of statistics and explanations -- becomes an important tool in identifying and analyzing performance problems.

But, the Association is dissatisfied with the performance of PROs as a whole with regard to the development of data useful to Medicare beneficiaries. PROs must take a larger role in getting the data systems on line and information out to the public.

AARP is pleased that the American Medical Review Research Center is about to convene a conference on this vital issue of PRO data disclosure, and we look forward to assisting in the development of a viable and publicly accountable disclosure strategy.

o PROs: Educators or Cops?

In light of recent developments that have arisen regarding both the process and focus of PRO sanction activity, we wish to make several points. Since the inception of the federal peer review program, there has been debate over whether peer review should emphasize a policing function involving the imposition of sanctions, or a strategy utilizing peer pressure and education to improve problem performance.

Everybody will agree that there are some doctors and some institutions whose performance in delivering care is so

far below acceptable standards that the only appropriate response is to interrupt that performance. No area of the state -- urban, suburban, or rural - should be immune from such scrutiny and such interruption where warranted by the application of peer review to compelling factual circumstances. Furthermore, a record of no sanction activity in a given PRO makes one question whether this element of peer review responsibility is being taken seriously.

At the same time, AARP does not seek a "body count approach" to quality of care review. AARP believes that the educational/feedback model can work to improve quality performance. But for such a model to work, it must be based on data of sufficient quality to win the confidence of the professional medical community.

Given this analysis, we will have to learn to live with unresolved tension between PROs as policemen and PROs as educators for the foreseeable future. An important factor in easing that tension, however, will be PROs' public accountability through communication of the results of their peer review activity.

As I mentioned in commenting on CMRI's recent disclosure, PROs have discretionary authority to inform the public about both utilization and quality problems identified in carrying out their responsibilities. What contributes, however, to public impatience and misunderstanding is PROs' almost complete failure to document and share with the public the nature and results of their review efforts, whether punitive or educational.

o HMO/CMP Scope of Work

The Health Care Financing Administration has recently published the scope of work for HMO/CMP quality of care reviews. The scope of work for this activity does contain some positive elements, including examination of patient care records from all types of health care settings; application of PRO data disclosure requests; and implementation of a beneficiary outreach program.

At the same time, AARP believes the scope of work has serious deficiencies, and that HCFA has misinterpreted the intent of Congress on important issues enacted under both the Consolidated Omnibus Budget Reconciliation Act of 1985 and the Omnibus Budget Reconciliation Act of 1986.

First, the absence of uniform and comprehensive data collection for a reasonable period means the scope of work will not foster the development of sufficient baseline data critical to the development of an effective HMO/CMP quality of care review program. In fact, we question whether well-founded and defensible decisions to expand or contract reviews of a particular HMO or CMP can be made in the absence of this baseline.

As presently written, there is little specificity in the scope of work regarding measures to use when assessing the adequacy of HMO/CMP quality assurance programs, and the assessment must be completed within the first 60 days of the review contract. If the scope of work remains as stated in

HCFA's RFP, we anticipate that every HMO and CMP will be approved for a limited review based upon inadequate structural reviews of an HMO's internal quality assurance program. We have reviewed the quality audits of several HMO's that were judged to have inadequate and ineffective quality assurance programs even though these programs met HCFA's standards at the time a Medicare contract was signed. AARP wishes to emphasize that it does not oppose a focused review strategy. The key to its constructive pursuit, however, lies in the application of carefully derived data that pinpoint over time where peer review can have maximum impact.

Second, once review is underway, AARP questions whether the number of medical records that will be reviewed under the limited review protocol will be sufficient to identify problems of quality, access, and appropriateness of medical care. We are specifically concerned that the limited review protocol requires an examination of patient records for only 4 of 13 sentinel conditions. Thus, AARP does not believe the review program will meet Congress' intention to have review based on medical outcomes.

Third, the review protocol inadequately addresses access problems within an HMO/CMP. Except for requiring reviews of complaint files, the review protocol relies solely on medical records. AARP suggests that review organizations should be required to survey HMO/CMP members who have not used any services during a calendar year period to ascertain whether they have had problems getting care. In addition, AARP suggests that medical

record reviews should also include reviews of non-trauma hospital admissions through the emergency room. We believe analysis of this data would provide a useful indicator of access and quality problems.

Finally, we are concerned that ambulatory care review will suffer from a failure to develop uniform and comparable information. AARP recognizes that ambulatory review requires innovation and experimentation, a perception that is reflected in the scope of work's encouragement of alternative review methodologies. We suggest, however, that the review protocal must include a core of uniform and mandatory standards so that review findings will permit comparisons among health plans.

Last, but definitely not least, Mr. Chairman, beneficiary outreach is a term that has come to encompass a number of undertakings and issues. We would like it to evolve into an overall manifestation of PROs' public accountability.

Thus, beneficiary participation in PRO policymaking bodies; recourse to the PRO for resolution of quality of care problems; access to PRO information; and PRO communication with beneficiaries about their care and rights and responsibilities under PPS: all should form the mosaic of a PRO-beneficiary outreach strategy aimed at helping improve the health care system's healing potential and preserving its caring and compassionate elements.

CONCLUSION

PROs have been thrust into a pivotal role, and it is not surprising that they are being asked to be all things to all people. The challenge to PROs is to find the proper balance among their roles as peer educator, community educator and protector, sanctioner, and medical practices arbiter, and to communicate the facts animating that balance to Medicare beneficiaries.

AARP thanks you, Mr. Chairman, and the Senate Finance Committee for this opportunity to state our concerns, recommendations, and hopes related to a program of such vital importance to the future of health care in this country.

RESPONSES TO SENATOR HEINZ' QUESTIONS

1. Would you elaborate on your concerns about HCFA's plans for HMOs review. Are you saying that it will provide very little guarantee that the HMOs are delivering high quality, accessible care? how would you improve on HCFA's quality assurance design?

First, we are distressed to learn that decisions about the level of medical record review will be based on the review organization's assessment of each HMO/CMP's internal quality assurance program rather than on an initial uniform and comprehensive review of medical outcomes in each HMO. This approach is not consistent with HCFA's methodology for reviews of hospital care under the prospective payment system. Nor is it in keeping with the Congress' intent that the review program emphasize patient outcome assessment.

Second, we are disturbed that the scope of work focuses at the outset on a limited review if the HMO's quality assurance process is determined to be adequate. Regardless of the adequacy or inadequacy of an HMO's quality assurance program we feel the initial review activities should concentrate on compiling uniform, comprehensive, comparable data on every HMO/CMP that is serving beneficiaries. We suggest therefore, that every HMO/CMP should be included in the basic review protocal during the first year of the review contract. We are not adequately assured that the limited review will provide enough cases to be reviewed. Developing comprehensive baseline data on all HMOs is essential in order to determine the HMO's performance.

Third, we are disappointed that the scope of work does not clearly delineate activities that will yield data on access problems within an HMO/CMP. With exception of requiring reviews of complaint files, the review protocal relies solely on medical records for data on quality, access, and appropriateness of care. We question whether this is adequate to capture information on barriers to care that prevent members from getting care at all. We believe a survey of HMO members who have not used any services during a calendar year period may yield useful information about access problems. We are also disappointed to learn that reviews of non-trauma hospital admissions through the emergency room have been eliminated from the review requirements. AARP believes analysis of this data would provide a useful indicator of access and quality problems.

2. How many PROs now have a consumer representative on their board?

   At least 21 states and the Virgin Islands have beneficiary representation on their boards. Of the 24 AARP members serving on PRO boards, 19 are full board members and 5 hold advisory positions.

3. Are Pros welcoming consumers on their boards or is there resistance?

   AARP Executive Director Cy Brickfield wrote to PROs in February 1987 offering assistance in recruiting beneficiary board members. In response, several PROs have requested assistance. Others indicated they already had consumer representation or were in the process of recruiting. Of the 16 states that did not respond, we have no information, but no resistance is apparent.

4. Based on your hotline programs in North Carolina and elsewhere, is there anything you can tell us about beneficiary understanding of the PRO program?

   The information has not been analyzed completely as of this writing. However, there appears to be confusion over Medicare and PPS in general with a consequent lack of understanding about the role of PROs.

   There were some calls concerning early discharge problems that should be referred to PROs, but it was not apparent that callers knew what a PRO is.

5. Are additional efforts needed by HCFA to educate beneficiaries about PPS and the PROs?

   HCFA has placed a gh priority on beneficiary outreach by PROs. However, HC did not add funds to PRO contracts to cover the cost of this important function. Additional funding is necessary to support these additional PRO responsibilities.

STATEMENT OF WARREN KESSLER, PRESIDENT, KENNEBEC VALLEY MEDICAL CENTER, AUGUSTA, ME, ON BEHALF OF AMERICAN HOSPITAL ASSOCIATION

Mr. KESSLER. Thank you, Mr. Chairman. I am the Chief Executive Officer of a 200-bed hospital in rural Maine and have been privileged to be a member of the Board of the American Hospital Association for two terms, one of those terms during which this legislation was formulated and endorsed by the American Hospital Association.

I will be speaking on their behalf this morning and also on behalf of some of my colleagues in the State of Maine.

The American Hospital Association has three major concerns about this much needed, and we think on the whole, beneficial program.

The first concern is lack of accountability of the PROs. The lack of an appeals process for providers, hospitals, and physicians goes beyond the PRO itself. And we would hope that that could be rectified as it has initially for the beneficiaries.

Our second major concern is that the PRO process, to date, is not a true peer review process. Often times physician admissions are reviewed by physicians in other than the specialty of the admitting physicians, sometimes in widely diverging specialties, sometimes in specialties which have very little cross-knowledge.

Physicians and hospitals have not been informed of the standards upon which they are being judged—both clinical and administrative. And it seems to me that if we had that information in our hands and understood it, we could do a great deal, in the institutional setting, of the work of the PRO. And we prefer to do it that way, rather than to undergo retroactive denials of payment.

And third, there is no recognition in the current peer review process of those people doing a good job in terms of their review. And we would like to see that rectified as well.

For my colleagues in Maine, I can assure you that there are some differences between rural and urban. While I would endorse the comments made earlier from both sides of this table that there should only be one standard of care, there may need to be different standards in terms of the administrative process which judges that standard of care.

Off site reviews are devastating for rural institutions. First of all, they are very expensive, and I'm glad to hear today that some of that problem is being addressed. At least one hospital, not a rural hospital, in the State of Maine—the Maine Medical Center—processed in one five-week period 16,000 copies for our local PRO. And I think that's a lot of paper and a lot of expense and a lot of wasted effort on some people's part.

In addition, rural physicians travel many miles to get administrative review of their cases and can spend an entire day with travel time and the time for the review itself. There are differences between rural and urban. And while the quality of care should not be different, there ought to be accommodations for the rural institutions of this nation.

And I think I'll end my comments with that.

Senator DURENBERGER. All right. Dr. Ring?

[The prepared written statement of Mr. Warren Kessler follows:]

STATEMENT
AMERICAN HOSPITAL ASSOCIATION

INTRODUCTION

Mr. Chairman, I am Warren Kessler, President of Kennebec Valley Medical Center in Augusta, Maine. On behalf of the American Hospital Association and its 5600 hospital and over 40,000 individual members, I appreciate this opportunity to present AHA's views on the Peer Review Organization Program. It is now almost two years since the AHA last affirmed its support for locally based, physician-sponsored peer review that focuses on the quality and appropriateness of care provided to Medicare beneficiaries. Yet our fundamental concerns about the shape of the PRO program remain. We believe that addressing these concerns will ensure that this program will contribute to the promotion of high quality medical services to Medicare beneficiaries.

Last summer, leadership from the Department of Health and Human Services (HHS) and the Health Care Financing Administration (HCFA) took the admirable step of bringing together groups with an interest in the PRO program to try to come to terms with the problems that have plagued the program since its implementation. Since then, HCFA has attempted to improve communication with providers and to tighten its management of the program. But HCFA never faced the fundamental questions that were raised--by us and by others--about the program's premise.

These are the key systemic problems with the program:

- The PROs are accountable only to HCFA. Because hospitals and physicians are precluded by law from pursuing appeals beyond a reconsideration by the PRO, there is no objective oversight of PRO actions and no incentive for the PRO to resist inappropriate demands from HCFA.

- PRO review is not true peer review. Little attempt is made to ensure that the physicians conducting the review are truly peers of the physicians under review. Clinical and program coverage standards PROs are required to promulgate in order to change medical delivery are not clearly stated and are not presented to hospitals and physicians so that they can make accurate Medicare coverage determinations. Nor are the beneficiaries provided this information so that they can better understand the limitations of Medicare coverage.

- There is no mechanism in the system for recognition of good performance by hospitals or physicians, and little relationship between the PRO's contractual performance objectives and the problems that exist in the community.

We believe that by addressing these systemic problems this program can move toward a goal of fostering a clearer understanding of Medicare's coverage rules and what constitutes good medical practice. All parties involved with the PRO program can agree on the desirability of this goal.

PRO ACCOUNTABILITY

PROs are not publicly held accountable for their actions. Their objectives are negotiated behind closed doors with HCFA, without public input. Neither the hospital nor the physician is able to challenge the PRO's decisions to an

entity outside of the PRO, so there is no objective oversight to assure the appropriateness of the PRO's denials or other punitive actions.

Under current law, hospitals, physicians, and beneficiaries are entitled to a reconsideration by the PRO of its original denial decision. Only beneficiaries can appeal beyond the PRO to a hearing before an administrative law judge (ALJ) and, if the claim is sufficiently large, to judicial review. As it now stands, the original decision reflects little more than a second physician's opinion. Hospitals have no access to an independent judgment of the PRO's decisions, and little guarantee that the reconsideration itself is going to be more impartial or fairer than the original review. The only external evaluation of the PRO's performance is conducted by HCFA itself through its regional offices and the "SuperPRO." Neither of these is adequate to ensure fair and equitable treatment of providers because both are funded by HCFA and operate under its direction. Furthermore, there is no opportunity for providers or beneficiaries to contribute to these evaluations and the results are withheld from public view.

The AHA recommends extending the right to an administrative hearing and judicial review to providers and practitioners so that they can get an objective review of PRO decisions. To this end, Section 1155 of the Social Security Act should be amended to grant hospitals and physicians the same access to administrative and judicial review as is now granted to beneficiaries.

In looking at the expansion of appeal rights, it may be timely to consider whether the current system of administrative law judges is appropriate for the resolution of disputes about Medicare coverage issues, particularly on the recondite questions of medical necessity and appropriateness. Questions have been raised in the past about the use of ALJs to resolve beneficiary disputes with the Social Security Administration, and similar questions apply to their use for resolving coverage disputes. Congress should again consider the issue of establishment of an independent body to adjudicate appeals of Medicare coverage and eligibility determinations.

In addition to allowing access to independent review of individual medical necessity decisions, there should be some mechanism for resolving abiding operational disputes between PROs, beneficiaries, and providers on issues related to inappropriate patterns of PRO decisions. A statewide council, consisting of PRO, hospital, physician, HCFA, fiscal intermediary, and consumer representatives, could arbitrate grievances against the PRO on operational objectives, standards, or procedural issues.

RETURNING TO PEER REVIEW

Perhaps the most significant fault in the implementation of the PRO program is failure to embrace the values and processes of peer review. The present mechanistic claims processing approach is damaging to PRO credibility in the provider community. PROs have been unable to articulate coverage criteria and standards clearly, test these in the field against the judgments of relevant medical groups, and educate physicians and hospitals so that they can consider Medicare coverage standards when making their own treatment decisions. Hospitals and physicians receive little feedback on the reasons for denials; they can infer what is expected of them only from patterns of retroactive denials.

Medicare's review system is designed on the premise that there are generally understood medical criteria and standards that hospitals and physicians can be expected to know and abide by. If that is the case, it should be possible for the PROs, on behalf of Medicare, to say what the standards are. It should be possible for hospitals to use these standards to avoid future penalties. But these standards do not exist as clear-cut rules or rigid criteria. Because medical care by nature is fraught with uncertainty, the lines being drawn by the PROs between appropriate and inappropriate behavior are being drawn arbitrarily and variably from PRO to PRO, and even by different physicians within the same PRO. The fact that the standards being enforced by the PROs are moving targets may help to explain why there appear to be so many cases--reportedly 40 percent to 60 percent--overturned upon reconsideration by the PROs themselves.

These decisions must be made in a less arbitrary manner. PROs must articulate the nature of the clinical standard upon which denials are based. Where there is doubt about medical necessity or appropriateness, the benefit of doubt should go to the treating physician. The "waiver of liability" in Section 1879 of the Social Security Act formerly served this purpose, but new rules implemented last year have all but eliminated this statutory protection against payment denial when the provider was acting in good faith.

PROs do not just enforce standards of clinical practice, they enforce Medicare coverage standards as well. It may be understandable that clinical standards are unclear, but it is inexcusable that program coverage policies should be so poorly distributed and subject to such variable interpretation. For example, in several states PROs are enforcing a policy regarding transfers that would make all transfers inappropriate if the transferring hospital technically could have provided care to be furnished in the receiving hospital. Rural community hospitals often transfer patients to a larger medical center for surgery, and receive the patient back so that recuperative care can be provided in the proximity of family and friends. Under the new policy, the transfer back to the original hospital would be denied, even if the admission is medically necessary and would likely improve the patient's recovery and speed discharge. In most cases, these ad hoc coverage rules have little to do with the clinical appropriateness of the treatment provided, and they are implemented without proper advance information to the hospital and physician community, leading to confusion and retroactively denied payment.

PROs are required to have educational intervention plans for problems identified during their review. PRO intervention plans have resulted in gradual increases in the volume of review when problems are found, rather than educational interventions regarding the standards to which the provider or practitioner will be held. As such, the PRO is performing claims review, not peer review. This type of review does not aim to promote standards of better health care; it serves only as a mechanism for denying payment after the fact for services provided to beneficiaries in good faith.

Hospitals and physicians are often in the dark regarding the nature of the transgression that has led to the denial, and if the providers can not understand the coverage standards, they will seem positively mysterious to the beneficiary. Unless beneficiaries can become better informed about the limits and extent of Medicare coverage, they can not be wise users of their Medicare benefit nor informed purchasers of supplemental coverage.

Medical criteria and standards must be subject to open discussion. HCFA should be required to assess the reliability and validity of the utilization criteria and quality review screens that are used by PROs. At the same time, PROs should perform periodic evaluations of the review criteria and screens in an effort to enhance their usefulness by providers in understanding and anticipating Medicare coverage decisions.

The extent to which these criteria can predict Medicare coverage decisions should play a significant role in deciding whether a provider could have known beforehand that the care they were providing would be denied. "Criteria" are written lists of clinical indicators of when treatment is necessary and that identify those cases that are generally appropriate. Those cases that fail to meet the criteria (that is, where there is no match of the patient's condition with those items on the list) are not necessarily inappropriate. The final decision is made by a reviewing physician based on his understanding of the "standards" prevailing in the community of what constitutes appropriate medical practice. PROs are required to use written criteria, but the standards, which make the difference in the ultimate judgment, are unwritten perceptions identifying those cases that are inappropriate and deserve censure. PROs must be required to identify just what these standards define as definitely inappropriate. The PROs must be required to be more specific about what Medicare does not cover if Medicare is going to be strict in its coverage decisions. Until Medicare defines its standards for coverage, providers, practitioners and beneficiaries will continue to be plagued by costly retroactive payment denials.

In addition, efforts to match the background and training of the reviewing and attending physicians would vastly improve the quality of PRO decisions. For example, initial decisions would be better if the original reviewers were specialists or consulted specialists in conducting reviews. Under current rules, the PRO is required to use a specialist, for example, a cardiologist to review heart surgery, only at the reconsideration stage. An obstetrician may review rehabilitation services, or an internist may review orthopedic surgery. This may contribute to the high rate at which decisions are overturned by PROs on further review, and it has affected the credibility of PROs within the physician community.

PROs should ensure also that physicians and nurses conducting review of rural hospital services are familiar with the way services are provided in rural areas. The PRO reviewers need to recognize that when applying quality standards there may be subtle variations medical practice and hospital utilization patterns in rural areas.

The AHA recommends that PRO reviewing physicians consult with appropriately trained specialists when requested to do so by the attending physician. In addition, for review of services with unique qualities like psychiatric and rehabilitation services, the initial reviews should be conducted by physicians with relevant specialty training. Finally, PROs should attempt to use physician and nurse reviewers with an understanding of medical treatment in rural areas when reviewing small and rural hospital services.

ENCOURAGING GOOD PERFORMANCE

The PRO statute authorized a flexible and efficient structure whereby local physician groups would be accountable to HCFA through their performance-basedcontracts rather than the prescriptive procedural requirements that characterized the antecedent PSRO program. The contracts could, in theory, vary by state allowing HCFA to address local problems, and give the PROs some latitude to be innovative in structuring their review plans and procedures to achieve a more efficient system, so long as the overall objectives were met.

While there is certainly some variety in the approaches taken by the many PROs, the opportunity for innovation and adaptability to local circumstances that is present in the statute has never been realized fully. HCFA has never been able to reconcile the objective setting, which should drive the PRO's review plan, with the set of basic reviews now required of all PROs. Rather than build a program on the investigation of actual abuse, HCFA has developed a uniform set of contracts that are based on hypothetical utilization and quality abuses anticipated by the incentive structure of the prospective pricing system (PPS).

PRO requirements seem to be predicated on the expectation that hospitals and physicians will circumvent the Medicare prospective pricing system to thwart its cost containment goals. Certain categories of claims are reviewed without regard to actual hospital performance, so all hospitals are subject to the same basic review. Hospitals with many admissions in the required review categories will be subjected to more intensive review, even if their overall performance is outstanding. Although the second contracts, entered into during the latter half of 1986, lowered the minimum review required in the review plan, all hospitals are still subject to review of at least a hefty 35 percent of Medicare discharges, and more intensive review when performance is poor. There is no reduction when performance is good. This inefficiency misdirects PRO resources and limits the attention PROs can give to the real problem providers.

The review system should focus review where there is a demonstrated problem and reduce unproductive review in those hospitals that demonstrate effective internal utilization control. These hospitals should continue to be monitored through a random sample of discharges, rather than the required categories of review, and should be subjected to more intensive external scrutiny only when their denial rates deviate unacceptably from the norms. If the PROs were granted some flexibility to adapt their required review plans to what they actually find when they conduct reviews, many of the resources now expended unproductively could be redirected to more useful purposes. For example, there is need for more on-site review in small and rural hospitals, greater access to specialized physicians during the initial reviews, and more educational functions.

CONCLUSION

The goal of the Medicare review program should be to improve the medical treatment of Medicare beneficiaries by assessing, and, where necessary, modifying hospital and physician behavior to ensure that beneficiaries get the care they need and only the care they need, and that this care meets

acceptable medical standards. This will only be accomplished by establishing a deliberate and coherent process for articulating standards of medical necessity, appropriate level of care, and quality of care. Ultimately, the effectiveness of peer review will depend on the extent and quality of peer interaction and education.

The current approach, with its focus on fiscal goals and claims denials, is more characteristic of the claims processing apparatus than it is of peer review. It is more burdensome than necessary and probably less effective than it could be in achieving changes in the practice of medicine.

Ideally, Medicare's peer review program should:

- Be driven by the best standards of medical treatment, not fiscal goals;
- Focus on identified problems, not anticipated or hypothetical problems;
- Ensure review by physician peers--by appropriately trained specialists to review specialty services, by physicians acquainted with treatment resources and standards in rural areas--and with as much peer interaction as possible;
- Provide for the education of physicians and hospitals about standards of medical necessity and appropriateness and conditions for Medicare coverage; and when these standards differ from those that prevail in the community, to state the differences clearly and educate the provider community before denying payment or issuing sanctions; and
- Provide incentives to promote the best possible internal utilization review and quality control so that the system is built systematically on the ability of good providers to control quality and utilization effectively.

Even if all these conditions were met, it would still be essential that the providers and practitioners affected by the PRO's decisions have an opportunity to challenge PRO decisions. An appeals process is necessary to insure that PROs remain accountable for their decisions and the appropriateness of their actions. Ultimately, we believe that Congress should consider establishing an independent body to adjudicate Medicare coverage appeals outside the administrative authority of HHS.

We appreciate this opportunity to present our views and recommendations on this important issue. The Association hopes that an effective PRO program, focused on fair and efficient review of the quality and appropriateness of care, can yet be achieved. We believe that such a program would benefit all involved--the Medicare program, the providers and physicians who provide the services, and most of all, Medicare beneficiaries.

STATEMENT OF JOHN J. RING, M.D., VICE CHAIRMAN, BOARD OF TRUSTEES, AMERICAN MEDICAL ASSOCIATION, MUNDELEIN, IL, ACCOMPANIED BY THOMAS WOLFF, ESQ., LEGISLATIVE ATTORNEY

Dr. RING. Mr. Chairman, I am a physician in the practice of family medicine in Mundelein, Illinois. Until last June, I was a board member of the PRO which serves the State of Illinois. I currently serve as Vice-Chairman of the Board of Trustees of the American Medical Association. With me today is Thomas Wolff of the AMA's Department of Federal Legislation.

Mr. Chairman, the AMA continues to strongly support medical peer review that focuses on quality assurance. We actively assisted many state medical societies in their efforts to become PROs, and we are pleased that a number of them are operating the PRO in their state. In addition, many other state societies supported the organization that received the PRO contract. These state societies maintain regular communication with their PRO.

We are seriously concerned, however, over a number of significant problems that have arisen with the PRO program. These problems, which unfortunately are increasing, are causing growing anger and resentment among physicians who must confront the PRO program on a daily basis. A major problem with the PRO program involves a lack of due process for physicians accused of violating the standard of care in the PRO area.

Under existing law, physicians have no right to an attorney, no right to present witnesses, and no right to cross-examine witnesses before a PRO can recommend a sanction to HHS. In fact, in some cases physicians may not even be able to find out who reviewed their case and therefore cannot confront their accuser.

In our view, the PRO law should be amended to specify appropriate due process requirements that all PROs must follow before they make a sanction recommendation to HHS.

The AMA has sought to intervene in litigation in Virginia on this very point. We urge prompt modification of the law so that this expensive litigation need not be pursued or repeated in other jurisdictions.

The PRO law also actually permits HHS to impose sanctions (including a civil monetary penalty and exclusion of the physician from the Medicare program) and to publish a notice in the newspaper of the sanction before the physician has an opportunity for any kind of a hearing.

We believe strongly that because the imposition of sanctions can result in severe and irreparable damage to a physician's reputation and standing in the community, the PRO law should be amended to provide physicians with an opportunity for a formal administrative hearing and judicial review before a sanction can be imposed and the public notified.

Another issue of concern is HHS's promulgation of a number of significant PRO program policies through the issuance of manual letters and transmittals rather than through the formal rulemaking process. By issuing such transmittals, HHS has actually circumvented the intent of the Administrative Procedure Act to pro-

vide interested parties notice and opportunity to comment on program implementation.

In our view, all major PRO policy decisions would benefit greatly from comment by interested groups as well as the general public.

Mr. Chairman, in my full statement, which includes our suggested amendments to the PRO program, we have discussed other areas of concern regarding the PRO program. They include undue emphasis on cost containment and punitive actions, the issuance of quality denial notices to patients without first giving the physician an opportunity to appeal, the qualifications of some PRO reviewers, the retroactive application of new directives, the disproportionate number of sanctions imposed on rural physicians, and HHS's policy of reimbursing PROs additional sums beyond their contract amount for sanction actions—while requiring PROs to fund educational activities out of their limited contract budgets.

In conclusion, Mr. Chairman, the AMA continues to strongly support true medical peer review that emphasizes quality assurance. We are concerned, however, that the problems with the PRO program are growing. Physicians are becoming increasingly frustrated and angry with the program. We believe strongly that the concerns we have identified must be adequately addressed or physician support for the program will be jeopardized.

Mr. Chairman, we commend you and this committee for holding this hearing, and for its oversight of the PRO program, and urge the committee to continue to monitor the program closely to help insure that it emphasizes quality assurance.

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

Senator DURENBERGER. Thank you, Dr. Ring. Dr. Ludden?

[The prepared written statement of Dr. John J. Ring and answers to questions from Senators Mitchell and Heinz follow:]

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Subcommittee on Health
Committee on Finance
United States Senate

Presented by
John J. Ring, M.D.

RE: Performance of the Peer Review Organization Program

March 27, 1987

Mr. Chairman and Members of the Committee:

My name is John J. Ring, M.D. and I am a physician in the practice of family medicine in Mundelein, Illinois. I currently serve as Vice-Chairman of the Board of Trustee of the American Medical Association. With me today is Thomas Wolff of the AMA's Department of Federal Legislation.

The AMA is pleased to have the opportunity to testify before this Committee concerning the performance of the peer review organization (PRO) program.

Mr. Chairman, the AMA continues to strongly support medical peer review that focuses on quality assurance. Quality assurance activities can also have positive impact on costs. Because of our strong commitment to ensuring that the PRO program emphasizes quality assurance, we

actively assisted state medical societies in their efforts to become PROs. We are pleased that a number of state societies are operating the PRO in their state. In addition, many other state societies supported the bid of the organization that was awarded the PRO contract for their state and maintain regular communications with their PRO. We are also pleased that the Department of Justice has recognized the appropriateness and importance of peer review by the medical profession in a December, 1986 letter. With less concern about antitrust actions, we expect voluntary peer review activities to increase.

We are seriously concerned, however, over a number of significant problems that have arisen with the PRO program. These problems, which unfortunately are increasing, are causing growing anger and resentment among physicians who must confront the PRO program on a daily basis. The major problems with the PRO program and our suggestions as to the appropriate means of addressing them are discussed below.

Due Process Concerns

Sanctions

The AMA believes strongly that patients must be protected from sub-standard care. We are concerned, however, over the lack of due process protection for physicians accused of violating the standard of care in the PRO area. The PRO law requires simply that reasonable notice and an opportunity for "discussion" be provided to a physician before a PRO can recommend a sanction to the Department of Health and Human Services (HHS) for an alleged violation. Thus, under existing law, physicians have no right to an attorney, no right to present witnesses,

and no right to cross-examine witnesses. In fact, in some cases, physicians may not even be able to find out who reviewed their case and therefore cannot confront their "accuser". While some PROs have established procedures that provide accused physicians a meaningful opportunity to review the charges against them and to respond effectively, many PROs have not established due process protections. In our view, the PRO law should be amended to specify appropriate due process requirements that all PROs must follow before they make a sanction recommendation to HHS. Such an amendment would remedy one of the most troublesome aspects of the PRO program.

Mr. Chairman, the AMA has petitioned to intervene in active litigation in Virginia on this very point. We urge prompt modification of the law so that this expensive litigation need not be pursued or repeated in other jurisdictions.

The PRO law also permits HHS to actually impose sanctions (including a civil monetary penalty and exclusion of the physician from the Medicare program) before the physician has an opportunity for any kind of a hearing. In addition, under existing regulations, after a sanction is imposed and before a physician has a right to a hearing, a notice of the sanction must be published in a local newspaper. Local hospitals, medical societies and other interested parties must also be notified.

We believe strongly that because the imposition of sanctions can result in severe and irreparable damage to a physician's reputation and standing in the community, the PRO law should be amended to provide physicians with an opportunity for a formal administrative hearing and

judicial review before a PRO sanction can be imposed and the public notified. Providing adequate protections to physicians should make the PRO sanctions process fairer and thus reduce the number of errors which inevitably result from a procedurally flawed process. We have developed draft legislation that would safeguard physicians' due process rights in the sanction process as well as remedy other problems with the PRO program. A summary of this draft bill is attached to our statement.

Quality Denial Notices

Another issue of concern involves the authority granted PROs to make so-called "quality denials." Last year, legislation was enacted that requires PROs to "promptly" notify patients whenever the PRO determines that the quality of a service does not meet "professionally recognized standards of health care." There is no requirement that this notice be sent only after the physician has an opportunity to challenge the initial denial determination. In fact, based on existing PRO notification procedures, such notification will likely occur before the physician is provided such an opportunity.

Serious adverse consequences to the physician-patient relationship as well as a possible increase in the number of unfounded professional liability lawsuits could result from prematurely notifying beneficiaries of quality denials. As a result, we believe that PROs should be prohibited from notifying a beneficiary of a quality denial until after the physician is afforded an opportunity to refute the charge. At a minimum, such due process safeguards should include the right to a reconsideration by the PRO and an independent panel of local practicing

physicians. We have also developed draft legislation that would accomplish this goal and urge you to give it careful consideration.

Insufficient Opportunity to Comment on PRO Regulations

Since the enactment of the PRO law, HHS has promulgated a number of significant PRO program policies through the issuance of manual letters and transmittals rather than through the formal rulemaking process. By issuing such transmittals, HHS has attempted to circumvent the intent of the Administrative Procedure Act (APA) to provide interested parties notice and an opportunity to comment on program implementation.

In our view, all major PRO policy decisions would benefit greatly from comment by interested groups as well as the general public. Thus we strongly urge that HHS be required to utilize the formal rulemaking process for any significant PRO program changes. Our view is supported by the decision in American Hospital Association v. Bowen. That case held that HHS must submit all rules that impose "a new procedure or obligation which is not directly derived from the language of a statute or regulation" to the notice and comment procedures of the APA. We hope that HHS will adhere to this ruling.

Other AMA Concerns

Undue Emphasis on Cost Containment

Since the inception of the PRO program, we have been concerned that the program places a greater emphasis on reducing Medicare costs than on ensuring that beneficiaries receive high quality care. While the new PRO contracts purport to place increased emphasis on quality issues, a widespread perception continues to exist, and is growing among

physicians, that the PRO program emphasizes cost containment often at the expense of the health of Medicare beneficiaries. We will continue to monitor this aspect of the PRO program closely and we urge Congress to do so as well.

Undue Emphasis on Punitive Actions

The AMA is concerned that HHS places undue emphasis on denial and sanction activity as a barometer of PRO effectiveness. This emphasis was evident in the recently completed PRO contract renewal process. In that process, the contract renewal bids of some PROs were reportedly hurt by the fact that they had not engaged in more aggressive sanction activity. While in some cases sanctions are undoubtedly warranted, it is often more appropriate for a PRO to work towards improving physician performance through non-punitive educational activities rather than denials or sanctions.

We are also concerned over HHS' policy of reimbursing PROs additional sums beyond their contract amount for sanction actions while requiring PROs to fund educational activities intended to address quality problems out of their limited contract budgets. Such a policy creates an inappropriate financial incentive for PROs to rely on sanctions rather than educational activities to address quality problems. In our view, reimbursement for the costs of educational activities should be a priority.

Qualifications of Reviewers

A major objection of many physicians concerning the PRO program involves the qualifications of PRO physician reviewers. Determinations

of PRO physician reviewers should be viewed as reasonable by most physicians in a community; too often this has not been the case. In addition, physicians are often reviewed by PRO physicians of a different specialty. This practice, which is not prohibited under existing law, is understandably upsetting to physicians who desire true "peer" review.

The AMA believes that PROs should assure that all physician reviewers have appropriate qualifications. Some PROs have developed good systems to accomplish this and these models should be disseminated by HHS to all PROs. In addition, the PRO reviewing physician should, in general, be in the same specialty as the physician being reviewed.

Retroactive Application of New Directives

Another concern with the PRO program involves HHS' policy of frequently requiring PROs to apply new review criteria and procedures on a retroactive basis. The result is that the criteria and procedures apply to patients admitted and discharged prior to any knowledge of the review criteria. This policy has caused considerable resentment among practicing physicians who are unaware of the new review criteria and procedures and who face retroactive denials before they are told the rules under which they are to operate. In our view, new policy directives should be implemented on a prospective basis only.

Excessive Number of Rural Sanctions

There are increasing indications that a disproportionate number of PRO sanction recommendations involve rural physicians and hospitals. This raises troubling questions concerning the appropriateness of the standards being used to evaluate medical care provided in rural areas.

We believe that this issue merits increased scrutiny to ensure that the care provided in rural areas is evaluated fairly.

Conclusion

In concluding, Mr. Chairman, the AMA continues to strongly support true medical peer review that emphasizes quality assurance. We are concerned, however, that the problems with the PRO program are growing. Physicians are becoming increasingly frustrated and angry with the program. We believe strongly that the concerns we have identified must be adequately addressed or physician support for the program will further erode and basic support will be jeopardized.

The AMA commends the Committee for holding this hearing and for its oversight of the PRO program. We urge the Committee to continue to monitor closely the PRO program to help ensure that the program emphasizes quality assurance.

Mr. Chairman, I will be happy to answer any questions members of the Committee may have.

2961p

January 1987

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(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.

(5) 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.

(6) 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,

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*All Section references except in Number 22 are to the Social Security Act

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.

(7) 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.

(8) 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.

(9) 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.

(10) 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.

(11) 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.

(12) Section 1154(a)(2) gives PROs the authority to determine whether Medicare payment will be made for a service. The amendment provides that neither the failure of a physician to obtain pre-admission review nor the admission of a patient despite a denial by the PRO would constitute per se grounds for withholding Medicare payment to the physician.

(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 1154(a) does not require PROs to provide regular written notice to all physicians in their area concerning the services that are subject to pre-admission review. The amendment would impose much a requirement on PROs.

(16) 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.

(17) 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.

(18) 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 administrative and judicial review of the Secretary's decision.

(19) Under Section 1156(b)(4), a practitioner who is dissatisfied with a sanction determination made by the Secretary is entitled to an administrative hearing and judicial review. However, the law does not require that the administrative hearing and judicial review occur before a sanction can be imposed. The amendment would impose such a requirement.

(20) 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.

(21) 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.

(22) Section 9401 of the Consolidated Omnibus Budget Reconciliation Act of 1985 requires PROs to perform 100% preadmission or preprocedure review of certain surgical procedures. The amendment would eliminate this requirement.

1. Question from Senator Mitchell:

In your testimony you expressed your concern about the apparent disproportionate percentage of rural physicians who are being sanctioned by PROs. Do you believe that the majority of these physicians are practicing the same quality of medicine as their urban counterparts and are being unfairly singled out for sanctioning? Or is there any substance to the position taken by some PROs that the quality of medicine practiced by rural physicians is inferior -- and that they are "not keeping up" with recent trends in medical care?

While individual cases of poor quality of care can be found in any setting including rural areas, the AMA believes strongly that the overwhelming majority of rural physicians practice high quality medicine. The skills of these physicians are comparable to those of urban physicians. Physicians within a state are subject to the same education, licensure and continuing education requirements regardless of locale. We have no evidence to indicate that patients in rural areas are less satisfied with the quality of their medical care. In fact, patients have defended many of the physicians accused by PROs of violating the standard of care. Data also indicate that more physicians, usually younger physicians, are locating in rural areas bringing with them the latest in medical knowledge and training.

Urban physicians do generally have greater access to advanced medical technology and resources. However, when a patient in a rural area needs a high tech medical procedure, his physician can send the patient either to a nearby rural hospital or to an urban hospital with access to such advanced technology. It is important to recognize that when time is of the essence or when a patient cannot be easily or safely transported, a rural physician and facility cannot duplicate the services in a tertiary care setting.

The methods used by PROs to detect potential quality problems may unintentionally have a disproportionate impact on rural health care providers. For example, a PRO may subject a hospital to 100% review or other corrective actions if 6% of admissions are denied. In a rural hospital, this percentage could be reached if a few admissions of one doctor on a three-physician hospital medical staff are deemed unnecessary. In a large urban hospital, one physician has no such impact in triggering corrective actions.

2. Question from Senator Heinz:

From the physician standpoint, what are the real day-to-day frustrations that they experience with the PROs?

The major day-to-day frustrations physicians experience with the PROs include inappropriate denials (particularly retrospective admission denials), the retroactive application of PRO directives, the lack of qualifications of some PRO physician reviewers, the lack of an opportunity for adequate appeal of adverse PRO reconsiderations and the lack of due process in PRO sanction determinations.

STATEMENT OF JOHN LUDDEN, M.D., MEDICAL DIRECTOR, HARVARD COMMUNITY HEALTH PLAN, BOSTON, MA, ON BEHALF OF GROUP HEALTH ASSOCIATION OF AMERICA AND AMERICAN MEDICAL CARE AND REVIEW ASSOCIATION, ACCOMPANIED BY RON HURST, AMERICAN MEDICAL CARE AND REVIEW ASSOCIATION

Dr. LUDDEN. My name is John Ludden. I am a physician and the medical director of Harvard Community Health Plan. With me today is Mr. Ron Hurst of the American Medical Care and Review Association. I am pleased to be here to represent the two national associations, AMCRA and GHAA, which are the the associations which represent the HMO industry. In the interest of brevity, I'm only going to present a summary of our testimony, but I would request that our entire statement be accepted for the record.

On June 1, the full range of health care services provided by HMOs under risk contracts with the Medicare program will come under scrutiny by existing peer review organizations or by the newly recognized QROs—quality review organizations. We support quality review.

Understand that ours is an industry that believes in a high standard of health care and further understands that both internal and external review of services must occur for quality of care to be maintained and assured. Quality assurance has been an integral part of HMO activities for over 40 years. Quality assurance requirements exist for us as a responsibility to our patients and at the federal and state levels because we have requested them; we have recognized the value of mandating such requirements as an affirmative statement in response to ill-founded charges that HMOs "skimp" or "skim" in their care in the interest of saving money.

And we understand the more recent drive for quality and quality review in organized prepaid health care systems which stems from Congress' concern that Medicare's prospective payment systems not be abused. But the record clearly shows that while the HMO business—like any other—has its occasional unscrupulous operator, the overwhelming majority of organizations in this industry are committed to providing health care consumers with a high quality product in an economically efficient manner.

One source of concern is that we are being singled out for systematic external review to verify that the quality of our health care services is good. As you know, fee-for-service physicians' offices—where the majority of ambulatory medical encounters occur—will not be subject to Medicare utilization or quality review until 1989. The "worst first" implications of this situation are not lost on us and are not likely to be lost on consumers. We believe consumers deserve to know what is happening in all health care settings, across all medical specialties, involving all third party payors and fiscal intermediaries.

But even if all providers were subject to review, we would still have to deal with the issue of a uniform and acceptable ambulatory care review methodology today. We are more than a little upset, therefore, that on June 1 of this year, in the absence of an acceptable methodology which has been demonstrated and proven, HMOs

with Medicare risk contracts will be subjected to quality review by the nation's PROs and perhaps some QROs. It disturbs us to think that the Federal government will behave as though there is currently a single workable HMO review methodology and will assure the public that this review methodology is "tried and true" with reliable and certain results. We politely but strenuously disagree. We have a number of specific comments around the proposed review process.

We applaud the strategy of attempting to reward plans with good quality assurance programs by lessening the burden of their reviews. But we would caution that there are some potential problems with the implementation of this strategy by so many different review organizations.

One major problem is that, given the general nature of the criteria for adequacy of a plan's own internal quality assurance program, the criteria will be interpreted differently by different review organizations and result in inconsistent assignment of HMOs to the basic and limited review categories.

The proposed review system could also have an impact—not necessarily positive—on innovation in HMO quality assurance programs. The cost of PRO mandated review may be too great to permit HMOs to explore other internal quality review techniques and methodologies. This would result in a stifling of quality review activities in the HMO setting where in fact the fairly uniform, voluntarily enrolled population provides a nearly ideal situation for studying quality of care.

We have expressed to HCFA our concern about their assumption that HMOs and CMPs will have information on all deaths among their Medicare enrollee population. This may produce incomplete, misleading mortality data. We have an underlying concern that this data will be released, as was the case with PRO review hospitals a year ago. We are heartened, but nervous, about HCFA's assurances that they will work with interested groups to identify what information should be routinely released and that they will let physicians, hospitals, and their providers, including HMOs, be in the forefront. We can assure you that we are not now in the feeling that we are in the forefront.

We have also expressed to HCFA our continuing concern about the in-state reviewer requirement.

Finally, we wish to go on record about what we consider to be one of the most disorganized policy intiatives we have ever experienced. The field of quality measurement is fraught with uncertainty. That a program of this scope would be put in place nationwide is a real indictment of the policymaking process. A number of well-planned demonstrations on a regional or statewide basis accompanied by careful evaluations would have allowed this initiative to go forward in a way that could have protected the health of Medicare enrollees, and advanced the state-of-the-art. This could have been accomplished without endangering the reputation and growth of an industry with a proud record of quality and cost-effective medical care.

Let me close by assuring you that, in spite of our strong feelings and legitimate concerns, we stand ready to work with you and with the officials at HCFA to ensure that this process is implemented as

equitably and as constructively as possible and that problems are identified and eliminated in a timely manner. Thank you.

Senator DURENBERGER. Thank you. Mr. Reibold?

[The prepared written statement of John Ludden, M.D. and answer to a question from Senator Mitchell follows:]

STATEMENT FOR THE RECORD

OF

JOHN LUDDEN, M.D.

MEDICAL DIRECTOR

HARVARD COMMUNITY HEALTH PLAN, INC.

My name is John Ludden, M.D. I am a physician and medical director of Harvard Community Health Plan. I am pleased to be here today on behalf of the two national associations which represent the HMO industry, AMCRA and GHAA. On June 1, the full range of health care services provided by HMOs under risk contracts with the Medicare program will come under scrutiny by existing peer review organizations (PROs) and/or by newly recognized quality review organizations (QROs). We support quality review. However, we are here today to express our concerns about some aspects of these imminent review activities, because a poorly conceived review effort which lacks a basis for fair comparison of HMOs with other providers may result in irreparable harm to our still developing industry.

Understand that ours is an industry that believes in a high standard of health care and further understands that both internal and external review of services must occur for quality of care to be maintained and assured. Quality assurance has seen an integral part of HMO activities for over 40 years. Rigorous quality assurance requirements were made a part of the federal HMO qualification process in 1973 and were incorporated into the eligibility requirements for HMOs and competitive medical plans (CMPs) seeking Medicare risk contracts ten years later. The vast majority of HMO enabling laws contain quality assurance provisions. These

requirements exist for us as a responsibility to our patients and at the federal and state levels because we have requested them; we have recognized the value of mandating such requirements as an affirmative statement in response to ill-founded charges that we "skimp" and "skim" on care in the interest of saving money.

And we understand the more recent drive for quality and quality review in organized prepaid health care systems which stems from Congress' concern that Medicare's prospective payment system (PPS) not be abused. This concern is one that is heightened by two General Accounting Office investigations of prepaid health plan irregularities, one involving California's Medi-Cal Program in the early 1970's and the other, more recently, concerning Medicare prepaid risk contract demonstrations in Florida. But the record clearly shows that while the HMO business -- like any other -- has its occasional unscrupulous operator, the overwhelming majority of organizations in this industry are committed to providing health care consumers with a high quality product in an economically efficient manner.

The very fact that virtually all Medicare risk contracting HMOs are providing the Federal government and Medicare beneficiaries with good value for their dollars merely underscores the serious complaint we now bring you with regard to the mandatory imposition of PRO quality review activities: HMOs are now being singled out from all other

providers of ambulatory care services for unique, unfair and discriminatory treatment. Our industry provides health care services to only 10 percent of the American population overall and to less than five percent of the Medicare beneficiary population. Yet we alone are being asked to undergo systematic external review to verify that the quality of our health care services is good. Should the reviews verify that the care is good -- and numerous studies over the years have concluded that the quality of care in HMOs is at least equal to if not better than care provided by fee-for-service practitioners -- then what useful information are we bringing to the 90 percent of Americans and 95 percent of Medicare beneficiaries who do not receive their care from an HMO? In fact, we will bring them no useful information because our quality of care equation will lack a denominator. As you know, fee-for-service physicians' offices -- where the majority of ambulatory medical encounters occur -- will not be subject to Medicare utilization or quality review until 1989. The "worst first" implications of this are not lost on us and are not likely to be lost on consumers. We believe consumers deserve to know what is happening in all health care settings, across all medical specialities, involving all third party payors and fiscal intermediaries.

Even if all providers were subject to review, we would still have to deal with the issue of a uniform and acceptable ambulatory care

review methodology today. We are more than a little disturbed, therefore, that on June 1 of this year, in the absence of an acceptable methodology which has been demonstrated and proven, HMOs with Medicare risk contracts will be subjected to quality review by the nation's PROs and perhaps some QROs. It is in fact possible that a different ambulatory care review methodology may be instituted in each state. Multistate HMO operators may find themselves subject to different review criteria in different jurisdictions. There will be no uniformity, and comparisons between HMOs will be difficult at best. Comparisons between HMOs and fee-for-service providers? Well, maybe in 1989 . . . It galls us to think that the Federal government will behave as though there is currently a single workable HMO review methodology and will assure the public that this review methodology is "tried and true" with reliable and certain results. We politely but strenuously disagree.

There is little evidence that the Congress, the Administration or anyone else has given serious study to the particular way in which HMOs and related systems do business in the quality assurance arena. Had this been done, it would be clear that quality health care is not the incidental by-product of physician interaction with patients. To the contrary, the HMO industry has long recognized that quality health care comes from conscious and systematic action to monitor, record and discuss the subjective judgments of patients and

providers. These efforts have early roots in the HMO industry and are well developed in mature organizations. But, and the important point is, these quality assurance activities are there and occur with purpose and conviction in well run HMOs. It would have been reasonable for the Health Care Financing Administration (HFCA) to draw on this reservior of knowledge and experience in designing their HMO quality review system. Instead the basis for this new system is the extremely labor intensive and expensive system of medical record review which the PROs currently employ.

We are disturbed to read that HCFA has asserted that "this Administration believes that competition among health care providers can be an effective incentive for quality in health care." The incentive to provide quality care should exist whether or not there is competition. The notion proposed by HCFA is dangerous and irresponsible. It is a vehicle for continuing the discriminatory regulation of HMOs involved with Medicare because of their being perceived as competitive systems while giving carte blanche to individual fee-for-service physicians. It falsely gives the public reason to believe that HMO physicians are inherently less concerned about quality of care because of their involvement in competitive systems. We are angry and upset that this type of thinking is behind the HMO review program that the government proposes to set in motion in a few short weeks.

We also have a number of specific comments regarding the proposed review process.

The strategy for HMO review as outlined in HCFA's recently published request for proposals (RFP), provides for three levels of review. Plans receive an initial review of their quality assurance program. Based on this review and an assessment by the review organization of the adequacy of the HMO's quality assurance program, plans are sorted into two levels of review -- limited (less review) and basic (medium level). Plans being reviewed under either level face the possibility of receiving intensified review if certain thresholds of problems are detected.

We applaud this strategy of attempting to reward plans with good quality assurance programs by lessening the burden of their reviews. But we would caution that there are some potential severe problems with the implementation of this strategy by so many different review organizations.

One major problem is that, given the general nature of the criteria for adequacy of a plan's own internal quality assurance program, the criteria will be interpreted differently by different review organizations. This could play out in a number of different ways. For example, it is conceivable that a review organization in one state would interpret the criteria strictly and put all the HMOs under the basic HCFA review plan. In another state, the initial review of the quality assurance program might be more cursory with

plans almost automatically being assigned to a limited review. Alternatively, in a state that is dominated by one HMO, their approach to quality assurance might be viewed by the review organization as a model, so that different approaches by other HMOs might be viewed as deficient because they are different. There is clearly a high potential for inequity in the interpretation of these criteria.

There is a second major problem. Throughout the RFP is an underlying assumption that the first -- if not the only -- way of assuring quality lies in the review of medical records. While we believe that peer review of medical records is an important component of good quality control, we also believe that targeted audits are also an extremely effective monitoring tool which allows review of a much larger number of cases for a given expenditure of effort. By using measurable performance goals, targeted audits also allow for a much higher degree of reliability in the review process. While HCFA has responded to this point by asking review organizations to propose methodologies for focused ambulatory review, it is our concern that in their initial review of the HMO/CMP quality assurance programs, the PROs will be proposing review activities similar to the ones they now perform in hospitals.

It is clear that traditional PRO review of HMOs will be burdensome both from a human resource standpoint and a cost standpoint. Because of the heavy reliance on medical records which must be located -- often at several locations for one patient -- and then photocopied, quality assurance may become an enormous paper pushing exercise in which true quality and caring for the patient become secondary considerations. Moreover, the cost of implementing PRO mandated review may affect the competitiveness and marketability of HMO risk contracts themselves. As you are aware, one of the attractions of these contracts is the ability of the HMO to convert "savings" into additional benefits for the beneficiaries. Increasing the cost of quality assurance activities will diminish the extra benefits that HMOs can provide under these contracts. Should the ability to provide extra benefits become too constrained, HMOs will find little incentive to participate in the Medicare risk contract program at all. This would be counter-productive to the stated objectives of the Administration and the Congress and a disservice to Medicare beneficiaries.

The proposed review system could also have an impact -- not necessarily positive -- on innovation in HMO quality assurance programs. For some plans whose quality assurance programs do not rely heavily on peer review of medical records, they will face a choice between undergoing the more burdensome basic review and

putting more emphasis on this component of their quality assurance process. The cost of PRO mandated review may be too great to permit HMOs to explore other internal quality review techniques and methodologies. This would result in an unfortunate stifling of quality review activities in the HMO setting where a fairly uniform, voluntarily enrolled population provides a near ideal situation for quality of care research.

We have also expressed to HCFA our concern about their assumption that HMO/CMPs will have information on all deaths among their Medicare enrollee population. The RFP is inconsistent on the point of whether this refers to deaths anywhere or only in the health care settings. However, the more fundamental problem is that systematic information on enrollee deaths is not readily available to HMOs. We have suggested that HCFA either limit the sampling frame to inpatient deaths, information on which is readily available, or that they use another source of data, such as Social Security records. The underlying concern is that incomplete and misleading mortality data not be released, as was the case with PRO reviewed hospitals one year ago. In this regard, we are heartened, but still nervous, about HCFA's assurances that they will work with interested groups to identify what information should be routinely released and that they will in fact let physicians, hospitals, and their providers, including HMOs, be in the forefront of the move to develop effective quality measures. However, we can assure you that we do not feel we are in the forefront of this effort at this time.

We have also expressed to HCFA our continuing concern about the in-state reviewer requirement, and the potential which it has to create conflict-of-interest situations. The problem is that because the pool of potential reviewers in any given state is generally small, and because the HMO industry is a highly consolidated one which grows more so daily, many plans will face the prospect of being reviewed by physicians from competing organizations or by fee-for-service providers. Since the PRO legislation was developed with a focus on the hospital industry, an industry which is much less consolidated than our own, the problem which the in-state reviewer requirement creates for HMOs has never been adequately considered. We are aware that the requirement is a statutory one. We hope to work with you to find an appropriate legislative solution for this situtation.

Finally, we wish to go on record about what we consider to be one of the more disorganized policy initiatives we have ever experienced. That a program of this scope would be put in place nationwide in an area -- quality measurement -- is fraught with so much uncertainty is a real indictment of the policymaking process. A number of well-planned demonstrations on a regional or statewide basis accompanied by careful evaluations could have allowed this initiative to go forward in a way that would have protected the health care of Medicare enrollees, and advanced the state-of-the-art

of quality measurement to the benefit of our whole society. This could be accomplished without endangering the reputation and growth of an industry with a proud record of quality, cost-effective medical care.

Let me close by assuring you that, in spite of our strong feelings and legitimate concerns, we stand ready to work with you and with officials at the Health Care Financing Administration to ensure that this process is implemented as equitably and as constructively as possible and that problems are identified and eliminated in a timely manner.

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John M. Ludden, M.D.
Medical Director

May 21, 1987

Honorable George Mitchell
Chairman, Subcommittee on Health
Committee on Finance
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

I am happy to respond to your letter of March 31 subsequent to my testimony at the Health Subcommittee hearing on March 27, 1987. Your question concerning whether, in light of the situation with the IMC health maintenance organization in Florida, PRO review of HMOs might shore up public confidence in the industry, is a good one.

The IMC situation is, indeed, unfortunate, for both the Health Care Financing Administration and the HMO industry. From our perspective a great deal of damage could befall HMOs as a result of the public perception that IMC might be representative of all HMOs. In fact, IMC has had unique problems. Our industry is proud of its strong record of high quality medical care and numerous studies support the conclusion that the quality of care provided by HMOs is equal to if not better than the quality of care provided in the fee-for-service system.

The PRO system is not widely known by the general public. It is questionable whether PRO review of inpatient services has had an impact on the public's perception or utilization of individual hospitals or physicians. Moreover, there is no guarantee that the public will perceive it positively; it is possible that the public might see it as a disciplinary response to a wayward industry.

In sum, I feel it would be unfortunate if PRO review of HMOs were promoted primarily to support public confidence. There is a certain "guilty until proven innocent" logic which surrounds this notion. Quality of care review should be promoted, carefully and thoughtfully, for its own sake in all health care settings. If quality review is perceived as a punitive measure it will never be accepted by HMO physicians and will ultimately fail. There is a real danger that HMOs, which have already had mixed experiences with Medicare risk contracting, will be driven out of the program altogether.

Finally, as I tried to point out in my testimony, our industry is troubled by two shortcomings of this review process. The first is that the current state of medical care quality measurement is crude: we have many doubts about the validity of the findings which will emerge from this system. The second and more fundamental concern is the lack of an adequate frame of reference: as long as the only comparison point for overall HMO quality is the ideal, HMOs are in danger of being found wanting. This is a potential hazard as long as there is not systematic information of the 95 percent of Medicare services which are delivered outside the HMO setting.

The Group Health Association of America is pleased to have been allowed to testify at the Health Subcommittee hearing on this issue, and remains eager to assist the Congress and the Administration in any way it can to assure a smooth PRO/QRO review implementation process.

Sincerely,

John M. Ludden, M.D.
Medical Director

cc: James Doherty
Margaret O'Kane

JML/tg

STATEMENT OF PETER REIBOLD, VICE PRESIDENT, PROVIDENCE HOSPITAL, COLUMBIA, SC

Mr. REIBOLD. Senator Durenberger, I am Pete Reibold, and I am the Executive Vice President of Providence Hospital in Columbia, South Carolina. I'd like to just share with you a little of our experience in South Carolina, because I think we face a rather unusual situation in our relationship with the Peer Review Organization that has responsibility in our state.

In November 1985 the agreement between HCFA and the then-existing PRO in South Carolina was terminated. South Carolina operated without a PRO from November of 1985 until July of 1986, when HCFA entered into a new contract with a North Carolina company, Metrolina Medical Foundation, Inc., to operate the South Carolina Peer Review Organization. It was not until October 1, 1986, that the new PRO began to review activities of South Carolina hospitals for Medicare claims. From November 1985 until the new PRO began its operations, hospitals in South Carolina used the same admissions review criteria that had been in effect with the old PRO.

South Carolina hospitals have experienced many problems with the South Carolina PRO that we feel impact upon the effective operation of our hospitals and the quality of care for our patients. These problems are not unique to a particular hospital but are affecting the delivery of medical care for patients throughout South Carolina.

First, hospitals did not receive adequate notice of the new PRO criteria. Hospitals received the PRO screening criteria for inpatient surgical and diagnostic admissions in November 1986. Hospitals began to immediately initiate utilization review and training programs to insure that the new guidelines would be followed. This review took place, takes place, and will continue to take significant time to effectively implement in South Carolina.

Unfortunately, the effective date for suffering financial loss from the application of these criteria may be retroactive to November 1, 1985, even though the notice was received by hospitals in November 1986—some 12 months later.

We contend, that even though there has been no literal change in the wording of the regulations governing the screening criteria, South Carolina PRO's interpretation is so radically different from that of the previous PRO as to be in effect new regulations, and therefore should be subject to the same rules of notice as the new regulation.

The South Carolina PRO contends that the South Carolina hospitals were informed on several occasions of the date on which the new procedures would be released. But in fact, the new procedures were received by the hospitals in November.

South Carolina hospitals feel that fairness would dictate that the hospitals be given a reasonable period of time to educate and train admitting physicians and our hospital staff and set up appropriate plans to insure compliance with new PRO criteria.

Second, we believe that the South Carolina PRO's interpretation of HCFA regulations has caused considerable confusion for hospitals in South Carolina. Major examples of the South Carolina

PRO's interpretation revolve around the Protective Overnight Observation policies. We believe that the South Carolina PRO's policy goes far beyond the PRO's statutory authority and exceeds the provisions of the Hospital Manual, Section 210.

The PRO is denying cases under this provision when the patient is in the hospital for fewer than 24 hours, regardless of his acuity or the expectation of the attending physician. It also will deny admission when the patient "presents with an illness of unclear character" and 24 hours of hospital care does not reveal the need for further hospitalization.

I'd like to share just one example of a situation that occurred in my hospital. On Friday, February 6, 1987, we issued a letter of noncoverage to an 84-year old female patient who had been hospitalized at our hospital for an extended period of time. This letter advised the patient that continued hospitalization was unnecessary and that, as a result, Medicare might not cover expenditures for additional services. The letter was issued in an effort for us to comply with what our understanding was of the South Carolina PRO guidelines.

After issuing the letter, the hospital staff spent hours on the telephone explaining the implications of the letter to both the patient's son-in-law and, in separate conversation, to the grandson who holds the power of attorney over the patient.

Conversations began on a Friday afternoon and continued throughout Monday, the following Monday, February 9. At 12:30 p.m. on Monday, the grandson requested that the PRO conduct an immediate review of the case to determine whether Medicare would cover the stay.

Realizing that the patient's medical records needed to be duplicated and mailed to the PRO by the next business day, Providence Hospital's medical records department began to duplicate the 1,200-page medical record.

At approximately 3:15 p.m., we notified the PRO of the difficulties were were having in completing the copying of the medical record in the one day that we were allowed. We requested a one-day extension of the record delivery deadline, but this was not granted. We then offered to have the record hand-delivered to the PRO's Columbia office—Columbia, South Carolina—on the following day. This was also not allowed. We then requested that the PRO's reviewers already assigned to our hospital be allowed to review the chart in the course of their routine chart review. This was also not granted.

The end result of this was that the PRO instructed us to Federal Express the chart to them late Monday afternoon and to duplicate and mail the remaining chart the following day. Total copying time for this one patient was 4 hours and 15 minutes.

Late Tuesday afternoon, we received notification from the PRO that although the patient no longer needed hospital care, a letter of non-coverage should not have been issued because the patient needed skilled nursing care, and these days could be covered under the patient's "lifetime days".

In summary, all of the above actions had been unnecessary and caused extreme concern and confusion to the patient and the family. These are the kinds of examples that we are experiencing

in South Carolina. I thought they might be of interest to you. Thank you.

[The prepared written statement of Mr. Peter Reibold follows:]

Remarks of Pete Reibold,
Executive Vice President of Providence Hospital
before a Subcommittee of the Senate Finance Committee

March 27, 1987

Mr. Chairman, members of the Senate Finance Committee. My name is Pete Reibold, and I am Executive Vice President of Providence Hospital, located in Columbia, South Carolina. Providence is a 239 bed hospital where our specialties are cardiovascular disease and ophthalmology. Providence is a non-profit Catholic hospital, founded June 1938, and operated by the Sisters of Charity of St. Augustine.

South Carolina hospitals face an unusual situation in their relationships with the Peer Review Organization (PRO) that has responsibility for our State. In November 1985 the agreement between HCFA and the then-existing PRO, the South Carolina Medical Care Foundation, was terminated. It is my understanding that HCFA was not satisfied with the denial rate of the Medical Care Foundation. South Carolina operated without a PRO from November 1985 until July 1986, when HCFA entered into a new contract with a North Carolina company, Metrolina Medical Foundation, Inc., to operate the South Carolina Peer Review Organization (SCPRO). It was not until October 1, 1986, that the new PRO began to review activities of South Carolina hospitals for Medicare claims. From November, 1985, until the new PRO began operations, Providence Hospital used the same admissions criteria that had been in effect under the old PRO.

Providence Hospital has experienced three major problems with the SCPRO that we feel impact on the effective operation of our

hospital and the quality of care our patients receive. These problems are not unique to Providence and are affecting the delivery of medical care for Medicare patients everywhere in South Carolina.

First, Providence did not receive adequate notice of the new PRO's Admission Criteria. Providence Hospital received from the SCPRO its screening criteria for inpatient surgical and diagnostic admission on November 15, 1986. Providence immediately initiated a utilization and review plan and a training and information program to insure that the SCPRO's screening criteria were followed. This review plan took, takes and will take substantial time to be effectively implemented.

Unfortunately the effective date for suffering financial loss from the application of these criteria is October 1, 1986. We received effective notice on November 15.

We contend, that even though there has been no literal change in the wording of the regulations governing the screening criteria, SCPRO's interpretation is so radically different from that of the previous PRO as to be in effect a new regulation, and, therefore, should be subject to the same rules of notice as a new regulation.

SCPRO contends that Providence, and other hospitals, were informed on several occasions of the date on which the new procedures would be released. In fact, the substance of the new procedures were received on November 15, 1986, forty-five days after SCPRO made the new procedures effective.

Fairness dictates that Providence and other South Carolina hospitals be given a reasonable time period to educate the

admitting physicians and set up appropriate plans to insure compliance with SCPRO's new criteria. Under the current effective date of October 1, 1986, Providence could suffer financial losses for denials for admissions after that date. Also, any denials after October 1st will count against Providence's profile. A high profile will lead to adverse publicity and intensive review.

Secondly, the SCPRO's interpretation of HCFA regulations has caused considerable confusion for Providence and other South Carolina hospitals. A major example is SCPRO's interpretation of the Protective Overnight Observation period. I am attaching the SCPRO's policy along with Section 210 of the Hospital Manual, published by HCFA, on which it is based.

SCPRO's stated policy goes far beyond the PRO's statutory authority and manifestly exceeds the provisions of Section 210. Under Section 210, a person is generally considered an inpatient if admitted with the expectation that he will occupy a bed overnight even if he is later discharged without doing so. The exception in Section 210A is quite specific: a patient with "known diagnosis" enters for "a specific surgical procedure... that is expected to keep him in the hospital for only a few hours" will be considered an outpatient. The PRO is denying cases under this provision when the patient is in the hospital fewer than 24 hours regardless of his acuity or the expectation of the attending physician. It also will deny admissions when the patient "presents with an illnesss of unclear character" and 24 hours of hospital care does not reveal the need for further hospitalization.

SCPRO's interpretation of this regulation has caused confusion, unhappiness and unnecessary stress on our patients. In addition, Providence and other South Carolina hospitals could suffer financial losses because of this erroneous interpretation by the PRO.

Thirdly, the confusion caused by the SCPRO in interpreting and applying the regulations has a direct impact on the patient and his or her family. Let me give you just one example. On Friday, February 6, 1987, Providence issued a letter of non-coverage to an 84 year old female patient who has been hospitalized at Providence since September 27, 1986. This letter advised the patient that continued hospitalization was unnecessary and that, as a result, Medicare might not cover expenses for additional hospital services. The letter was issued in an effort to comply with SCPRO guidelines.

After issuing the letter, Hospital staff spent hours on the telephone explaining the implications of the letter to both the patient's son-in-law and, in separate conversation, to the grandson who holds power of attorney over the patient.

These conversations began on late Friday afternoon and continued throughout the morning on Monday, February 9, 1987. At 12:30 p.m. on Monday, the grandson requested SCPRO to conduct an immediate review of the case to determine whether Medicare would cover continued stay.

Realizing that the patient's medical record (as per the attached SCPRO "Procedures for Issuing Notices of Non-Coverage for Continued Stay") would need to be duplicated and mailed to the SCPRO by the next business day, Providence's medical records

department began to duplicate the 1200 page medical record. On that particular day, not only was the medical records department short of staff, but also the copy machine was broken

At approximately 3:15 p.m., we notified the SCPRO of the difficulties which we were having in meeting SCPRO's time frames. We requested a one day extension in the record delivery deadline but this was not granted. We then offered to have the record hand delivered to SCPRO's Columbia office on Tuesday, February 10, 1987. The SCPRO advised that the record must be delivered to the Charlotte office. We then requested that SCPRO's reviewers (already assigned to our hospital) be directed to review the chart in the course of their routine chart review activities on Tuesday, February 10, 1987. This was not granted.

As an end result, SCPRO instructed us to Federal Express part of the chart to them on late afternoon Monday and to duplicate and mail the remainder the following day. Total copy time was 4 hours and 15 minutes.

Late Tuesday afternoon, we received notification from SCPRO that although the patient no longer needs hospital care, the letter of non-coverage should not have been issued because the patient needs skilled nursing care (typically offered in extended care facilities). Therefore the remaining portion of the patient's hospitalization would be covered by the "lifetime days" provisions of the Medicare policy. In summary, all above actions had been unnecessary, and had caused extreme concern and confusion for the patient and her family.

While the above complaints about the peer review organization that serves South Carolina are specific and are

based on singular instances, we believe that they are not unique. We further believe that they represent a mentality and an approach to enforcement of the laws and regulations that have a direct effect on the quality of care received by patients.

If PRO's are anxious to save dollars so that they can look good and establish a "good" record for HCFA that they cause confusion for patients and hospitals, they do the program a disservice and present a threat to quality care for patients.

We strongly suggest, Senator, that your committee take appropriate action to ensure that HCFA oversees the peer review organization program in a fashion that will be fair, and financially effective, but will also be tempered with the realization that the ultimate purpose of the Medicare program is quality care for sick people.

Thank you.

Senator MITCHELL. Thank you very much. My apologies to the witnesses for not having been here during your oral testimony. I will review the written statements. Senator Durenberger? That's a vote that has just begun, so we'll only have a few minutes for questions.

Senator DURENBERGER. Mr. Chairman, I ask unanimous consent to the statement by our colleague, Senator Heinz, together with some questions that he has of this and the other witnesses be made part of the record.

Senator MITCHELL. Without objection.

[The questions follow:]

Senator DURENBERGER. I just want to make a comment on Dr. Ludden's testimony that concerns the HMOs' medical plans, etcetera.

And since you used words like being upset and having strong feelings, as one of the people that intends to agree with you in terms of the haste with which this policy was put together, I want to just add a comment for the record that says that those who think that the way in which this was done might be confused with the way in which it is going to be implemented, would rush to assure you and other who are involved in this new phase of peer review that we are very, very sensitive to the fact that nobody is trying to throw the prepaid at-risk baby out with the bath water of so-called quality assurance.

It isn't so much that HMOs, or anybody else similarly instituted, are being singled out or picked on. I think the reality is that everyone is being subjected to a certain amount of scrutiny. That's what these hearings are all about.

But there is, in the HMO, a certain built-in incentive to underutilize service. There is a built-in incentive, if you want to, to skimp in one way or another. And since that's there, you and we need to find the assurance that is not happening.

And also to find—and I think this is the most important part of this process—to find the ways in which quality, or access to quality health care in this country is being facilitated by using the private health plan option or the competitive medical plan approach. I tend to look at this experiment, or this thing we're going through—not experiment; it's fact—as an opportunity for you to tell the world that the values in accessing consumers to quality health care, rather than to look at it as though you are being picked on by the peer review process.

Dr. LUDDEN. The concern is that the output of the process may be misleading, at least at first. I am grateful for your comments. I think it is clear that HMO physicians have for many years been very concerned both about the incentive structure and about the appearance of the incentive structure. And that's why as an industry we have been so active in building up our internal quality assurance mechanisms and why we are so aware of the very grave difficulties that exist in trying to appropriately and accurately review ambulatory medical care.

Senator DURENBERGER. But I think if Senator Heinz would have been able to stay here in person, you would have gotten sort of an angry reaction from him to your statement, because when he chaired the Committee on the Aging, he was hearing sort of first

hand, a lot of the testimony. And, of course, he was principally behind this effort to get quickly into quality review. And that's been moderated somewhat in this process and I just, I assure you that we here are I think who have been involved with this are all sensitive to the fact that we need to encourage more utilization of PHPOs. We certainly need your help in the peer review process to accomplish this.

Mr. Chairman, thank you very much.

Senator MITCHELL. Thank you very much, Senator. Thank you, gentlemen. I apologize again, especially to my good friend Warren Kessler, who came all the way down from Augusta, Maine to testify here.

I have a series of questions for you which I will submit to you in writing. Senator Durenberger, I now have to get to the floor to vote in the next few minutes. We thank you all. The hearing has been very informative, and we look forward to working with all of you. The hearing is closed.

(Whereupon, at 12:10 p.m., the hearing was concluded.)

[By direction of the chairman the following communications were made a part of the hearing record:]

AMERICAN ACADEMY OF OPHTHALMOLOGY

SECRETARIAT FOR
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April 7, 1987

Hon. George Mitchell
Chairman
Subcommittee on Health
Committee on Finance
U.S. Senate
Washington, DC 20510

Re: March 27 Hearings on Peer Review Organizations

Dear Mr. Chairman:

The American Academy of Ophthalmology, representing 90%, or 15,000 ophthalmologists in the U.S., wishes to make the following comments for the record of the March 27 hearings on Medicare Peer Review Organizations.

Second Opinion Program. The Consolidated Omnibus Budget Reconciliation Act (COBRA), signed into law in April, 1986, includes a Medicare second opinion program for ten high volume elective surgical procedures, to be implemented by the state Peer Review Organizations.

Since the PROs are likely to review cataract surgery as part of the second opinion program, the Academy has taken a pro-active position. We developed guidelines on cataract surgery, and encouraged our state ophthalmological societies to work closely with their PROs to adopt mutually agreeable guidelines. We have met formally and informally on a national level with PRO medical directors and staff.

Post-operative Care. In our minimum guidelines for cataract surgery (see Attachment A), we emphasize the importance of the doctor-patient relationship, in that the operating surgeon should be responsible for doing the pre-operative "work-up" on the cataract patient, as well as the post-operative follow-up for an appropriate period of time (approximately 2-3 months). The provision of appropriate post-operative care has been a cornerstone of the American Academy of Ophthalmology's Code of Ethics (which was supported by the FTC).

Florida PRO Guidelines. In the anticipation of a January 1, 1987 implementation of the second opinion program, the Florida PRO, in conjunction with local ophthalmologists, adopted an edited version of the Academy's suggested pre-surgical review guidelines. The PRO then submitted them to the Medicare Regional Office in Atlanta for approval. The Regional Office rejected the Florida proposal (see Attachments B and C). We are concerned that this rejection may be an encroachment by HCFA into the PRO's mandated authority to establish criteria for determining medical necessity and quality of care.

We urge the Committee to assure that HCFA does not impede the state PROs efforts to work with their local medical associations and specialty societies in establishing appropriate guidelines for insuring medically necessary quality care.

Assistants-at-Surgery. On March 1, 1987, the state PROs implemented a review of requests for a second surgeon (assistant-at-surgery) during cataract surgery, as mandated in COBRA. We understand that many PROs consulted with their state ophthalmological societies in establishing a process for considering the medical necessity of an assistant-at-surgery. Many states adopted edited versions of the Academy's guidelines. We believe this approach could work well for the second opinion program, too.

We would be happy to supply the Committee with further information or assistance.

Sincerely,

Hunter R. Stokes, M.D.
Secretary for Governmental
Relations

Attachments

Celebrating 75 Years 1912-1987
Advancing Foot Health...
Enriching the Quality of Your Life!

American Podiatric Medical Association

March 27, 1987

The Honorable George Mitchell
Chairman, Subcommittee on Health
Committee on Finance
U.S. Senate
S. C. 205
Washington, D.C. 20510

Dear Mr. Chairman:

With regard to your recently held subcommittee hearing on Peer Review Organizations, the Association files this letter for the purpose of the printed record. It serves to express our strong support for peer review as a most effective tool to assure the delivery of quality health care services. Equally important, however, we wish to register a grievance which, as far as doctors of podiatric medicine are concerned, impedes their participation in the PRO program.

The APMA and its component societies have promoted and engaged in peer review for many years. When permitted to effectively function, peer review represents the most reliable means to assure the quality and the efficiency of health and medical care services. The Congress acknowledged that fact in 1982, when the Peer Review Improvement Act was enacted. Putting aside initially our particular grievance with the law, we can and do support in every respect that which the statute seeks to accomplish.

As physicians under Medicare, doctors of podiatric medicine find it incomprehensible that the Peer Review Improvement Act limits the meaning of that term to medical doctors and osteopaths. The effect of that limitation has been to rule out the participation by podiatrists at any PRO policy making level. Yes, the law states that ones other than MD's and DO's must be consulted and utilized by PRO's when their services are affected. In some cases, this has worked reasonably well. In most, it doesn't work at all or the "must be utilized and consulted" is merely superficially imposed.

In instances where PRO's have been reluctant to involve podiatrists in the review process, the Health Care Financing Administration has been helpful in making known to the organizations the law's clear intent. This has been a ridiculous, though often necessary, exercise to undertake in order to gain something the law specifically directs to happen anyway.

American Podiatric Medical Association

The Honorable George Mitchell
Chairman, Subcommittee on Health
Committee on Finance
U.S. Senate
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Presumably, the law limited PRO governance to allopathic and osteopathic physicians in order to placate their opposition to the initiative in the first place. By so doing, other medicare physicians, specifically podiatrists, were given second class citizenship status in the peer review process. We can think of no public interest purpose whatsoever to justify that decision.

Unlike our allopathic colleagues, who now seek to repeal the act, all we seek is the opportunity to participate on a co-equal basis in the program. In addition to being consulted, we want the authority to participate at the policy making levels of the PRO program. Until and when that happens, peer review is a facade as far as doctors of podiatric medicine are concerned.

I trust you will see merit in our concern and appreciate the opportunity to share it with you.

Yours truly,

John R. Carson

John R. Carson, Director
Governmental Affairs

STATEMENT

OF THE

AMERICAN SOCIETY OF INTERNAL MEDICINE

TO THE

SENATE FINANCE SUBCOMMITTEE ON HEALTH

ON

MEDICARE PEER REVIEW ORGANIZATIONS

March 27, 1987

The American Society of Internal Medicine (ASIM) takes this opportunity to provide testimony for the record on the Medicare Peer Review Organization (PRO) program. The Society has over 22,000 practicing internist members, many of whom are primary care practitioners for Medicare patients and, therefore, have had personal experience with the PRO program. At ASIM's behest, many members also actively participate in their PROs as physician reviewers, directors of medical review, board members, and in other leadership capacities. The Society has also established a Committee on Utilization and Quality review to help ASIM monitor the PRO program at both the national and local levels. This testimony reflects the Society's experience in these areas with the PRO program.

Although ASIM has been a firm advocate of voluntary physician-directed peer review, the present PRO program is of growing concern to the Society. Members are reporting with increasing frequency instances where peer review has not been conducted in the best interest of beneficiaries, practitioners and providers. Specific concerns that members are reporting include the following types of problems:

- Cases where health care that normally is considered prudent is denied because, in retrospect, it could have been provided in an outpatient setting or in some other manner, e.g., the PRO decides retrospectively that a patient treated in the hospital for stroke symptoms could have been cared for on an outpatient basis.

- Cursory review of medical cases that overlook or omit pertinent details in the medical record.

- Pro forma reconsideration hearings with little or no meaningful discussion of the case in question.

- Denial notices that denigrate physicians' care and/or do not properly explain the reasons for denial, i.e., notices that term denied care as simply "inadequate care" with no other explanation.

- Threats of sanctions for good medical care primarily because it does not meet pre-established criteria - even in some instances when the reviewer disagrees with the blanket application of the criteria.

- Increasing demands on physicians for satisfying PRO requirements, such as unreasonable requests for additional documentation or information and unreasonable requirements to travel considerable distances for reconsideration hearings.

Although the Society realizes that some review organizations are doing adequate jobs despite limited funds and a lack of program flexibility, ASIM is concerned that the above problems are negatively affecting the practice of medicine and, ultimately, patients' health care. While admittedly much of the information the Society has received is anecdotal, some complaints are well documented and the volume of letters and phone calls ASIM has received about the peer review program indicates that the credibility of the PRO program and the integrity of the Medicare program are being undermined. To further ascertain the extent of these problems, ASIM will be initiating a project to more accurately assess problems physicians and patients are experiencing with the PRO program. Based on the reports received from internists to date, however, the Society has reached the following disturbing conclusions:

- **Physicians are being forced to delay patient admissions to ensure that the patients are sick enough or will become sick enough so as to not be retroactively denied reimbursement for their care.** One internist wrote that, "There is no question that [delay of hospital admissions] is a factor in my practice. . . Under the current circumstances, there is definitely pressure to permit the patient to become extremely ill, setting up a situation where hospitalization could not possibly be denied, and yet resulting in more suffering for the patient and longer hospital stays." The reason doctors submit to this pressure is because they are afraid that if they admit a patient earlier and the medical care is later denied, then the patient could be stuck with a large medical bill that he or she cannot afford.

- **Physician resentment toward PROs and peer reviewers is growing, making it increasingly difficult for the review process to be constructive.** Another ASIM member wrote, "The net result [of peer review] is that our hospital is

suffering an unnecessary cash flow deficit from Medicare, physicians are being unfairly harrassed, and, most importantly, our Medicare population is being exposed to increasingly counterproductive scrutiny relative to admission review."

- **Patient confidence and trust in practitioners who provide good quality care is being undermined because of inappropriate PRO denials of payment for appropriate care.** Yet another ASIM member reported that a PRO denial notice for what he considered to be appropriate care was worded in such an inflammatory manner that he initiated legal action.

ASIM believes that a major reason for many of the above problems is that the review program has been expanded greatly during the past several years without parallel efforts to strengthen the actual review process to ensure that proper review takes place under the new programs. When assessing the current problems with peer review, it is important to realize that the PRO program has undergone vast changes since it was implemented in 1984. For example, concerns about premature hospital discharges, inappropriate care in the ambulatory and HMO settings, and poor quality care under the the prospective payment system, led Congress to recently expand the scope of the PRO program to include health maintenance organization/competitive medical plan (HMO/CMP) review, post-acute care review, ambulatory review, and more.

In addition to this broader scope of peer review, PROs are more closely examining the quality of health care. The PROs' 1986 "scope of work" requires them to eliminate adverse outcomes through focused review on certain practitioners and providers, as well as on designated DRGs. The "scope of work" also requires PROs to review all hospital readmissions within 15 days of discharge. Since the passage of the Omnibus Budget Reconciliation Act (OBRA), PROs soon will be required, in addition, to review 25% of the readmissions that occur within 16 and 31 days after discharge. Further, PROs are more closely scrutinizing the quality of all cases under review through the use of generic quality screens.

Another area of change is an increase in the sanctioning of providers and practitioners for alledged poor quality or unnecessary care. PROs rightfully are expected to take action against "bad" practitioners and providers, and the Department of Health and Human Services' Inspector General and the Health Care Financing Administration (HCFA) have actively encouraged PROs to meet this program requirement. Part of HCFA's evaluation criteria for renewing PROs' contracts included reviewing their record in sanctioning providers and practitioners. These increased sanction activities, however, have raised some concerns that practitioners and providers are not being provided due process or are being subjected to inappropriate standards when sanctions against them are being considered. The California Medical Association and the California Peer Review Contractor are currently in federal court over precisely this issue.

Finally, the PRO program has been used increasingly to limit health care costs--an objective that is often in conflict with the goal of assuring high quality care. As in the past, PROs are expected to limit unnecessary medical care, thereby saving Medicare money. In addition, HCFA has instructed Medicare carriers to deny Part B reimbursement that is related to denied Part A services. Similarly, PROs have been required by Congress to deny payment for Part B services that are "substandard."

Although each of the above changes to the PRO program may individually have merit, ASIM believes that the aggregate effect of those changes has in some instances proved counterproductive because not enough time and effort were spent developing,

establishing and refining the review process, particularly for new review programs. This is due partly to the fact that PROs have not always had sufficient resources to implement new programs. HCFA has negotiated lean budgets for the PRO contracts that may not be adequate for the changing work load. Some ASIM members working for PROs have reported that the time allowed for reviewing individual cases is sometimes inappropriately limited because of budgetary constraints. ASIM is also aware of at least one PRO that has cut its already modest hourly fees paid to physician reviewers because of budget limitations. ASIM believes that as Congress and the Administration expand the review requirements of PROs, adequate funds should be provided for these purposes.

Another contributing factor is that PROs often are under severe time pressure to get their programs set up and running. For example, many PRO contracts were awarded only days before they took effect, leaving the organizations little time to get established. Similarly, those review organizations that are competing for the HMO/CMP review contracts will have less than a month to get their programs operational. Such time constraints contribute to oversights and omissions in establishing a program or training personnel.

A third problem with some of the review programs is that they are not adequately flexible. For example, one Virginia hospital has undergone "intensified review" because the hospital exceeded a preset denial rate even though half of the denials were subsequently overturned on appeal. Similarly, some providers and practitioners are being sanctioned even though their cases are still under appeal. Such inflexibility on the part of PROs lead to both unnecessary review and resentment on the part of physicians and providers.

These constraints on PROs' time, budgets and flexibility are of deep concern to ASIM because their ultimate result is a review program that is not sufficiently sensitive to the intricacies of patient care. Each patient and each episode of illness is different, requiring physicians to carefully assess each patient's need and then use their professional judgement to determine what course of treatment is best for the individual patient. Because of these subjective elements to patient care, there may be several ways to properly treat a patient and, sometimes, no clear "best" way to care for a patient. If review programs do not have the flexibility to allow these practice differences, PROs can impose an improper standard of care rather than protect the current standard of high quality medical care.

In addition to physicians' medical decisions, there are a number of other factors that can inappropriately influence a review decision. Physicians who specialize in internal medicine, in particular, appear to experience high rates of inapprorpriate denials due to characteristics of internal medicine practice that are not well-understood by most PROs:

- As primary care physicians, internists see patients on a continuous basis - prior to episodes of illness, during the course of an illness, and after the patient has recovered. These extended periods of care provide more opportunities for internists' care to come under scrutiny, regardless of the quality or efficiency of the care.

- As both primary care physicians and as consultants, internists work in conjunction with a variety of other practitioners. The quality of these other practitioners' care can reflect upon internists' work.

- Internists provide care in a more uncertain environment than some specialists. Other specialists may provide a service only after a diagnosis has been made or a procedure indicated. Internists, however, by nature of their profession are expected to assess a variety of factors in order to determine what course of treatment is needed. This uncertainty makes it more difficult for reviewers to standardize and assess the necessity or quality of an internist's care.

- As specialists, internist frequently care for patients with multiple and complex or advanced illnesses. These difficult cases can make the diagnosis and prognosis of a patient's care less predictable. This uncertainty can make internists particularly susceptible to second guessing when PRO review takes place retrospectively.

While the Society does not believe that the above characteristics of internal medicine should preclude internists from being subjected to peer review, ASIM does believe the PRO program should be sufficiently sensitive to these practice variables that can influence physicians' treatment of patients.

ASIM believes that HCFA can make several genèral improvements to the PRO program that will address some of the concerns mentioned above. Specifically, the Society believes that HCFA should institute the following requirements for PROs:

1) **Physician reviewers must be competent by training and experience in the particular service that they review.**

ASIM has received complaints from internists who believe that the physicians reviewing their cases were unfamiliar with the particular service under review. Currently, PRO regulations permit any physician to review another physician's care, regardless of specialty, training or experience. While the Society believes the qualifications of a reviewer to review a particular physician should not be based solely on specialty designation or certification, the Society does believe that physicians should be qualified by training and experience in the services they review. By establishing the above requirement for reviewers, HCFA can be more certain that the care under review is being properly assessed.

2) **Individual reviewers who render a denial determination should discuss the pending denial with the attending physician prior to making his or her determination.**

Although PROs are presently required to discuss pending denials with the attending physician, the PRO representative who contacts the attending physician is not required to be the physician who actually reviewed the care, and, as a consequence, the representative may know very little about the care. Further, some PROs specifically require that the contacting representative not be the reviewer in order to protect the reviewer's anonymity.

ASIM believes that the person who reviews the case should also be the person who discusses the case with the attending physician. This places a greater burden on the reviewing physician to provide his or her rationale for the decision. Further, if the physician is competent by training and experience, as stated above, then a more constructive dialogue can take place between the physician and the peer reviewer.

3) **Review organizations should provide reviewers with a thorough orientation session and a comprehensive review manual that include the necessary information to conduct competent, consistent, thorough and accurate medical review.**

Although some PROs have extensive training programs for reviewers, other PROs provide minimal orientation to physician reviewers before beginning their review. Consequently, review is not always conducted in a clearly defined manner to ensure that necessary details or procedures are included in the review process. At a minimum, the Society believes the training sessions should provide an overview of the review process, guidelines for reviewing cases, details for any due process or supervision requirements, appropriate criteria for conducting review, and a review manual for physicians' later reference.

4) **The wording of denial notices should be changed so that they state the denied care "does not fulfill the criteria for Medicare reimbursement."**

The Society does not believe that it is accurate or appropriate for patient denial notices to term denied care "inappropriate" or "not medically necessary," as currently is required by HCFA. As mentioned earlier, treatment decisions in the medical care of a patient can be highly subjective, often with no clear "best" way to treat a patient. Since it is the PRO criteria upon which denials are based, which may not necessarily reflect community standards of acceptable medical practice, ASIM believes it is more accurate and appropriate for the denial notices to explicitly state that the care "does not meet Medicare criteria." Such wording establishes whose judgement the denial is based upon and does not malign what may be valid differences of opinion on the appropriateness of care by the attending physician. ASIM urges the Committe in its oversight capacity to request HCFA to make this change.

ASIM believes that the above changes would enhance the review process and alleviate some of the concerns physicians have with the PRO program. In addition to instituting these changes, however, the Society believes that Congress and the Administration need to realize the limitations and problems of the current program, given PROs' current work load, funding levels and time allowances for establishing new programs. Although the Society's recommendations for the PRO program address some of the program's problems, the current credibility of the program has been damaged to the extent that the Senate Finance Committee should consider other ways it can strengthen the PRO program. ASIM will also continue to investigate problems with the program and will be developing other recommendations to submit to the committee at a later date.

G-IB-0718

STATEMENT FOR THE RECORD SUBMITTED ON BEHALF OF THE ACCREDITATION ASSOCIATION FOR AMBULATORY HEALTH CARE TO THE HEALTH SUBCOMMITTEE OF THE SENATE FINANCE COMMITTEE IN CONJUNCTION WITH A HEARING HELD ON THE ROLE AND PERFORMANCE OF PEER REVIEW ORGANIZATIONS UNDER THE MEDICARE PROGRAM

March 27, 1987

The Accreditation Association for Ambulatory Health Care ("AAAHC") is pleased to submit the following statement for submission to the record in conjunction with the hearing held on March 27, 1987, by the Health Subcommittee of the Senate Finance Committee on the role and performance of peer review organizations under the Medicare program.

On June 1, the quality of care of the health care services provided to Medicare beneficiaries by Health Maintenance Organizations ("HMOs") HMOs and Competitive Medical Plans ("CMPs") under risk contracts with the Medicare program will come under scrutiny. Effective July 1, Medicaid state plans are required to conduct quality review of health care services provided to Medicaid enrollees under risk contracts with the state Medicaid programs.

AAAHC is dedicated to quality care, and has extensive experience in the survey and accreditation of ambulatory care providers and HMOs, and the bulk of all care delivered by HMOs is ambulatory care. Yet, unfortunately, it is likely that neither the Medicare nor the Medicaid HMO review program will obtain the full benefits of the extensive experience gleaned by AAAHC and other private accreditation organizations in the evaluation of quality of care in ambulatory environments. Rather, although last year's budget legislation theoretically gave non-PROs an opportunity to participate in these HMO review programs, HCFA's implementation of these provisions likely will

make it difficult, if not impossible, for AAAHC and other private accreditation organizations to seek and obtain Medicare and Medicaid contracts to conduct quality of care reviews of HMOs serving Medicare and Medicaid patients.

I. BACKGROUND

AAAHC is a private accreditation association which since its founding in 1979, has enjoyed enthusiastic support and endorsement of its accreditation program not only from ambulatory health care providers, but also from third party payors, government agencies, and members of the general public. Since its founding, AAAHC has become involved in the survey and accreditation of a wide range of ambulatory care providers, including ambulatory health care clinics, ambulatory surgery centers, birthing centers, college and university health services, community health centers, emergency centers, faculty medical practice plans, hospital sponsored ambulatory care clinics and surgery centers, multi-specialty group practices, networks and groups of ambulatory health care organizations, office surgery centers and practices, single-specialty and multi-specialty group practices, and urgent or immediate care centers.

AAAHC has perhaps more experience than any other single organization in the country in the survey and accreditation of health maintenance organizations and ambulatory care providers providing care to HMO enrollees. The Arizona Health Care Cost Containment System (AHCCCS) Demonstration Project, under which all care to Medicaid beneficiaries is delivered on a prepayment basis, has contracted with AAAHC to undertake annual medical audits of all the participating prepaid plans, after serious concerns were raised regarding the quality of care being delivered. AAAHC's activities in this regard have been highly successful, and, in fact, the quality assurance program instituted by AAAHC in Arizona is in its fifth year. Under that program, as of January 1, 1986, AAAHC evaluated the quality of care and quality assurance programs of Arizona HMOs serving 146,000 eligible Medicaid enrollees.

AAAHC also accredits 15 HMOs in the country, including all of the Cigna staff and group model HMOs in the country. In total, AAAHC accredits 100 different ambulatory care providers providing care to 2 million enrollees, involving 6,000 physicians.

The standards applied by AAAHC in the accreditation process represent nearly 20 years of effort by thousands of experts in the delivery of ambulatory health care services. Each accreditation survey is tailored to the type, size, and range of services offered by the organization seeking

accreditation. Surveyors are physicians, dentists, nurses, and administrators who practice in ambulatory care settings, and specific survey team members are selected, to the extent possible, on the basis of their knowledge of and experience with the range of services provided by the applicant organization. AAAHC has conducted hundreds of accreditation surveys of all types of ambulatory care organizations.

Since its inception, AAAHC has been dedicated to promoting and ensuring the maintenance of high quality standards in ambulatory care facilities. Because of the quality of the standards and thoroughness of its surveys, AAAHC has been recognized and accepted by all types of third party payers (Blue Cross/Blue Shields plans, commercial carriers, HMOs, governmental agencies) as meeting their conditions for participation in reimbursement programs. In fact, in recognition of the requirements for risk control and quality assurance in AAAHC's standards, a number of major professional liability carriers extend a discount and premium coverage to ambulatory surgical centers and single and multi-specialty group practices accredited by AAAHC, and CHAMPUS has cited AAAHC as an appropriate accreditation agency.

II. The Medicare Program

Last year's budget legislation, which was endorsed by the Administration, was specifically intended to enable HCFA to authorize organizations other than PROs (Quality Review Organizations or "QROs") to conduct quality review of risk contract HMOs serving Medicare beneficiaries. Unfortunately, the review methodology proposed by HCFA to implement this provision likely will thwart the legislative intent to encourage QROs to take an active and primary role in HMO review activities.

Preliminarily, it is important to note that the evaluation of the quality of care delivered by HMOs presents its own peculiar and intractable problems arising, in part, from lingering opposition from the fee for service community and tensions among competing HMOs themselves. Perhaps more importantly, because the bulk of care in HMOs is rendered in outpatient settings, in order to obtain the most reasonable assessment of quality, review of ambulatory care should be emphasized. Perhaps the single most important conceptual flaw in HCFA's implementation of HMO review activites is that the agency has failed to take sufficient account of this fact in the design of the review methodology.

More specifically:

The review methodology proposed by HCFA is elaborate, complex, and costly, and has not been demonstrated to be more effective than simpler and less costly programs for review of ambulatory care.

As discussed above, AAAHC has had extensive experience both in the review of ambulatory care providers generally, and in the review of HMOs specifically. As a result of this experience, AAAHC has accumulated extensive knowledge of the administrative problems involved in reviewing the quality of care of HMOs and ambulatory care providers and has designed the simplest and most appropriate methodologies to be used in accumulating data. Yet, under HCFA's proposed review methodology, data is to be gathered through intermediaries who are required to gather the data from hospitals. This "UB82" data system, which has been used by PROs in conjunction with their review of inpatient hospital services, simply is not suited to the review of the quality of care rendered by HMOs. Therefore, HCFA has chosen to institute a complex system for the accumulation of data, primarily in order to accommodate the needs of the PROs, and despite the experience of AAAHC which strongly suggests that needed information can be accumulated in a simpler and more direct manner.

Even more significantly, HCFA's methodology focuses on inpatient records as the trigger for review. This focus is entirely inconsistent with the fact that ambulatory care constitutes the bulk of the care delivered by HMOs. The review methodology designed by HCFA is not tailored to teh particular

quality of care which may arise for HMOs, but rather is for the most part, an inappropriate replication of the methodology used for review of inpatient services.

* The review methodology proposed by HCFA will stifle innovation and erode support for private accreditation programs operated at no cost to the government.

Given the complexity of the review methodology derived by HCFA, compliance by HMOs will require significant time, effort, and cost. Consequently, HMOs will likely be forced to dedicate the bulk of their quality assurance resources to compliance with HCFA requirements, and support for private accreditation programs likely will wain. As a result, the HMO industry will become more and more dependent upon quality assurance mechanisms instituted by HCFA as their sole means of assuring quality of care to HMO enrollees.

* The three-tiered initial assessment system, as currently proposed by HCFA, will not result in accurate, fair and uniform categorizations of HMOs.

Under the review methodology proposed by HCFA, the level of review to be undertaken of a particular HMO's health care services to Medicare patients, will depend upon an initial categorization of the HMO, based upon the HMO's own internal quality assurance mechanism. AAAHC applauds HCFA's decision to conduct such initial assessments of HMOs and to use that assessment as the basis for subsequent decisions concerning the level of review. However, AAAHC believes that such assessments

should be conducted on the basis of uniform national standards by an independent organization not involved in ongoing quality review. In this manner, fairness and objectivity are assured and conflict between the HMO and the organization conducting ongoing routine review are minimized.

* The review methodology proposed by HCFA includes insufficient safeguards against the unique conflict of interest problems likely to arise in HMO settings.

Unfortunately, the HMO industry still experiences difficult and intractable political problems. Conflict exists both between the HMO industry and fee-for-service providers, and within the HMO industry itself. As a result, AAAHC's experience demonstrates the utility of the use of out-of-state physicians to conduct review activities. Yet, HCFA's proposed review methodology requires that reviewing physicians be from the same state where the HMO is located.

III. The Medicaid Program

In the Omnibus Budget Reconciliation Act enacted last year, Congress likewise provided state Medicaid programs with the flexibility to contract with private accreditation organizations, rather than PROs, to conduct quality review of HMOs serving Medicaid patients. Unfortunately, it now appears that the governing legislation is being interpreted to permit

states choosing PROs to obtain 75 percent matching funds from the federal government, while states choosing private accreditation organizations may be eligible only for 50 percent matching funds. Legislative history neither expressly nor impliedly authorizes such a distinction.

Such a construction of this legislation essentially negates the opportunity of private accreditation organizations to obtain contracts from states to provide quality review of HMOs serving Medicaid enrollees. States, under their own fiscal constraints, are highly unlikely to contract with private accreditation organizations to perform quality review functions, where such a choice would entail a significant loss of reimbursement.

We find no policy justification whatsoever for providing a higher level of funding for states contracting with PROs rather than private accreditation organizations. PROs' primary experience has been in the utilization review of inpatient hospital services, while private accreditation organizations, such as AAAHC, have significant experience in conducting quality review of ambulatory care, including care rendered by HMOs. Moreover, in providing the states with flexibility to contract with private accreditation organizations to perform quality review of HMOs serving Medicaid enrollees, Congress specifically applauded the quality reviews performed by AAAHC in Arizona under the Arizona Health Care Cost Containment

System Demonstration Project, discussed above. Despite the success of AAAHC's experience in Arizona, however, last year's legislation is being interpreted in a manner which will strongly dissuade other states from contracting with AAAHC to conduct similar quality reviews in their states.

Moreover, such a differential reimbursement rate is inconsistent with longstanding practice in the Medicaid program, which encourages innovation by state Medicaid plans. Under the Medicaid program, states have traditionally been afforded the flexibility to structure their programs to serve Medicaid enrollees in a manner which accommodates local circumstances. By "leveling the playing field," Congress could encourage innovation at the state level which could be used to improve the Medicare review program over the long haul.

We appreciate the opportunity to submit these comments, and hope to discuss several of the issues discussed herein with the Committee in the near future. If you have any questions, please contact AAAHC's Executive Director, Ronald Moen, at 312-676-9610 or AAAHC's Washington counsel, Wendy Kranser or Diane Millman, at 202-887-8000.

3316h

Statement by
Congressman Beau Boulter
Concerning Peer Review in Texas

prepared for
the Finance Subcommittee on Health
April 3, 1987

It greatly encourages me to see that the Senate Finance Committee is aware of the grave problems Texas and other states with extensive rural areas are facing with the peer review system. I would like to take this opportunity to share with the Subcommittee the severe threat to rural health care posed to the Panhandle and North Texas by the over-zealous sanctioning being conducted by the PRO in Texas.

Of the approximately 35 doctors who have received sanction notices from the Office of the Inspector General nationwide, 5 of these (1/7 of the national total) are in the 13th District of Texas which I have the privilege of representing. Nine of the recent referrals from the TMF to the OIG for sanction are in my district.

During the hearing conducted by the Subcommittee, Mr. Thomas Dehn, President of the American Medical Peer Review Association of Milwaukee, stated that the main thrust of his organization's efforts in peer review are educational. He also stated that his organization feels that it has "failed" if it must recommend exclusion from the Medicare program for a given physician. In addition, he reported that "on-site" inspections are the rule rather than the exception for review of Wisconsin physicians. These emphases are not the rule, but rather the exception, in the review process conducted in my district by the Texas Medical Foundation.

It is not my intent to protect truly negligent doctors, but to ensure that every doctor in my district receives due process. Bank robbers receive more "due process" than the physicians of my district have received. My doctors have not been given true "peer review" by a panel of their rural peers. At least in my district, I know of no "on-site" inspections by the TMF in reviewing a physician's practice. In cases where TMF has subjectively judged physician's violations as "gross and flagrant", these doctors received initial, accusatorial notices from TMF letting them know of TMF's intention to recommend exclusion from Medicare. They were then called to Austin for one hearing to respond to their practice in specific cases (often cases cited from 1984 at which time these physicians had no idea

what peer review guidelines were) and were then recommended for sanction. Not only does TMF not view sanctions as "failures", I see very little emphasis on educating or working with the doctors of my district toward improving their rural practice before recommending their exclusion from the Medicare program, ruining their reputation and often denying access to health care to rural residents.

I will soon be circulating petitions to doctors in my district which will express the corporate feeling of the medical community in the 13th District that those doctors who have been sanctioned were not afforded due process. This petition will request that TMF intitiate a thorough re-examination of these cases when positive revisions in the process have been made to ensure true "due process" to the physicians of my district and across the state of Texas.

Senator Mitchell asked Administrator Roper at the hearing if HCFA had a certain number of sanctions they expected from individual PRO's in order to justify cost-effectiveness. I would certainly hope that the tide of sanctions in Texas is not a result of TMF's need to fiscally justify its existence and effectiveness to HCFA. Long before Texas Medical Foundation became the Peer Review Organization for Texas, Texas had and still has true "peer review" by the Texas Board of Medical Examiners--without the tide of current sanctions. It appears to me that the Texas Medical Foundation is out of control. If cost-containment is a major justification for the proliferation of sanctions in Texas, then the American taxpayer is not getting a lot for his or her money, as $18 million dollars has been spent to sanction approximately 20 doctors statewide.

In a letter cosigned by other Members of the Texas delegation, I wrote the OIG expressing my concerns about the threat to rural health care in Texas by over-zealous sanctioning currently in progress in my state. Possible remedies to the current problem which I proposed for Inspector Kusserow's consideration were: 1) extending corrective action plans to the final stage of the sanctioning process, as the only options available to his office at present are either exclusion from the Medicare program or imposition of a monetary penalty (many of our doctors state that they are being charged for cases which occurred up to 2 years ago before peer review guidelines were made known to them); 2) amending the existing PRO regulations to stipulate that concerns unique to the rural practice of health care must be taken into account in peer review decisions; and/or 3) providing for appeal before an administrative law judge before final OIG sanctioning is imposed.

The Texas Medical Association is presently finalizing its recommendations for legislative and procedural changes in the peer review process in Texas. I wholeheartedly support the work TMA is doing to improve peer review in Texas and would recommend that the Subcommittee look into these proposals in addition to an omnibus bill to soon be introduced in the House of Representatives by the Rural Health Care Coalition. This bill will seek to allow appellate recourse before final sanctioning by the OIG (except in cases where patients are placed in "imminent danger" as a result of gross negligence exhibited by the physician in question) as well as mandating a certain percentage of "on-site" inspection by PROs. I believe that these changes could go a long way toward ensuring greater due process to rural doctors in peer review in the state of Texas.

Buna Medical Center

P O DRAWER H BUNA, TEXAS 77612 409 994-3578

March 18, 1987

Chairman Mitchell
Health Sub Committee of Finance Committee
219 Dirksen office bldg.
Washington, D.C. 20510

Gentlemen:

I attempted to testify before your committee regarding Medicare/DRG payment/ PRO's as they are now being administered, especially, regarding small (under 50 beds) hospitals in this country. As the schedule is already full I am writing my testimony. I have been a small hospital administrator since 1955 and a small hospital and Nursing Home Administrator since 1963 located in a small unincorporated East Texas town. I served six years on the State of Texas Governors Hospital Advisory Council. Before entering medical administration I was a Bacteriologist, Clinical Chemist, Medical Technologist, Radiological Technologist and a licensed Nursing Home Administrator, and should be with over 30 years experience, knowledgeable in small hospital administration. In the late 50's and early 60's the Government introduced a program to assist the rural and metropolitan areas of the country with the Hill Burton program to build medical facilities. Due to the foresight of these legislators plus Medicare the welfare of our elderly have improved tremendously with increased life span and the quality of life improved in their latter years. As we all know, this has been a costly adventure for our country. About six years ago, there appeared in this country a number of the people now in control of our government initiating a trend to eliminate this benefit to our elderly citizens. They soon realized that to come out openly for such a change would be political suicide, therefore, they introduced a program and procedure to achieve their goals without the knowledge of the people effected. This program was termed DRG's with a hidden

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(2)

clinche called PRO; under the heading of improving the quality of care. This scheme was first started by putting a ceiling or charges called TEFRA LIMITS. If a hospital received a high cost in the base year due to inefficient operation they received a higher DRG rate. If the hospital was efficient they received a lesser DRG rate of payment. This penalized a hospital that was keeping cost down. Then they began DRG's - telling hospitals that the first year your DRG payment would be calculated on TEFRA limits + 25% national and 75% hospital. The following year hospital 50% and 50% national. Then the following year to 100% national average This all sounded fair, although, the government did not keep their word and stayed at 50% - 50% level. By this scheme large hospitals with higher charges received the largest benefit in higher DRG payment - also, their % on medicare patients was not as high as in the rural areas. This again penalized the more cost efficient smaller hospitals. Then they instituted the PRO with the power of the Pharoes and the authority of Kings to deny claims on our elderly population and they state they are not responsible to our courts or anyone - as an enclosed letter from a doctor attending a hearing states (see attached letter). They do hold hearings hearing regularly. I cannot believe this is happening in the United States.

There have been eighteen (18) small hospitals closed in Texas this year and unless changes are made there will be more next year. You cannot give $3,000.00 of services and receive $1,500.00 in payment and stay in business for long. This is what HICFA expects small hospitals to do. If there was a division of HICFA set up just for small hospitals it would be a step forward in obtaining the facts. I have read reports that some large hospitals have received by the DRG method 15%, 17% more profits. It would be interesting to see what profits or losses have occurred in hospitals

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(3)

under 50 beds in the country. The PRO's in Texas is paid sixteen (16) million a year to deny claims on our elderly under the auspices of improving quality of care. One physician in charge of the PRO's program stated that all small hospitals with swingbeds should be closed - a complete about face from the laws passed by Congress and the Medicare and Hill Burton Program. I had a review by one PRO reviewing physician who stated that the 10 patients was too sick to be placed in a swing bed. I appealed this to another DRG physician hearing and this PRO physician stated the 10 patients were not sick enough to be placed in swing bed and both denied payment of the claims. This is a catch 22 - No way to win with this type of physician review. I also had an attorney and another physician representing me at the hearings. I have the evidence in their own handwriting.

If small hospitals were paid a designated amount as the present DRG's for a designated number of days for each illness and a fee of a certain amount per day for extended stay beyond the perimeter for their diagnosis, small hospitals would receive a fair payment for services and be able to continue operation. The PRO's could review all charts of extended stay to establish that they were medically necessary. If some relief is not given the rural small hospitals in this country, they will become an endangered species and the elderly of our nation will be the losers.

Sincerely,

Wayne D. Butchee

Wayne D. Butchee
Administrator

cc: Attorney At Law, Mary Bearden

cc: Senator Max Baucus

CONGRESSMAN LARRY COMBEST

19TH DISTRICT OF TEXAS FRIDAY, MARCH 27

SENATE FINANCE SUBCOMMITTEE ON HEALTH

HEARING ON PEER REVIEW ORGANIZATIONS

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE, I APPRECIATE HAVING THE OPPORTUNITY TO APPEAR BEFORE YOU TODAY AND TO SHARE WITH YOU THE CONCERNS OF MANY OF US IN WEST TEXAS ABOUT THE PEER REVIEW PROGRAM. I COMMEND YOU FOR YOUR TIMELY ATTENTION TO THIS MATTER.

I WOULD LIKE TO PREFACE MY REMARKS BY SAYING THAT THE SWELLING COSTS OF MEDICAL CARE AND THE GROWING NUMBER OF MEDICARE RECIPIENTS MAKE PEER REVIEW A NEEDED AND WORTHY PROCESS. AS A NATION, WE MUST WORK TO REDUCE THE FEDERAL DEFICIT BY ELIMINATING WASTE IN GOVERNMENT PROGRAMS. IN THE CASE OF MEDICARE, IT IS NECESSARY NOT ONLY FOR THE GOOD OF THE COUNTRY, BUT FOR THE SOLVENCY AND PRESERVATION OF THE MEDICARE SYSTEM FOR FUTURE GENERATIONS. OUR ELDERLY CITIZENS DESERVE HIGH QUALITY, RESPONSIBLE MEDICAL CARE, AND I BELIEVE THAT THE PEER REVIEW PROCESS HAS THE POTENTIAL TO MAKE AN IMPORTANT CONTRIBUTION TOWARD THAT GOAL.

WHEN CONGRESS AMENDED THE SOCIAL SECURITY ACT IN 1982 WITH THE PEER REVIEW IMPROVEMENT ACT, THERE WAS A DEFINITE INTENT: TO PROVIDE SERVICES FOR MEDICARE RECIPIENTS WHICH ARE MEDICALLY NECESSARY AND WHICH MEET PROFESSIONAL STANDARDS OF MEDICAL CARE. SINCE THAT TIME, NUMEROUS STATES HAVE ESTABLISHED PEER REVIEW ORGANIZATIONS WHICH SEEM TO BE PERFORMING THAT FUNCTION VERY WELL.

IN RECENT MONTHS, HOWEVER, MY COLLEAGUES WHO REPRESENT RURAL AREAS OF TEXAS AND I HAVE RECEIVED NUMEROUS COMPLAINTS ABOUT THE EFFECT THAT THE TEXAS PEER REVIEW ORGANIZATION (PRO) IS HAVING ON THE AVAILABILITY AND LONG-TERM SURVIVABILITY OF MEDICAL CARE IN RURAL TEXAS TOWNS. AS OF DECEMBER 1986, 14 PHYSICIANS PARTICIPATING IN THE MEDICARE PROGRAM IN THE STATE OF TEXAS HAD BEEN RECOMMENDED TO THE OFFICE OF INSPECTOR GENERAL FOR EXCLUSION FROM THE MEDICARE PROGRAM. SINCE THAT TIME, NINE HAVE BEEN SANCTIONED. ALL NINE HAD ONE CHARACTERISTIC IN COMMON -- THEY PRACTICE IN RURAL AREAS OF TEXAS.

I WOULD BE THE FIRST TO ADMIT THAT THERE ARE SOME VERY DISTINCT DIFFERENCES BETWEEN LIFE IN RURAL AMERICA AND LIFE IN METROPOLITAN AREAS. I GREW UP IN MEMPHIS, TEXAS WITH A POPULATION OF LESS THAN A THOUSAND PEOPLE. OUR FAMILY DOCTOR DELIVERED BABIES, SET BROKEN LEGS, RESPONDED TO ACCIDENTS ON THE FARM AND CARED FOR THE AILMENTS OF OUR ELDERLY NEIGHBORS. HE WAS DEDICATED AND WELL-RESPECTED. WHILE I HAVE NO MEDICAL TRAINING, I THINK IT IS INDISPUTABLE THAT THE PRACTICE AND CIRCUMSTANCES OF THIS SMALL TOWN DOCTOR DIFFER SUBSTANTIALLY FROM THOSE OF A CARDIAC SURGEON IN HOUSTON.

I THINK IT IS PRECISELY THOSE DIFFERENCES, MR. CHAIRMAN, THAT ARE NOT ACCOUNTED FOR IN THE EXPECTATIONS, REQUIREMENTS AND REGULATIONS THAT GOVERN THE PEER REVIEW PROGRAM. FOR INSTANCE, THE SIZE AND PERSONNEL CAPABILITIES OF THE MAJORITY OF RURAL HOSPITALS MAKE COMPLIANCE WITH EXTENSIVE RECORDKEEPING REQUIREMENTS DIFFICULT. I AM NOT SAYING THAT RURAL DOCTORS SHOULD NOT BE REQUIRED TO MAINTAIN ACCOUNTS OF THEIR TREATMENT OF MEDICARE PATIENTS, BUT THERE ARE SOME VERY REAL DIFFERENCES ASSOCIATED WITH A RURAL PRACTICE THAT MUST BE CONSIDERED. ANOTHER EXAMPLE OF THE INEQUITY IN THE SYSTEM IS THAT THE LAW REQUIRES A REVIEW OF A SAMPLE OF THREE PERCENT OF ADMISSIONS TO EACH HOSPITAL. THIS MEANS THAT DOCTORS PRACTICING IN A 40-BED HOSPITAL ARE MUCH MORE LIKELY TO UNDERGO SCRUTINY THAN DOCTORS PRACTICING AT LARGE URBAN FACILITIES.

I BELIEVE THAT THERE ARE SEVERAL AREAS IN THE PEER REVIEW SYSTEM THAT COULD BE MODIFIED TO ACCOUNT FOR THE SPECIAL CHARACTERISTICS OF RURAL LIFE AND TO IMPROVE THE PEER REVIEW PROCESS AS A WHOLE. ONE OF THE MOST SIGNIFICANT CHANGES WOULD BE AN EMPHASIS ON THE PEER REVIEW CONCEPT. RURAL DOCTORS UNDERSTAND RURAL DOCTORS AND RURAL LIFE. THEY SHOULD PLAY A PROMINENT ROLE IN THE PROCESS IF DOCTORS ARE TO BE SUBJECTED TO TRUE PEER REVIEW. ALTHOUGH ANY DOCTOR ACTIVELY PRACTICING IN A HOSPITAL THAT HAS BEEN CLEARED THROUGH THE TEXAS STATE BOARD OF MEDICAL EXAMINERS MAY BECOME A PHYSICIAN REVIEWER, I FIND IT DISTURBING THAT THERE ARE NO RURAL PHYSICIANS IN THE TOP LEVEL OF THE TEXAS MEDICAL FOUNDATION.

MR. CHAIRMAN, WE IN WEST TEXAS HAVE WORKED HARD FOR HIGH QUALITY, AVAILABLE MEDICAL CARE. THERE STILL EXISTS A SHORTAGE OF PRIMARY CARE PHYSICIANS IN OUR PART OF THE COUNTRY, AND THE LOSS OF EXISTING PHYSICIANS HAS A DEVASTATING POTENTIAL. AT THE SAME TIME, WE MUST PRESERVE OUR COMMUNITY HOSPITALS THAT PROVIDE ESSENTIAL CARE TO RESIDENTS WHO WOULD HAVE TO TRAVEL HUNDREDS OF MILES TO THE NEAREST MEDICAL FACILITY.

I WANT MY CONSTITUENTS TO RECEIVE HIGH QUALITY MEDICAL CARE, AND I WANT TO SEE THE MEDICARE PROGRAM ADMINISTERED IN A RESPONSIBLE MANNER. I DO NOT, HOWEVER, BELIEVE THAT MY ELDERLY CONSTITUENTS AND THE RESIDENTS OF RURAL WEST TEXAS SHOULD HAVE THEIR ACCESS TO HEALTH CARE THREATENED BY A SYSTEM THAT FAILS TO ADDRESS FAIRLY THE UNIQUE CIRCUMSTANCES OF RURAL COMMUNITIES.

I THANK THE COMMITTEE FOR HOLDING THIS HEARING, AND I HOPE THAT THE TESTIMONY PRESENTED TODAY WILL BE INSTRUMENTAL IN MAKING THE PEER REVIEW PROCESS MORE WORKABLE AND MORE FAIR.

JOSEPH B. LONGINO, M. D.
530 NORTH DAVIS STREET
SULPHUR SPRINGS, TEXAS 75482

March 18, 1987

Senator George J. Mitchell, Chairman
Health Subcommittee of the Senate Finance Committee
219 Dirksen Office Building
Washington, D.C. 20510

Dear Senator Mitchell:

Having been sanctioned by the Texas Medical Foundation, the peer review organization of Texas, and this sanction having been sustained by the Office of the Inspector General, Department of Health and Human Services, the patients who chose to have me treat them and their families have been deprived of the right of freedom of choice. Having been informed by legal counsel that doctors who have had sanctions against them were invited to write you prior to a hearing to be held Thursday, March 26, 1987, this letter is being sent.

Without any counseling or forewarning from the Texas Medical Foundation, the Hopkins County Memorial Hospital where I do my hospital practice, the medical society or any other group, a package sent by certified mail was found on my desk, it having been accepted by an employee on Friday, June 13, 1986. This was accompanied by a vicious letter to the effect that the TMF planned to recommend that I be excluded from Medicare participation for a period of five years. It also stated that there would be a meeting at Austin in the Texas Medical Foundation headquarters at 11:00 A.M. on Saturday, July 26, 1986, which I was invited to attend. The tone of the letter, the lack of which I had never previously experienced, caused terror. The TMF stated that there had been gross and flagrant mishandling of seven patients. I had 20 days to reply to the charges and did so.

Before replying to the charges, I contacted the director of the Texas Medical Association to ask about legal counsel, the tone of the letter from the TMF being of such nature that I felt legal counsel would be necessary. I was told by the director of TMA that they wanted to keep the hearing within the profession and actually ask me not to seek legal counsel. I contacted the director of the TMA on several occasions as this situation was very disturbing to me after having practiced medicine in the army for three years from 1943 to the end of 1946, and in my home town of Sulphur Springs, Texas, from January 1947 to the present time. During that time, I felt like I had gotten along well with my peers, with the hospital and

with the patients who ask me to take care of them. Each time I contacted the TMA, I was discouraged from seeking legal help. I decided to cooperate with the TMA.

I had been referred to Dr. Daugherty, a pathologist in Paris, Texas, who apparently had been active in the TMF. After I discussed the cases briefly with him, he stated that he felt that they might recommend some continuing medical education. This did not disturb me because I participate in continuing medical education and feel that it is necessary. On July 26, 1986, I met with the people at the TMF headquarters in Austin. The meeting was called for 11:00 A.M., but did not get started until about 12:00 noon because of the slow arrival of the participating physicians. The meeting went on for about two and one-half hours. The "peer group" consisted of a man who stated that he was the coordinator of the family practice residency program at the University of Texas at Houston, a cardiologist from San Antonio, a family practitioner from Georgetown, Texas, and an internist from Austin. I was told that I would hear in about 30 days the decision of the board.

About 30 days after this meeting, I received a communication from the TMF stating that they would recommend that I be permanently excluded from participating in Medicare, although admitting that two of the cases were not gross and flagrant violations. The other five consisted of four who were chronically ill with advanced multiple diseases and I do not feel that anybody could, at this stage, have given them any permanent help. One was a man with a pacemaker, congestive heart failure repeatedly over the years, who suffered a stroke and was brought into the hospital from a nursing home. He was treated with diuretics to try to keep him from developing more congestive heart failure but he did not respond and expired. Another was an 87 year old man who was confined to the nursing home. He could not swallow but there was no abnormality of his upper gastrointestinal tract found. It was felt that he might have suffered a stroke or a brain tumor but this was not found on his CT scan. He developed congestive heart failure after he was given fluid to try to replace the fluid which he was not able to take in and he expired. One was a patient who developed anemia. She had malignant lymphoma and had had all the chemotherapy which she could take as stated by the oncologist. The patient was anemic and was given blood to make life more bearable. I was faulted for not having done a barium enema but no responsible surgeon would have dared operate on this patient in her condition. Another patient was an elderly man who had had a stroke years ago. He was brought from the nursing home to the hospital for care. He developed urinary tract infection which could not be treated by oral medications. He got over the urinary tract infection and was returned to the nursing home. He was anemic but his sensorium was so cloudy that a barium enema could not be performed. The fifth patient was a patient with coronary artery disease who developed severe cardiac arrhythmia with sinus pauses. This was compensated while he was in the hospital and he was discharged. Approximately two years later, he again developed sinus pauses. He was referred to the cardiac clinic at Baylor Hospital under the care of Dr. Michael Donsky, who inserted first a temporary and then a permanent pacemaker. The patient is doing quite well. The other two patients were patients who had cerebrovascular accidents. Fortunately, there is no permanent residue. Both of them are living and doing as well as could be expected at this time, both being able to take care of themselves at home.

It seems to me that the TMF has focused its attacks on elderly doctors in rural areas. In my case, many of the Medicare recipients for whom I practiced started out with me as people in their 20's and early 30's. In the natural course of events, since the Medicare program has been instituted and the age has been defined, these people are Medicare recipients. In addition, over the years, other patients have requested that I help them. A number of older patients were treated by my father with whom I practiced until 1975 at the time of his death. A large number of these patients have requested that I help them and I have attempted to do so. It appears that in purchasing an insurance policy, which in essence they have been forced to do, people are being deprived of their right of freedom of choice. It also appears that "passive terrorism" has been created which, if allowed to fluorish, could tear away the fiber of the strength of this nation, bringing about its decay from within.

Yours truly,

Joseph B. Longino, M.D.

JBL:bar

MSFMC TRANSMITTAL

MID-SOUTH FOUNDATION FOR MEDICAL CARE, INC.
6401 POPLAR AVENUE SUITE 400
MEMPHIS TENNESSEE 38119 • (901) 682-0381

NO: 32 DATE: January 5, 1987

TO: PRO CONTACTS
ALL HOSPITALS

FROM: Rose Lindsey, R.N., R.R.A. RL
Director, Review Systems

Patsy Beal, A.R.T. P
Assistant Director, Review Systems

Carolyn Brandon, R.N., Manager CB
Quality Assurance

SUBJECT: MSFMC QUALITY ASSURANCE PLAN
THRESHOLDS AND INTERVENTIONS

The Mid-South Foundation for Medical Care has formulated a Quality Assurance Plan as part of their objective in the excellence of health care.

Enclosed is a copy of the Thresholds and Interventions of the Quality Assurance Plan and a copy of the MSFMC definition of the severity levels. The interventions will be effective January 12, 1987.

Please share this information with your hospital Administrator and the appropriate staff.

Thank you for your cooperation and assistance.

Enclosures

Revised
12/29/86

MID-SOUTH FOUNDATION FOR MEDICAL CARE, INC.

QUALITY ASSURANCE PLAN

THRESHOLDS and INTERVENTIONS SUMMATION

SEVERITY	CATEGORY I	CATEGORY II	CATEGORY III	CATEGORY IV
I	5 cases by physician or 5 cases by provider Profiling	7 cases by physician or 7 cases by provider Query each case Letter to physician/provider May suggest education 50% Post-payment Review	10 cases by physician or 10 cases by provider Warning letter May require CAP 100% Prepayment or Post-payment Review	Over 10 cases by physician or over 10 cases by provid Refer to QA Committ May issue initial notice of sanction
II	3 cases by physician or 3 cases by provider Profiling 50% Post-payment Review	5 cases by physician or 5 cases by provider Query each case Letter to physician/provider May require CAP 100% Post-payment Review	8 cases by physician or 8 cases by provider Warning Letter Required CAP 100% Prepayment or Post-payment Review	Over 8 cases by physician or over 8 cases by provider Refer to QA Committ May issue initial notice of sanction
III	1 case by physician or 1 case by provider Query each case Letter 100% Prepayment or Post-payment Review (1 Premature Discharge will initiate 100% pre-payment Review)	2 cases by physician or 2 cases by provider Query each case Warning letter Potential for punitive action Require CAP 100% Prepayment or Post-payment Review	3 cases by physician or 3 cases by provider Refer to QA Committee 20 Day Sanction Notice	30 Day Sanction Notice
IV	1 case by physician or 1 case by provider Refer to QA Committee 30 Day Sanction Notice			

NOTE: The sequence of interventions presented here for each level of violations terminates with possible notice of sanction. At the point that a notice of sanction is issued, the MSFMC Sanction Plan becomes OPERATIVE.

Revised
12/29/86

MID-SOUTH FOUNDATION FOR MEDICAL CARE INC.

QUALITY ASSURANCE PLAN

THRESHOLDS AND INTERVENTIONS SUMMATION

QUALITY INTERVENTIONS

I. SEVERITY LEVEL I

Whenever five (5) cases are identified by practitioner or five (5) cases by provider, the following intervention is instituted.

A. Category I Intervention

1. Profiling by practitioner or provider for any utilization/quality issue.

When seven (7) Level I cases for practitioners or seven (7) cases by providers are identified, Category II interventions are triggered immediately.

B. Category II Intervention

1. Notification of cases identified for any utilization/quality issues, as determined by Physician Advisor with opportunity for peer discussion of the identified issues.

2. Letter to practitioner/provider

3. May suggest education

4. Intensified review, 50% post-payment will be instituted. Intensification will continue for at least one quarter after the problem is resolved.

When the next threshold is met which is ten (10) cases by practitioner or ten (10) cases by provider are identified, Category III Interventions are triggered immediately.

C. Category III Intervention

1. Warning letter to practitioner/provider with the following notification:

   a. Case limits met
   b. Explain potential for punitive action
   c. May require Corrective Action Plan (CAP) to be submitted by either the provider or physician within 15 days. The recommended CAP will be subject to the approval of MSFMC.
   d. Intensified Review, 100% post-payment will continue, or 100% pre-payment review may be instituted. Intensification will continue for at least one quarter after the problem is resolved.

QUALITY INTERVENTIONS

I. SEVERITY LEVEL I
PAGE 2

Referral to MSFMC Quality Assurance Committee if the next threshold is met which is over ten (10) cases by practitioner or over ten (10) cases by provider.

D. Category IV Intervention

1. Validation of nature and scope of the problem by the MSFMC Quality Assurance Committee. (QAC)

2. QAC conference with practitioner and/or provider to discuss problem cases.

3. Unresolved problems will be handled through MSFMC QAC action/ denial process. A sanction recommendation by the QAC may be applicable.

QUALITY INTERVENTIONS

II. SEVERITY LEVEL II

Whenever three (3) cases are identified by practitioner or three (3) cases by provider, the following intervention is instituted.

A. Category I Intervention

1. Profiling by practitioner or provider for any utilization/ quality issue.

2. Intensified review, 50% post-payment will be instituted. Intensification will continue for at least one quarter after the problem is resolved.

When five (5) Level I cases for practitioners or five (5) cases by providers are identified, Category II interventions are triggered immediately.

B. Category II Intervention

1. Notification of cases identified for any utilization/quality issues, as determined by Physician Advisor with opportunity for peer discussion of the identified issues.

2. Letter to practitioner/provider

3. May require CAP to be submitted by either the provider or physician within 15 days. The recommended CAP will be subject to the approval of MSFMC.

4. Intensified review, 100% post-payment will be instituted. Intensification will continue for at least one quarter after the problem is resolved.

When the next threshold is met which is eight (8) cases by practitioner or eight (8) cases by provider are identified, Category III Interventions are triggered immediately.

C. Category III Intervention

1. Warning letter to practitioner/provider with the following notification:

   a. Case limits met
   b. Explain potential for punitive action
   c. Required Corrective Action Plan (CAP) to be submitted by either the provider or physician within 15 days. The recommended CAP will be subject to the approval of MSFMC.
   d. Intensified Review, 100% post-payment will continue, or 100% pre-payment review may be instituted. Intensification will continue for at least one quarter after the problem is resolved.

QUALITY INTERVENTIONS

II. SEVERITY LEVEL II
PAGE 2

Referral to MSFMC Quality Assurance Committee if the next threshold is met which is over eight (8) cases by practitioner or over eight (8) cases by provider.

D. Category IV Intervention

1. Validation of nature and scope of the problem by the MSFMC Quality Assurance Committee. (QAC)

2. QAC conference with practitioner and/or provider to discuss problem cases.

3. Unresolved problems will be handled through MSFMC QAC action/ denial process. A sanction recommendation by the QAC may be applicable.

QUALITY INTERVENTIONS

III. SEVERITY LEVEL III

For the first (1) case identified by practitioner or one (1) case by provider, the following interventions are instituted.

A. Category I Intervention

1. Notification of case(s) with identified utilization/quality issues, as determined by physician review with opportunity for peer discussion.

2. Letter to practitioner/provider.

3. Intensified Review (100% prepayment or 100% post-payment) will be instituted.
Intensification will continue for at least a quarter after the problem is resolved.

   a. Premature discharges will be classified as severity level #3. If one (1) case is identified by either physician or provider, profiling and 100% pre-payment intensified review will be instituted.

When two (2) cases by practitioner or two (2) by provider are identified, the following Category II Interventions are triggered immediately.

B. Category II Intervention

1. Notification of case(s) with identified utilization/quality issues, as determined by physician review with opportunity for peer discussion.

2. Warning letter to practitioner/provider giving notice of the following:

   a. Case limits met
   b. Explain potential for punitive action
   c. Require Corrective Action Plan (CAP) to be submitted by either the provider or physician within 15 days. The recommended CAP will be subject to the approval of MSFMC.
   d. Intensified Review (100% prepayment or 100% postpayment) will be instituted.
   Intensification will continue for a least a quarter after the problem is resolved.

QUALITY INTERVENTIONS

III. SEVERITY LEVEL III
PAGE 2

(1) Premature discharges will be classified as severity level #3. If two (2) cases are identified by either provider or physician, 100% pre-payment intensified review will be instituted. A CAP as previously outlined will also be required.

Immediate referral to MSFMC Quality Assurance Committee if next threshold is met which is three (3) cases by practitioner or three (3) cases by provider. The following Category III Interventions are implemented.

C. Category III Intervention

1. Validation of nature and scope of problem by Quality Assurance Committee.

2. MSFMC Quality Assurance Committee recommendation regarding substantial violations.

3. Initial notification of sanction (20 day notice) which includes:

a. The authority and responsibility of MSFMC to report violation of obligations
b. The obligation involved and the issues of concern
c. The situation, circumstances, or activity that resulted in a violation
d. A suggested methodology for correcting the situation and a 90-day time period for the Corrective Action Plan (CAP)
e. The sanction that the MSFMC could recommend to the OIG if the violation continues during the CAP or fails to communicate or meet with the QAC.
f. An invitation submit additional information or to agree to discuss the problem with the QAC within twenty (20) days of receipt of the notice; the date of receipt is presumed to be five (5) days after the date on the notice unless there is a reasonable showing to the contrary.
g. A summary of the information used by the Committee in arriving at its determination of the violation.

4. If the practitioner or provider fails to comply with the CAP (Corrective Action Plan), i.e. continuing to have Severity Level III problem cases, referral will be made to the MSFMC QA Committee with a sanction recommendation.

D. Category IV Intervention - 30 Day Sanction Notice

The Medical Director analyzes all information pertaining to the sanction case, ascertains that appropriate due process has been followed, and prepares the 30-day notice.

QUALITY INTERVENTIONS

III. SEVERITY LEVEL III
PAGE 3

The formal 20-day notice is an initial notice sent by the MSFMC QAC. A 30-day second notice is sent for failing to respond to the 20-day initial notice, failing to adhere to or not agreeing to a Corrective Action Plan. These notices include:

1. The authority delegated to MSFMC to report certain violations
2. The obligation that has been violated
3. The basis for the determination, which includes a synopsis of cases and issues of concern
4. Copy of material used by MSFMC in arriving at the determination
5. The sanction to be recommended to the CIG
6. The opportunity to submit to the MSFMC QAC within 30 days of receipt of the notice, additional information or a written request for a meeting with the PRO to review and discuss the determination, or both. The date of the receipt is presumed to be 5 days after the date on the notice, unless there is a reasonable showing to the contrary.

IV. SEVERITY LEVEL IV

1. One (1) case identified as Level IV will immediately be referred to the MSFMC Quality Assurance Committee.

2. If MSFMC Quality Assurance Committee (QAC) determines that the quality problem is a gross and flagrant violation, a 30-day sanction notice will be issued.

3. The practitioner or provider has 30 days to provide additional information to MSFMC Quality Assurance Committee.

4. If the QAC determines the Severity Level IV problem case is only a substantial violation of the standard of care, a Corrective Action Plan will be instituted as outlined previously.

5. If the QA Committee determines that the problem case is a gross and flagrant violation of the standard of medical care, it will recommend a sanction to the OIG.

MID-SOUTH FOUNDATION FOR MEDICAL CARE, INC.

SEVERITY LEVEL DEFINITIONS and EXAMPLES

LEVEL I: Medical mishap or mismanagement without potential for adverse outcome on the patient.

Examples of quality problems meeting the conditions for a Level I determination:

1) The physician orders a drug for pain to be administered every four hours for a twenty-four hour period, but the patient receives only two doses in that time period (patient did not refuse medication).

2) The physician orders that a patient may self-administer a medication (Hydrodiuril) that is routinely taken by the patient at home; the staff continues to administer the medication; therefore, one cannot tell if the patient is getting a double dosage.

3) The physician fails to order a vegetarian diet, per patient preference, but not related to the patient's medical condition or treatment.

4) The physician fails to note a lab report that the patient's sedimentation rate is high, but the nursing history states the patient has a history of lupus erythematosus.

5) The patient is discharged following surgery with slight anemia and the physician does not order an iron supplement.

6) The physician orders a Ba enema and patient receives a poor preparation and returns to X-ray.

LEVEL II: Medical mishap or mismanagement with the potential for adverse outcome on the patient but not resulting in actual adverse outcome. -

Examples of quality problems meeting the conditions for a Level II determination:

1) A patient has a mild allergic reaction to a drug which is administered even though there is chart documentation that the patient is allergic to the drug.

2) The physician does not request an antibiotic sensitivity test for a patient with septicemia, but no significant harm results.

3) The physician orders 50 units of insulin daily for a hospitalized patient who routinely self-administers 30 units a day at home. The patient begins showing signs of hypoglycemia which the nurse responds to and treats effectively. The physician is notified and the dosage error corrected.

4) The physician does not timely monitor the electrolyte balance of a patient with diarrhea; the patient experiences changes in sensorium but recovers without longlasting effects.

5) A urinary tract infection is discovered in a patient prior to discharge. The patient is discharged without treatment for the infection, but is subsequently treated when returned to a SNF.

LEVEL III. Medical mishap or mismanagement resulting in actual adverse outcome requiring additional medical or surgical treatment.

Examples of quality problems meeting the conditions for a Level III determination:

1) A patient has a serious reaction (progressive symptoms of anaphylactic shock) to a drug which is administered even though there is chart documentation that the patient is allergic to the drug.

2) The physician does not request an antibiotic sensitivity test for a patient with septicemia, the organism is insensitive to the antibiotic administered, and significant harm results (e.g., prolonged hospitalization and complications or death).

3) A patient who is unstable at discharge is readmitted for the same or related condition for treatment that was not provided during the initial admission.

   a) A urinary tract infection is discovered in a patient prior to discharge, the patient is discharged without treatment for the infection, and is subsequently readmitted with symptoms of renal complications.

   b) A patient discharged with a temperature of 101.6 is readmitted as an acute care patient with — pneumonia. --

4) The physician does not timely monitor the electrolyte balance of a patient with diarrhea, the patient experiences changes in sensorium, falls, and fractures a hip which requires surgery.

5) Readmission as a result of premature discharge.

6) Infection at site of spinal or local injection.

7) Injury to organ during administering of anesthesia - broken teeth, scleral edema, corneal abrasion, burn, vocal cord injury, etc.

8) Repair of organ as a result of injury during surgery or invasive procedure.

9) Life threatening complications of anesthesia such as cardiac arrhythmias, aspiration, pneumothorax, pulmonary embolism, etc.

LEVEL IV: Medical mishap or mismanagement resulting in disabling or dismembering injury to body or mind or in death.

Examples of quality problems meeting the conditions for a Level IV determination:

1) Amputation of leg as a result of gangrene. (Physician did not check patient during treatment.)

2) Paralysis due to laminectomy.

3) Permanent damage resulting because a cast is applied incorrectly or is not removed in a timely manner when the patient's limb swells excessively under the cast.

WRITTEN TESTIMONY: PRESENTED TO THE HEALTH SUBCOMMITTEE OF THE SENATE FINANCE COMMITTEE.

PRESENTED BY: MEMBERSHIP OF THE MIDWESTERN DIVISION (DISTRICT VI-A) OF THE TEXAS HOSPITAL ASSOCIATION.

For years it has been widely recognized that the number of physicians in rural areas was totally inadequate to meet the medical needs of this segment of our society. As distances from metropolitan areas increase and the distances between rural communities increase, particularly in west and northwest Texas, the problems become more acute.

The Federal Government has long been aware of the medical problems confronting rural America. The percentage of elderly residents in rural areas is far higher than those in urban communities. Commonly the range is between 30-50 percent. Their medical needs are much greater than younger, healthier persons. Programs, such as Hill-Burton and HUD, have provided funds and low interest loans to rural communities to enable them to build hospitals to serve their residents. Other programs have been established to encourage new physicians to establish medical practices in rural communities. One of the primary reasons family practice residency programs were developed as a new specialty was to provide additional primary care physicians to rural communities.

With the advent of Medicare's Prospective Payment System (PPS) and peer review programs, the very survival of rural medicine is threatened in many communities. Hospital admissions have decreased dramatically over the past three years. In rural Texas hospitals, 30-40 percent is not unusual. Though most hospitals have responded with staff reductions, the basic requirements for Medicare participation keep staffing overhead abnormally high. With fewer patients over which to spread the overhead, the costs per patient have risen steadily. The Medicare Conditions of Participation and peer review organizations hold rural physicians and hospitals to the same standards as those required of urban providers. However, there is usually a great disparity in payments between urban and rural providers.

Rural hospitals' low volume makes it more difficult to offset losses from reduced Medicare revenues as opposed to larger institutions that can spread losses across a greater volume of patients. Compared to urban hospitals, rural hospitals are compensated at lower rates for the same procedures based on the assumption that costs are less in rural areas. PPS regulations also specify lower wage adjustments for rural hospitals although many of them must compete with urban hospitals for the same labor pool.

Although many hospitals demonstrated an overall improvement in their financial position since the implementation of PPS, most small rural hospitals did not do so. And because of their greater dependence on Medicare patients and the probable tightening in future PPS reimbursement policy, small rural hospitals will fare even worse in the coming years.

Three years ago, changes in the payment mechanism were welcomed by many of us as a system which would encourage more efficient use of resources and would promote greater accountability for the Federal Medicare dollar. However, peer review organizations, such as the Texas Medical Foundation, have been chartered to reduce medically unnecessary admissions. Their efforts, combined with the overall national trend to less inpatient hospitalization, have been most effective in this regard. The graphs provided to you reflect the decline in patient discharges and patient days for 21 North Texas hospitals during the past five years. Discharge declines average 39 percent. Patient days have dropped an average of 47 percent.

There are three areas of particular concern for rural health care:

1. The inequities of the Prospective Payment System.

2. The inequities of the Medicare peer review and the sanctioning process.

3. Problems with the Medicare Conditions of Participation for Hospitals.

Each of the above concerns are addressed in separate attachments.

MEDICARE PEER REVIEW AND THE SANCTIONING PROCESS

BACKGROUND

When the Prospective Payment System (PPS) was implemented in 1983, peer review was one element of the program. In most instances an agency within the state contracted with the Health Care Financing Administration to carry out this function. In our state the Texas Medical Foundation (TMF) is the review agency.

Peer review has two primary purposes:

1. Reduction of medically unnecessary admissions. Care judged to be unnecessary is not compensated, thereby saving Medicare Program dollars.

2. Assuring quality health care services rendered to Medicare beneficiaries.

Providers who fail to comply with written guidance or TMF interpretation of quality standards are subject to sanctioning, a process which excludes the individual or facility from Medicare Program participation. This simply means that the Program will not pay for any services given by that provider.

In an urban area the exclusion of one or two physicians from the Medicare Program has little impact on the overall system, though individual patients may be inconvenienced when forced to find another doctor. In a rural community which has only 1-3 doctors, the effects are devastating. Not only does it place additional responsibility on other community physicians, if there are others, the hospital may close as a result of reduced inpatients. Information concerning the financial problems of area hospitals is contained in another portion of this testimony.

PROBLEMS

Rural Texas communities are threatened with three basic problems:

1. Loss of their physicians through the Medicare sanctioning process. Several area communities have had their physicians sanctioned. In Haskell two of the three doctors have been sanctioned--the third voluntarily ceased to see Medicare patients last December. In Crowell the only physician was sanctioned--the same happened in Henrietta. The Medicare beneficiaries in these communities now have no local access to health care. Their hospitals could very well close.

2. Rural medicine is now perceived by many physicians as subjecting them to a much higher risk of sanctions. Their Medicare patient load percentage is usually much higher than in urban areas. Because there are only a few doctors in the town, when the TMF audits patient charts, there is nearly a 100% chance that their patients' records will be reviewed. This is not so in an urban setting.

All physicians are being charged to comply with "professionally recognized

standards of medical practice." Most rural physicians are willing and able to comply, but the standards are not clearly indentified. Consequently, they are being held accountable for these standards and penalized by sanctions if not met. In addition, some physicians are not even given an opportunity to change their method of practice when deficiencies are identified. If they cannot explain the deficiency to the satisfaction of TMF, they receive sanctioning with little recourse. As a result, we, in rural communities, are beginning to experience difficulty in retaining our current physicians. Moreover, the task of recruiting new doctors is becoming increasingly difficult as rural medical practice is perceived to be at a much greater risk of sanctioning.

3. Many rural communities are now confronted with the closure of their hospitals. This situation is due to loss of patients because physicians have been sanctioned and because of inadequate reimbursement.

The health needs and the economics of the rural community are closely interrelated. Loss of or limitations placed on physicians impact the hospital's financial viability. If the hospital fails, jobs and payroll are lost, income to local business is reduced, families move to seek other employment, the school system loses students and eliminates teachers, more payroll is lost, local business loses additional income, some firms close, more jobs are lost. This domino effect is commencing in Texas and may be the beginning of the end for many rural communities.

Aside from the financial implications, lack of doctors and/or the absence of a hospital creates severe problems for the elderly and the poor. Distance between communities increases as one travels west. Persons who have no vehicle or who are unable to drive will be denied reasonable access to routine medical care. In an emergency the problem is compounded. Residents will have to travel 35-60 miles or more for care. Public transportation is limited or non-existent in most rural towns.

We believe that the peer review and sanctioning process, as currently implemented, is flawed:

1. Attempts to salvage problem physicians are not uniform. Opportunities for improvement of medical practice are not offered to all physicians prior to sanctioning.

2. The "professionally recognized standards of medical practice" are neither clearly identified nor understood by all physicians.

3. The impact on the community does not appear to be fully considered prior to sanctioning decisions.

RECOMMENDATIONS

1. That all physicians be given an opportunity to improve the quality of their care prior to sanctioning. This could be accomplished by requiring attendance at continuing education seminars and consultations with other physicians in appropriate instances.

2. That a project be undertaken to clearly identify the "professionally recognized standards of medical practice" and these standards be provided to all physicians.

3. That a comprehensive community impact assessment be accomplished

prior to sanctioning decisions. The assessment should consider community demographics, reasonable access to other physicians, travel distances, and public transportation. The results of the assessment should be a major factor when considering appropriate action.

Statement of
John Horty, President
National Council of Community Hospitals

Before the
Subcommittee on Health

of the
COMMITTEE ON FINANCE
UNITED STATES SENATE

March 27, 1987

NATIONAL COUNCIL OF
COMMUNITY HOSPITALS

My name is John Horty. I am President of the National Council of Community Hospitals ("NCCH"). NCCH is an organization comprised of over 100 hospitals and health systems located in 30 states across the country, who in the aggregate operate more than 60,000 acute care beds. NCCH members are particularly concerned in maintaining and improving the quality of care given in this country and in reforming the health care system so that care can be provided in the most efficient manner possible. It is because of these interests that NCCH is disturbed about the formulation and operation of the peer review organization ("PRO") program.

I first will describe what we believe are the conceptual weaknesses of the PRO program; then I will discuss specific operational problems. The attachment to this statement sets forth suggested amendments to Title XI which are the minimum necessary to improve the operation of the current program.

1. Safeguards against unnecessary care should be provided by economic forces rather than by regulatory agencies such as the PROs.

PROs are deemed to be necessary under the current Medicare system because of the incentives under PPS for hospitals to increase admissions. It would be better to change the incentives than to force the desired conduct by regulation. The perceived need for PROs to review the need for admissions could be eliminated if the Medicare system is changed to introduce economic forces to ensure that hospitals do not unnecessarily admit patients. Specifically, we believe that federal assistance should be distributed through a defined contribution which the beneficiary could use to obtain insurance coverage (a voucher is one way of doing this). This would promote the development of a competitive market among insurance companies and health plans and force them carefully to monitor hospitals' admissions.

It is far preferable for plans and hospitals to work out among themselves what is a necessary admission than for a PRO, influenced by HCFA, to make this determination by diktat. The plans will have an interest not only in saving money but also in accommodating the patient's needs. PROs have no such need to consider the patient's interests and, as discussed below, often do not do so. Hospitals and plans operating under market constraints are more attuned to the patient's needs and can do a better job of balancing the level of care needed against its costs than can a regulatory system like PROs.

2. Responsibility for economic and quality review should not be combined in the same organization.

As presently structured, PROs are responsible for determining the necessity for and the efficiency of care. But they also are required to determine if the care provided meets

standards of quality. We believe it is inappropriate for PROs to be responsible for both economic and medical quality determinations.

In theory it would be salubrious for a review entity to be required to take into account the tension between economic efficiency and quality. However, PROs do not view their responsibilities in this integrated way.

The combination of quality and economic review, in addition, confuses operation and analysis of the program. Criticism of PROs for adversely affecting quality in pursuing the goal of economic efficiency often is deflected by reference to the provisions in the statute requiring PROs to review quality. The problem is that the word "quality" is being used in two different contexts. Provider objection to a PRO denial of an admission is based on the provider's belief that quality of care is adversely affected by not admitting the patient. The fact that the PRO may also have jurisdiction to review the quality of care provided by physicians does not change the fact that in its economic decisions it is seen to be adversely affecting quality.

Further, we fear that quality can be used as a facade for what are in reality economic decisions. The thrust of the PRO program, because of the federal government's budgetary problems, is on preventing excessive and unnecessary care. PROs know they will be judged on their ability to reduce admissions or the number of certain procedures performed. The authority to perform both functions makes it possible to clothe economic decisions as quality determinations.

3. Quality review should be focused where it is needed.

The federal government should focus its quality review where it is needed and where other institutions -- state licensing agencies and hospitals through their peer review activities -- cannot do the job.

Hospitals and members of their medical staff monitor and improve the quality of care provided in hospitals through the peer review and credentialing process. The hospital peer review mechanism is the most effective mechanism in place for reviewing the quality of care. Congress recently recognized the importance of the hospital peer review process and provided hospitals additional tools to strengthen that process. See Title IV of P.L. 99-660. Yet the PRO program has been formulated and operates without acknowledgement of the hospital peer review process.

The federal quality effort should build on the strength of the hospital peer review process and focus on areas where the hospital may be under an economic conflict of interest (i.e., assuring, where Medicare reimbursement is based on the PPS, that

there is not underutilization). But where the hospital has an effective peer review process, PROs are not needed to review the quality of the particular services which are provided.

4. Responsibility for review decisions should be clear.

The PRO program has inappropriately blurred the responsibility for PRO review decisions. HCFA is able to take the position that denials are made by a private group of local (state) doctors, when in fact it is HCFA that in large part determines the outcome. It does so (as discussed below) by imposing numerical goals (or guidelines) on PROs, by its efforts to have appropriate care judged by national rather than local standards, and by pressuring PROs to meet predetermined reductions in admissions or procedures. If there is to be a government program of determining what care is necessary and what is not, the government's role should be acknowledged so that providers, the beneficiaries, and the public in general are aware of it. The divided responsibility between the government-sponsored agency and the government which gives each the ability to ascribe responsibility for an action to the other should be ended.

5. The need for admissions should be determined prospectively.

Because there will always be differences of opinion on how a patient should be treated, PRO review of a hospital stay should occur prior to admission and not retroactively. It is too easy for PROs to deny reimbursement after an admission has taken place (and the patient has had the benefit of the hospitalization) and to second-guess what hospitals and physicians had to decide at the time of admission. Under the present system, hospitals and physicians too often provide services in good faith and then learn that the PRO has denied the hospital reimbursement for the services. It would be more appropriate if PRO decisions on the appropriateness of admissions were made prior to admission, provided that if the PRO did not act within a stated period of time after being asked to review a proposed admission, the admission would be deemed to be appropriate.

6. HCFA has wrongly eliminated the 2 1/2 percent presumption for determining waiver of liability.

The standards of what is medically necessary are not mechanical and are subject to debate in an individual case. There always will be legitimate disputes as to whether or not a particular procedure or admission was medically necessary. The 2 1/2 percent presumption which was in effect before HCFA repealed it on February 21, 1986, provided a rough estimation of the good faith differences that can arise; it permitted full reimbursement, even if there were some disputes. Without that

presumption, hospitals are forced to challenge each disallowance, raising costs for everyone in the system. The presumption should be restored.

7. The PRO program is being administered in an arbitrary and unfair manner.

In numerous respects, the PRO program is being administered in an arbitrary and adversarial way. This increases provider distrust and resistance to the program.

(a) Although the PRO legislation requires that a PRO's relationship with each hospital be governed by a contract with that hospital, the contract negotiating process is a charade. The intent of the legislation is that hospitals and PROs work out their relationship, subject to statutory requirements. In the real world, however, HCFA has dictated to PROs the contract terms they may agree to. HCFA wants uniform procedures. It has taken the totally erroneous position that anything that is not required by the statute is prohibited by it, and has directed PROs not to administer their program the way the PRO and hospitals have agreed upon. This destroys local flexibility, inhibits hospitals and PROs from working together cooperatively, and demonstrates to providers that the PROs are instruments of the federal government.

(b) Hospitals have no appeal (administrative or judicial) from a PRO denial. The statute merely permits a rehearing to the PRO -- the very entity that has made the decision an issue. It is essential that hospitals have the right to an administrative appeal before an independent body, and to judicial review thereafter. One PRO was willing to allow review of its decisions by an arbitration process, but HCFA prohibited it from including the procedure in the contract with hospitals (as discussed above), even though its own PRO Program Directive No. 2 recommended arbitration.

(c) The procedures for imposition of sanctions are unfair and harsh. The procedures are inadequate in many ways, but most important is the fact that there is no provision for even a hearing before either the PRO or the Inspector General prior to imposition of a sanction. A sanction (including exclusion from the program) can go into effect, and the sanction be publicized, long before any hearing has been held or any appeal brought to determine the validity of the sanction.

(d) The PRO program has been run not by regulation but by a stream of directives and transmittals. The directives and transmittals are confusing, and difficult to keep up with. More importantly, HCFA fails to give hospitals and physicians a chance to participate in the process of developing them. Indeed, until recently hospitals and physicians have not even been sent the directives, which are transmitted by HCFA to the PROs. The PRO program has been run on the assumption that policies are worked

out by HCFA and PROs, which then inform the providers (often retroactively) of them. Doctors and hospitals, whose conduct after all is what the PRO program is intended to affect, are treated as if they are the passive objects of HCFA's decisionmaking. The assumption is wrong, and the attitude behind it counterproductive. HCFA's recent decision to send manuals to hospitals is a step in the right direction. However, even this is unlikely to work well. HCFA did not directly distribute the manuals to hospitals; instead, it sent them to fiscal intermediaries for distribution to hospitals. It is unclear how the process will work for the distribution of the various transmittals and directives.

(e) HCFA has sought to subvert the Congressional intent that medical standards be determined locally. Section 1154(a)(6) states that the PRO shall apply professionally developed norms based upon the typical patterns of practice within the geographic area served by the PRO, taking into consideration national norms where appropriate. HCFA has attempted to use the "where appropriate" language to require PROs to use national norms across the board. It thus has undercut the premise of the PRO statute that care would be evaluated on the basis of local standards.

(f) The program increasingly is being administered on the basis of aggregate statistics rather than individual circumstances. HCFA has set arbitrary, predetermined goals of reduced admissions for a number of DRGs which bear no relation to the performance of the hospital at issue. These assume the appropriateness of admissions can be determined on the basis of statistics. It is inappropriate to impose a priori targets on PROs and hospitals, whether they be quotas or "merely" guidelines. It is not enough to say that the numerical "guidelines" are just one item to be considered in evaluating the PRO's performance. The operative fact is that HCFA states it will consider the PRO's success in meeting the guidelines when it reviews the PRO's performance. This naturally puts pressure upon the PRO to live up to these arbitrary and a priori numbers.

As the program focuses more on quality, it risks determining what is proper care on the basis of statistics and formulae. This could only produce "cookbook" medicine enforced by the federal power to deny reimbursement.

(g) HCFA has forced PROs to review targeted DRGs or procedures, even if there is no indication that a physician or hospital is providing unnecessary services. There should be a requirement that the minimum review requirements are not applicable if the hospital or physician has a sufficiently low denial rate.

(h) PROs are required to send letters to beneficiaries after a disallowance which indicate that the physician or hospital has circumvented the PPS system or has performed an inappropriate

medical practice. It is wrong to send such allegations to PRO beneficiaries. They cannot understand them and are troubled by them. These notices imply that the patient's doctor is incompetent or dishonest, when the matter typically involves a legitimate difference of opinion on how care should be provided. The notice implies that the physician is guilty of wrongdoing when in many cases his only fault is that he differed from the PRO on whether the patient needed to be admitted (and the PRO may well be the one which is wrong).

This problem is exacerbated where payment is in fact denied for quality reasons pursuant to Section 1154(a)(2), as amended by COBRA. In that case, the PRO will in fact have made a quality determination. It is not proper to inform patients of PRO's view of their physicians' quality of care where there has been no chance for the physician to obtain either administrative or judicial review of that determination. Patients should not be informed of what are in essence accusations.

(i) The PRO process has too often been conducted as the heavy and arbitrary hand of a bureaucratic government. PROs have determined that an admission was unnecessary in cases where any objective observer would agree that the admission was appropriate. They have in too many cases refused to consider the particular circumstances of individual patients in determining whether an admission was necessary. Thus, although a procedure typically does not require admission, it may for a patient who lives far from the hospital, has no support at home, has comorbidities, or is just plain frail. PROs often do not factor these very relevant individual considerations into their determinations. And the absence of an appeal process prevents this error from being corrected.

PROs have failed to act in a timely fashion. They have set arbitrary conditions: in one instance a PRO set one day and one time in which a physician could call for preadmission approval, regardless of the physician's schedule. They have held reconsideration proceedings at distant places, making it expensive and difficult for physicians to attend and on other occasions have denied attendance by the physicians at reconsideration hearings.

(j) PROs fail to take into account not only the individual circumstances of patients, but the individual circumstances of physicians and hospitals. This is particularly true with respect to care provided in rural areas. Rural medicine is not provided in the same way as it is in urban areas: rural health care tends to be personal and informal, less technical -- more often a "family" matter. The reviewers must recognize the unique needs and perspectives of rural physicians. The fact that these physicians deal with their patients and their records in a less formally documented manner does not necessarily result in less than optimal quality of care. The social impact of sanction proceedings on rural communities is significantly greater than in

urban areas. Rural citizens personally feel the results, since physicians are increasingly unwilling to live and practice in rural areas.

(k) Because of the shortage of qualified staff and to save their time and expense, PROs have forced hospitals to Xerox massive amounts of medical records (which ties up the hospitals' medical records department and forces them to incur large Xerox costs). When a PRO sends a nurse reviewer to evaluate cases during an "on-site" review, the nurse often requests a copy of the full medical record (usually quite a lengthy record) for further review by a physician. After leafing through only a few pages of the record, the physician usually finds "no problem" and indicates his approval. The hospital has borne the financial and administrative cost of hundreds of pages of photocopying. Hospitals should not be required to bear PROs' duplicating costs. HCFA should pay those costs -- not merely the per-page costs of duplication, but the related labor charge.

In this connection, the different understandings of what is on-site review should be mentioned. Some believe that on-site review means that the physician consultant is present at the hospital to review records and thus is able to talk to the physicians involved and promote the educational process. This would be beneficial if it occurred, but in actuality an on-site review means the nurse reviewers, not the physician, review the files at the hospital. Even then, the nurse reviewer will request copies of some records to take back to the physician consultant. As a practical matter, the choice is between an on-site review where the nurse reviewer comes to the hospital (but still requires copies of some records) or off-site review where all the records are sent to the nurse reviewer.

(l) The PRO program has been run, consistent with the attitude established in the Health Standards and Quality Bureau, in an adversarial way. PROs typically act by disallowance notice rather than by discussion and consultation. If the purpose of the PRO program is to change the conduct of physicians who erroneously admit patients, it would be far more successful if PROs discussed questions with physicians and listened to physicians' responses. Instead, PROs assume their determination of what is an appropriate admission is correct and then take a legalistic and adversarial stance. Rather than discussing the question with the physician in a cooperative way, they accuse him. Often the first indication the physician has that the PRO is questioning his method of practice is a notice of denial.

(m) Despite the contemplation of the program that there be peer-to-peer consultation prior to a denial, the reality is that the attending physician often does not have an opportunity to discuss the case with the physician consultant before an initial denial is made. At that point it has become an appeal from a denial, which is entirely different from consultation.

Not only is there often not peer-to-peer consultation, but the hospital and physician frequently do not even know what physician is considering a case. At the same time that HCFA's regulations require peer-to-peer consultation, they also, totally inconsistently, make the name of the reviewing physician confidential. Indeed, hospitals are not always certain that physicians themselves are making the denial decision. Typically, the initial notification received by an attending physician is an initial inquiry (notice of potential denial) from the nurse reviewer. The attending physician then may submit comments (still no oral communication with a peer). But he has no way of knowing whether those comments are reviewed by the nurse reviewer or by a physician.

(n) PROs are not engaging in the educational process contemplated by Congress. As described above, initial denials often are made without any consultation with the physician and before the physician has any notion that the PRO disagrees with his treatment. Once the initial denial has been made, the process necessarily becomes adversarial. The accusation of wrongdoing precludes education and consultation. The PRO program is now being run almost exclusively through the denial process. An informal process by which physicians receive a thorough and accurate explanation of potential problems, as seen from the PRO perspective, and can discuss the questions with PRO doctors would be a much more time-and-cost-effective method.

As part of the educational process, greater emphasis should be placed upon developing consensus standards. Physicians often do not know what the standards are or have disagreements with them. Also, they face different interpretations of the standards at the PRO and regional offices.

Finally, the public must be better educated to make health care choices. This should be done by community outreach programs in which not only the PRO but physicians and hospitals participate as well.

Conclusion

Many aspects of the PRO program are fundamentally flawed. It is an effort to determine and enforce economic efficiency by regulation. A competitive system which permitted economic forces to operate would be more effective. The program is delving into areas of quality where hospitals and state licensing agencies are more appropriate. And the mixture of quality and efficiency regulations is inappropriate. A review of the fundamental premises of the purpose and nature of the PRO program should be undertaken.

In the interim, the administration of the program must be improved. The program should be more flexible, and permit PROs and hospitals to work out their own arrangements, so long as they carry out the law. PRO determinations should more accurately reflect the facts in individual cases -- individual admissions

and individual hospitals and practitioners -- rather than being shaped by statistical aggregates. The program should be administered through cooperation and consultation rather than denials and notices of violation, as has been the case. And the procedures should be made fair: hospitals should not be denied reimbursement without review of PRO actions by objective and disinterested administrative agencies and courts; providers should have a fair hearing before they are sanctioned (and the sanction is publicized).

C. M. Randal, Jr., M.D. 817-888-3131

SEYMOUR CLINIC
201 Stadium Drive - Suite 4
SEYMOUR, TEXAS 76380

March 9, 1987

Senator Lloyd Bentsen
Senate Office Building
Washington, D.C. 20510

Dear Senator Bentsen:

After talking to your office the other day, I decided to delay this letter until Representative Beau Boulter was in Amarillo to see if any additional input could be obtained in order to make my letter more brief, but as those of us who practice rural medicine see it, as brief as I can tell it, the following situation more or less exists:

I live in Seymour which is 50 miles southwest of Wichita Falls and 100 miles north of Abilene. Stamford is approximately 20 or 30 miles north of Abilene. Henrietta, which is approximately 15 miles east of Wichita Falls, has had it's physician sanctioned. Archer City, which is approximately 30 miles equal distance in a triangle between Wichita Falls and Seymour, has had it's physician sanctioned. Haskell, which is approximately halfway between Seymour and Abilene, has had two of it's three physicians sanctioned, the third now declining to take Medicare or Medicaid patients. Crowell, which is approximately 35 miles from here at right angles north and west, has one physician who is up for sanctioning. Paducah, which is an additional 30 or 40 miles west of Crowell, I believe has had their physician sanctioned. Consequently, patient's in this area, if we should be sanctioned also, would have the inconvenience of a 50 mile trip, a 100 mile trip or a 40 mile trip to Vernon towards Wichita Falls to see a physician.

This would not only be a great inconvenience to the patients who have families which could take them but many of the people in our community would be unable to make the trip and those that do have families would put the family under extreme hardship to render attention to them in another community. Our community is relatively a retirement community and consists of a Medicare and Medicaid percentage of approximately 70 to 80 percent of our practice..

Another consideration is that nearly all of these area hospitals have either been built by Hill-Burton or HUD or have been remodeled under one of these programs and still have outstanding federally guaranteed bond issues.

The main gist that I got from hearing of Representative Beau Boulter's meeting in Amarillo was that apparently he felt that due process of law was being violated by the sanctions and the inquiries and the hearings which have been held. My personal feeling is that a physician is licensed to practice by his state board and that no particular segment of society (Medicare or Medicaid) should be denied his service. If his quality of care is inadequate for this segment, it should seem to be inadequate for all segments and should justify revocation or at least special attention to his license and/or our licensing procedures. It is to be noted that a considerable number of physicians who have been sanctioned (according to my information) have not been named in a malpractice action.

One of our local physicians has recently been called for an appearance before the sanctioning committee. As a result of this so-called interview, although sanctioning was withheld, he is moving his practice to the more protected circumstances of the city, i.e. Wichita Falls as of the 15th of April and during the last six weeks has only admitted to our hospital 4 or 5 patients because of the severe uncomfortableness which the inquiry made him feel. Other admissions have been referred to physicians, most likely outside of this community. This will leave two physicians here, myself included, and because of my age (70), I respond only to limited call and limited office hours (approximately 3½ days a week), and do no obstetrics. The other physician remaining also does no obstetrics.

I was born in Seymour, returned to practice here following World War II and have been practicing a total of 45 years. My mother was instrumental in the campaign to build the first hospital in our county so you can understand my feelings when there is contemplation over the possibility of our hospital ceasing to exist, especially when the three physicians here have been in practice a total of 75 years without any independent malpractice action being taken against any one of us.

I personally feel that this is a form of harassment while being considerably more profound than the word would imply and having more basis than the concept which is being implemented by the Texas Medical Foundation and their method of peer review. The reason for this assumption is that if the papers are correct, TMF is receiving 19.3 or 18.1 million dollars for their 2 year facilitation contract with whoever is paying them. It seems reasonable to me that unless they can save the third person intermediary at least this much money there ceases to be a reason for their existance and that this procedure is to be facilitated irregardless of who or what must be sacrificed in the process. I would be interested in seeing a true investigative type of report as to the exact distribution of the monies mentioned above, i.e. individual's and board of director's salaries, expense accounts and contracts.

Being only partially aware of the significance of the above mentioned procedures, 1900 individuals in this community, in a period of one day, Saturday, February 28th, signed a petition which in summary was to preserve the means and methods of the components of the rural practice of medicine in Seymour.

Representative Charles Stenholm is holding a meeting in Abilene on March 14th, which I certainly plan to attend, although we are not in his district at the present time. I personally am certainly considering retiring from practice rather than running the risk of being told that my care was of such a quality that I should not be allowed to practice on Medicare or Medicaid patients when, as regards the Medicaid (indigent) patients, it at least seemed like at the time that we looked after them as well as other patients for the past 100 years with no thought of getting paid for their care. If I were to be sanctioned I would feel like I had spent my life's work for nothing. It would be like quitting in semi-disgrace and I can't make up my mind whether I want to take that chance. I'm personally sure that this is the way the 3rd physician has felt even though he survived his sanctioning and is consequently moving to practice in a more protected environment.

After devoting much time, thought, worry, fretting and frustration over all of the aforementioned it is apparent that if rural communities that have small hospitals lose their physician through sanctions or any other reason, they will be forced to close. This will produce a source of great inconvenience (understatement of the year) to our retired personnage in the nature of Medicare and Medicaid patients. A few suggestions which might be of assistance are as follows:

1. Better co-ordination and cooperation between state board and peer review sector of TMF so that society in it's different catagories would not separate any group in a discriminatory way such that the state board which has been criticized for what would appear to be it's leniency and the peer review board and TMF could become less critical especially in things that do not have a major influence on patient care i.e. for example, if a rural physician is seeing 40 to 75 patients per day, as some do, it should be kept in mind that his diligence in ordering appropriate tests to diagnose a case whose incidence is only one in a million population is less than acute and/or energetic, I would think that a single board of licensing and review might be considered as an initial license process for new physicians and for the older physicians in rural practice some type of preliminary evaluation prior to the critical offending and sometimes letter of inconsequential substance, the inquiries, and the sanctioning procedures take place, so that an individual is predetermined whether or not he can practice on Medicare and/or Medicaid patients and the general public, prior to a bunch of time consuming, frustrating and sometime inappropriate meetings are held and actions taken.

2. Following the results of this determination it seems to me there should be no immediate revocation of license or limitation of this physician's practice to a certain segrated clientele until he had been given the opportunity and then failed to meet whatever recommendations that evaluating board should make in the nature of post graduate education, post graduate courses, post graduate meetings, etc.

I am inclined to agree with Representative Beau Boulter that less than this would violate the physician's constitutional rights of due process of law and what would be considered the patient's constitutional rights of free choice of physician which, to me, comes under the classification of "life, liberty and the pursuit of happiness." I am sure that my attitude is necessarily biased and prejudiced but I can see the beginning of the end of the fun, the excitement, and the emotional uplift that the rural practice of medicine gives an individual.

If your feelings happen to be turned in the same way and if I can be of any assistance, I would appreciate your calling on me. If our opinions are in either major or minor conflict I would appreciate any suggestions which would make it easier for us to adapt.

Signed,

C.M.Randal Jr. M.D.

CMR/pk

STATEMENT

SOUTH CAROLINA HOSPITAL ASSOCIATION

ON THE IMPLEMENTATION
OF THE PEER REVIEW ORGANIZATION PROGRAM

Submitted for the Record of the
Subcommittee on Health Hearings March 27, 1987
U. S. Senate Committee on Finance

I. Background

South Carolina hospitals have experienced serious problems with the implementation of PRO activities. The S.C. Medical Care Foundation, the first PRO for the state, terminated its contract with HCFA on November 1, 1985. S.C. hospitals operated according to the first PRO's guidelines until the new PRO's policies went into effect on November 1, 1986. The new PRO, SCPRO, is a division of Metrolina Medical Peer Review Foundation, Inc., which is located in Charlotte, N.C. SCPRO was awarded the PRO contract on July 1, 1986 and first started retrospective review activities on October 1, 1986 with November 1, 1986 as the effective date for newly developed SCPRO policies.

II. Retroactive Application of SCPRO Criteria and Policies

SCPRO is performing retrospective reviews for discharges occurring after November 1, 1985 through admissions occurring on October 31, 1986. Retrospective denials are issued and money is recouped. Hospitals do not object to retroactive reviews and denials, as long as such activities utilize the previous PRO's criteria which were in effect at the time the care was given. However, SCPRO is retroactively applying their policies and criteria in these retrospective reviews. This results in inappropriate denials being issued. Hospitals suffer unjust financial penalty, and beneficiaries receive copies of the denial letters issued by SCPRO. These denials are inappropriate and may erode the beneficiaries' confidence in the health care provider.

III. Inadequate Communication from SCPRO to Hospitals Regarding Criteria and Policies.

Although SCPRO informed hospitals that they would receive at least 30 days notice of new criteria and policies, hospitals actually received less notice on at least two occasions: the nurse screening criteria was mailed on October 15, 1986 with an implementation date of November 1, 1986. The review procedure and criteria for assistant surgeons during cataract surgery was mailed on February 27, 1986, received on March 4 and implemented on March 1. HCFA and congressional intervention was required in order to rescind SCPRO's policy, which also did not meet all HCFA requirements outlined in HCFA's Transmittal 12 of the PRO Manual. Hospitals should not have to request HCFA and Congressional intervention in order to ensure that the PRO complies with HCFA regulations.

IV. Questionable PRO Interpretation of HCFA Regulations

S.C. has had to request HCFA and congressional assistance in evaluating the appropriateness of SCPRO's interpretation of HCFA guidelines in a SCPRO policy entitled "Protective Overnight Observation."

The Medicare Hospital Manual (page 210) defines an "inpatient" and the exceptions to the general rule. The first exception indicated is related to hospitalization for minor surgery. The SCPRO's Protective Overnight Observation policy uses this exception to apply to all patients, not just those admitted for minor surgery. Their policy refers to an original HCFA policy in vember 1984 and a clarified HCFA policy in November 1985. The SCHA/SCP lations Ad Hoc Committee has requested a copy of these two HCFA po and SCPRO has refused to provide a copy indicating it is the interme responsibility to provide this.

HIM 210 been the standard regulation under the previous PRO and is the sta in the majority of states. HIM 210.A does not imply that any stay of than 24 hours should be automatically denied.

As recent as December 22, 1986, Dr. John DuBose, Chairman of the SCPRO Medical Review Committee, admitted that the SCPRO policy has not "made it to the practicing physician level." However, SCPRO is applying this new policy in their retrospective reviews and inappropriately issuing denials.

In sum, the South Carolina Hospital Association (SCHA) questions SCPRO's interpretation of HCFA regulations, does not agree with retroactive denials based on this SCPRO policy, and questions why SCPRO refuses to provide us with copies of the "original November 1984 HCFA policy" and the "November 1985 clarified HCFA policy." SCHA continues attempts to resolve these issues through all available avenues.

V. Conditions of Participation

Although the Conditions of Participation allow 30 days for filing the discharge summary in the medical records and 48 hours for filing the History and Physical, SCPRO requires 20 days for the discharge summary and 24 hours for the History and Physical. South Carolina has requested that SCPRO's contract be modified so that their requirements are consistent with federal regulations.

VI. Appropriateness & Adequacy of SCPRO Review

A. Referrals by nurse reviewers

Nurse reviewers are not adequately reviewing the charts against the screening criteria. The documentation in the chart clearly indicates the admissions were appropriate. For example:

> A patient suffered from recent onset of syncope with three episodes of seizures. Was admitted to ICU. Remained there for 21.5 hours and was transferred to telemetry. Remained in telemetry for 28.5 hours. Was taken off telemetry and discharged the following day. The criteria indicate "seizures"

and "fluctuation in level of consciousness" as meeting severity of illness and "cardiac monitoring device in use" and "observation and monitoring of vital signs every 4 hours" as meeting intensity of service. The patient was in the hospital for 3 days. The information indicated above is clearly documented in the record and yet the nurse reviewers referred the case to a physician advisor.

In addition, it does not appear that the physician reviewers are adequately reviewing the records which are copied and sent to Charlotte. The case mentioned above was referred and a preliminary denial letter was issued which states that the necessary evaluation and treatment could have been accomplished during 24-hour observation period and billed as outpatient services. The attending physician was then required to write a letter stating again the same information which was documented in the chart. As a result the hospitalization has been approved.

VII. Coordination & Dissemination of Information Among SCPRO, the Fiscal Intermediary, and Hospitals

SCPRO has given hospitals instructions which conflict with guidelines from the F.I., e.g. instructions to bill as an outpatient. This causes needless confusion and miscommunication.

VIII. Recommendations submitted to HCFA and Senator Hollings on Feb. 26, 1987

A. HCFA's administrative management of SCPRO should be strengthened. HCFA should review PRO policies to ensure PRO's appropriateness of interpretation of HCFA regulations. Retrospective application of SCPRO policy is inappropriate. Hospitals should receive 30 days notice of policies prior to PRO application. Communication and education are integral. SCPRO and fiscal intermediaries should strengthen their communication with each other and with hospitals. Hospitals should not have to resort to congressional intervention and requests for HCFA assistance in order to resolve local problems.

B. More on-site reviews should be performed. Cost-outliers could easily be reviewed on-site. This would decrease medical record copying costs, and personnel time spent copying records.

C. Valid screening criteria and correct application of criteria by well trained PRO reviewers are essential and should be checked for interrater reliability and validity. However, hospitals currently have little recourse when they question the criteria or the review process. Ideally, valid criteria and their correct application should result in a low percentage of reversals; otherwise they do not promote cost efficient patient care. Such actions will decrease the potential for physicians and hospitals to focus on denial profiles and financial status rather than on providing efficient patient care. In addition, appropriate application of valid criteria should decrease the number of records referred to physician reviewers which result in pre-denials and denials issued by the PRO, challenged by the hospitals/physicians and later reversed. Medical record copying costs could be expected to decrease. In South Carolina, medical

records costs for the year are projected to exceed one million dollars. Physician and hospital personnel time expended in responding to pre-denials and denials could also decrease because reconsiderations would not normally be requested if the physician/hospital determined that valid criteria were appropriately applied and that the probability of obtaining a reversal was minimal. The net result would be concrete cost-efficient care because of the savings (retrieving, copying and mailing medical records; responding to pre-denials and denials; maintaining tracking systems; diminished photocopying costs; and decreased postage.) Cost-efficient use of federal funds to support PRO activities would also be enhanced because the PRO would not be wasting its time reviewing records, issuing pre-denials and denials, and conducting reconsideration processes which result in the reversal of their denials.

D. A consumer representative and a hospital representative should be appointed immediately to SCPRO's Board and Implementation Committee to enhance communication.

E. The SCPRO's contract should be modified so that their requirements are consistent with the Conditions of Participation.

F. SCPRO should provide hospitals with exact copies of the denial letters given to patients.

TENNESSEE HOSPITAL ASSOCIATION
500 Interstate Blvd. South ● Nashville, Tennessee 37210 ● 615/256-8240

April 2, 1987

Mr. William J. Wilkins
Staff Director and Chief Counsel
U. S. Senate Committee on Finance
Room SD - 205
Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Wilkins:

The Tennessee Hospital Association represents over ninety-five percent of the hospital Medicare providers in the state of Tennessee. On their behalf we have the following comments with regard to the Peer Review Program.

Provider Representation
Hospitals should have seats on the boards of the PROs. As the focus of the activities of the PRO the hospital industry should have a major role in the deliberations of the procedures, reporting processes, the various requirements to be placed on hospitals, etc. It is currently an option of the area PRO to include hospital representation on its governing board. We feel it is inequitable for this to be an option, that some PROs permit the representation while others do not, that the hospitals of some areas do not have an official voice at the governing table.

The PRO is assumed to be somewhat knowledgeable of how to go about implementing the activities it is required to perform. It apparently is also assumed the Health Care Financing Administration Regional Offices are guidance for the PROs in this regard. We submit much time has been wasted by PRO staffs and hospital personnel by the failure of PROs to adequately consider the hospital perspective when issuing directives and making major decisions on policy. Such actions have routinely led to numerous telephone calls and letters seeking clarification, the unnecessary reproduction of medical records, and poor relations between the PRO and the hospitals.

It would be far better to grease the wheels by getting hospital provider involvement up front.

Beneficiary Notices of Denial
Provide for more flexibility by the PRO and wider latitude for the provider with regard to getting denial decisions reconsidered. The PRO has taken the position that it is required, in some instances, by the time frames of the regulations, to send denial notices to beneficiaries, even though the providers had not exhausted their response time for getting the denials reconsidered. This has resulted in instances of legal action being taken, even though the cases were ultimately resolved with decisions supporting the patients'

physicians' actions.

Provider/PRO Performance Factor
The program is so structured and inflexible that PROs are afraid to recognize that some hospitals/physicians are reliable, competent, effective, efficient, etc. In other words, out of fear of losing their contract they are afraid to judge some providers worthy of a reduced level of review.

How can PROs fail to put emphasis on developing sanctions against providers when they are by implication being measured on this activity? While the two-year contract seems to be a fair way of getting services under a new program, the contractor performance measures are like a number of guillotines ready to drop within a few months. A contractor would be foolish not to try and find some of the things which are more than rumored to be major factors to be considered in the contract renewal process. The program has a definite slant toward the encouragement of witch hunts, which serves no one effectively and efficiently.

Standards and measurement
Enclosed is our PRO transmittal #32, a perfect example of the kind of directive which fails to take into consideration the providers it is directing!! This also points out the general problems and weaknesses of the program. Enclosed with the PRO transmittal is an analysis of it by one of the most reputable health care institutions in the country.

Thank you for the opportunity to provide these comments. We look forward to the actions of this subcommittee. Providers feel, for the most part, that the odds are in favor of most any action improving on what we now have.

Sincerely,

James R. Alexander
Senior Vice President

Enclosures

VANDERBILT UNIVERSITY HOSPITAL
NASHVILLE, TENNESSEE 37232 TELEPHONE (615) 322-7311
Office of the Director • Direct phone 322-2415

March 23, 1987

Dr. Kenneth Phelps, Chairman
Board of Directors
Mid-South Foundation for
Medical Care
6401 Poplar Ave., Suite 400
Memphis, TN 38119

Dear Dr. Phelps:

We at Vanderbilt University Medical Center applaud the PRO's efforts to effectively monitor the quality of care provided to Medicare patients and support the goals of your organization in this effort. We at Vanderbilt have implemented an inclusive program designed to effectively monitor the quality of care provided to all patients admitted to our institution. As you have no doubt discovered, monitoring the quality of patient care is a complex undertaking. The preliminary effort by your organization, while simplistic in approach, is recognized as an effort to establish some system for quality review assessment.

The Quality Assurance Committee of Vanderbilt University Medical Center was requested by the Hospital Medical Board to develop a critique of the PRO plan and submit this to you as noted in our preliminary letter to you. We would like to offer the following comments and suggestions for enhancement regarding your current plan:

Standards of care are not defined. To effectively measure quality of care, standards must be established and are an integral part of the process. Departures can only be evaluated in terms of clearly specified standards, procedures, and policies.

Monitoring for departures from established standards of care should be designed to detect systematic problems or patterns rather than individual occurrences.

Standards, at the very least, must reflect the patient case mix and/or the individual patient acuity. Expected outcomes and frequency of errors will be different in an 80 bed hospital vs. a 600 bed tertiary care hospital. Standards should recognize the difference between an essentially healthy patient treated electively as opposed to the acutely ill patient with an acute, complex illness.

The presumption that a specific untoward event or poor outcome is equivalent to poor quality of care is not supportable. This approach essentially equates a poor outcome as poor practice or negligence. Acceptable and reasonable standards of care must recognize that untoward outcomes will occur even in the absence of deviations from standards of care.

Many of the examples used as quality indicators are poorly defined. They lack specificity, i.e., slight anemia (Severity Level I), and do not address the clinical circumstances in which such manifestations of disease might occur. For instance, in the example citing physician for not ordering an antibiotic sensitivity test for a patient with septicemia - the patient may have been treated at another hospital prior to admission, (Severity Level II). Specific examples would help.

There is a lack of clarity regarding how accountability is determined, i.e., physician, provider or both.

Following the review of your quality assurance plan, we would suggest the following recommendations:

Establishment of standards of care based on relevant regional and/or national statistically sound data.

Consideration in monitoring for departures from quality of care standards must take into account the individual patient severity of illness and the patient case mix of the institution in determining reasonable outcomes.

Monitoring should examine patterns of practice with consideration of overall incidence rather than focus on specific instances.

Meaningful standards which have a significant impact on patient care must be derived.

Definition of accountability must be established, physician and/or institution and cases where care is provided by more than one physician (patient admitted, had surgery, transferred to medicine and died).

Define information released to the patient.

We recognize the complexity of monitoring quality of care. We, on the other hand, must insist that when such monitoring is done it be performed in a way that is not detrimental and that does not effectively inhibit the institution's and physician's ability to provide quality patient care.

We appreciate your attention to our comments and would welcome any questions you may have. We would be happy to work with you in developing a meaningful quality assurance plan.

Sincerely,

Dan Spengler, M.D., Chairman
Hospital Medical Board

Norman Urmy
Hospital Director

Fred Gorstein, M.D., Chairman
Quality Assurance Committee

DS/NU/FG:ps

cc: Otis Warr, III, M.D., Medical Director MSFMC
The Honorable Jim Sasser
The Honorable Albert Gore, Jr.
Ira Lane, THA
Jim Alexander, THA
L. Hadley Williams, TMA
Otis Bowen, M.D., Secretary, HCFA
MSFMC Board of Directors
Henry Desmaris, M.D., Acting PRO Regional Director, HCFA