IMPLEMENTATION OF PSRO LEGISLATION

HEARINGS

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON FINANCE

UNITED STATES SENATE

NINETY-THIRD CONGRESS

SECOND SESSION

MAY 8 AND 9, 1974

Part 2 of 2 Parts

APPENDIXES

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CONTENTS

(Parts 1 and 2)

ADMINISTRATION WITNESS

PUBLIC WITNESSES

COMMUNICATIONS

APPENDIXES

APPENDIX A

APPENDIX B

APPENDIX C

APPENDIX D

APPENDIX E

APPENDIX F

APPENDIX G

APPENDIX H

SUBJECT INDEX

Appendix A

Communications Received by the Committee Expressing an Interest in These Hearings

Statement of the American Optometric Association

The American Optometric Association supports the concept of peer review as one of many instruments available to assure the overall quality of health care in this nation. The concept of standards review has progressed from the idea of cost containment of federally supported health programs like Title XVIII and XIX dealing with in-patient care. This method of review can also assure quality care in additional areas and with additional provider groups. For example, such review can include the services, on an out-patient basis, which the optometrist provides under Title XVIII.

However, we are still talking about a review that is structural and process oriented. That is, the review considers the facilities and manpower used and the processes involved. The Association feels strongly the need to progress to "outcome review."

In an effort to move on to this type of review, one of the current projects of the American Optometric Association will be of great help. Current Optometric Information and Technology (COIT) is being compiled into reference-book form. This reference will detail every vision condition involved in optometric care, with symptoms, typical remedy, criteria for diagnosis, treatment or referral, rate of occurrence, and typical patient problems.

As development of the Professional Standards Review Organizations now stands, medical practitioners will comprise the entire membership of the statewide PSRO, with all final responsibility for review. The American Optometric Association strongly recommends that the advisory groups be given greater authority in influencing the final review decisions. Also the Association recommends that there be more positions with voting power for the various independent health professionals, i.e., dentists, optometrists, podiatrists, etc., on the statewide advisory councils.

In addition, regardless of the number of PSRO's in any state, AOA recommends mandating the creation of a state advisory council and areawide advisory councils. All these advisory groups should carry more authority than presently assigned. This would allow expert evaluations into final decision-making. Again, at all levels, more positions on these advisory groups should be created, in order to allow participation of a wide range of health professionals.

In the administration of the national PSRO program, the Association strongly urges that the health sector of the Department of Health, Education and Welfare retain this responsibility. This is the most logical and workable arrangement.

The Association wishes to recommend for your consideration the creation of the advisory group to the national PSRO council. Again, with this national advisory group, more positions should be created, so that primary health care providers, those dealing directly with patient health, may be involved in the decision-making process.

This coordination with advisory groups can prevent potential difficulties as the review process widens and includes out-patient services provided by varied health professionals. Such coordination will eliminate hassling between the medically-dominated PSRO and the advisory Councils of other health groups.

Each independent health care professional should be called upon to evaluate his own specialty. Optometrists must review the care provided by optometrists. By virtue of education, training and practice, they are the only health care practitioners capable of fully reviewing such situations.

In the case of optometry, practitioners have been educated and trained at one of the 12 schools and colleges of optometry in the nation. In addition to course

work, during the fourth year of professional study the student spends at least half of his time gaining clinical experience, under professional supervision. After 2–3 years of undergraduate training and 4 years of optometric education, the graduate is ready for the state optometric examination and licensing procedure.

The question becomes, how can any profession not familiar with all these procedures and education, establish criteria for evaluation of optometric situations and assume final review for that profession? Evaluation implies that the evaluator will rely on judgments based on his own background and experience. A medical practitioner will surely look into his experiences, which are more oriented toward surgery and eye disease. The optometrist, in concern with the vision performance of the eyes, deals with binocular vision and coordination, vision development, visual perception and development and eye health.

The state optometric groups have already been at work in the area of establishing review organizations. Massachusetts, Michigan, California, Kansas, New York and New York City are some of the areas developing optometric review systems. In addition, AOA has developed a manual on peer review to aid the state groups in this endeavor.

The American Optometric Association, with its membership of 18,000 throughout the nation, is committed to the principle and practice of quality optometric care to all Americans. The profession of optometry is willing and ready to participate fully in a program of true peer review and a Professional Standards Review Organization system which is equitable to all of the health professions.

Testimony by Alice Gosfield, Staff Attorney for the Health Law Project, University of Pennsylvania Law School

Under a grant from the U.S. Department of Health, Education, and Welfare, the Health Law Project is in the process of preparing a detailed and technical analysis of the PSRO program, based on the statute, the regulations and other examples of PSRO policy implementation. Our focus in this work, as in the other studies we are developing, is the user-patient perspective. The following comments reflect our concern that the patient's perspective be considered of paramount importance in the development of the PSRO program. The five areas we have chosen to address are broad areas which represent some of the problems PSRO decision-makers must face now, lest the program be immutably molded into one which works to the patient's detriment.

1. ACCOUNTABILITY

The statute as written embodies no general legal requirements that the program interact with the public it will serve. As a result, the development of "Support Centers" was possible. There is no legal authority in the statute for these entities, and as the comments below demonstrate, they may seriously undermine the local orientation of the program. No attempt was made to include consumers or their representatives in the negotiations which lead to the development of "Support Centers". This public program which will allocate public monies must not be developed in isolation from public scrutiny. Without affirmative, legal requirements of PSRO inter-action with consumers and the public generally, any systemic accountability will depend on the good will of particular individuals. The development of Support Centers, and their potentially bad effect, is ample evidence of the incontrovertible need for public in-put into this new system.

2 INFORMATION

The PSRO statute gives the Secretary wide discretion in providing information about the program to the people who will be affected by it. (§ 1166; 42 U.S.C. § 1320c–15). There has been no affirmative attempt to circulate information about implementation of the program generally. Once PSROs are operational, their data development potential is enormous. The information obtained in PSRO operations must, of course, be subject to meaningful strictures for confidentiality;

but the basic information about the health care systems of this nation which will be developed must be made public.

PSROs may have the potential for upgrading the quality of care by forcing accountability of physicians to each other. But whether strict review results in improvement of the quality of care will not be known unless PSROs themselves are accountable to the public. PSROs need to make available a range of information: for example, how their review system is working; the evaluation criteria being used; quality performance of the hospital and nursing homes being reviewed. Unless information about PSROs and their findings is made available, an unaccountable system for determining allocation of public monies will have been created.

3 NON-PHYSICIAN ROLE

Although the law is clear that none but physicians may participate in final PSRO determinations, there are important roles for non-physicians which must be recognized. In the development of norms, criteria and standards, there will be areas in which there is no immediate consensus among all physicians. (Tonsillectomies and Mastectomies are two examples.) In those situations where there is no direct, scientific or technical data which mandates a specific choice, norms and their applications will be determined by non-medical factors—costs or social needs, for example. Physicians do not have a monopoly on the ability to make non-medical decisions. The consumer and other non-physicians, must be given the opportunity to affect non-medical decisions by participating in norms development, and advising in their application—in Support Centers, Statewide Councils and local PSROs.

Little attention has been devoted to non-technical aspects of quality care such as informed consent or other psycho-social factors of care. It is in these matters which are professionally recognized elements of good medical care that consumers can make a valuable contribution and are, perhaps, better able to evaluate care. There must be an affirmative effort made to include consumers in these ways in the program.

4 PSRO DESIGNATIONS

The following comments demonstrate and support the need for small, locally oriented PSROs, from the consumer perspective.

a. Legislative Intent

Section 1152 of the Social Security Act (42 U.S.C. § 1320c–1) provides the statutory authority for designation of PSROs. There are seven specific criteria for designation. Originally the Act (P.L. 92–603, § 249F of H.R. 1) did not specify the geographical boundaries for PSROs. The Senate Finance Committee Report on the Social Security Amendments of 1972 (Report No. 92–1230, 92d Cong., 2d Sess.) is, however, quite explicit on the issue of local emphasis. "Priority in designation as a PSRO would be given to organizations established at local levels . . . *Local* sponsorship and operation should help engender confidence in the familiarity of the review group with norms of medical practice in the areas as well as in their knowledge of available health care resources and facilities." (Emphasis added) (Senate Finance Committee Report (1972) at 259). The Report distinguishes clearly between state and local entities. (See Report (1972) at pp. 258, 259 and 268.) In the Report, statewide designations are to be restricted to "smaller or more sparsely populated States." (at 258).

The dispute over statewide as opposed to local PSROs has been fomented primarily by state medical societies. (See American Medical News, January 7, 1974, October 22, 1973, May 14, 1973 and March 5, 1974, for example.) In none of the reports does it appear a local or county medical society has sought domination of the PSRO in its area by its state society counterpart.

The following additional comments present other reasons for which statewide organizations should be discouraged in all but small sparsely populated, medically underserved areas.

b. Consumer Accountability

Generally speaking, the PSRO program does not provide for affirmative action by PSROs to seek consumer in-put or response on most issues including granting contracts, developing profiles of medical care, imposition of sanctions and development of norms, among others. Because of this basic lack of consumer accountability in the foundation of the program, it is imperative that PSROs be structured in such a way that consumers can gain access to them. The consumers who will be affected by this program are poor and old people who will not have the resources to involve themselves in the activities of a statewide organization whose center of activity may be geographically and financially inaccessible to them. The general public, as well, will have additional burdens placed on them, should they seek to exercise their right to influence and comment on the activities of a program that will dispose of their tax dollars. PSROs will determine issues which are inherently local—the effectiveness of a particular hospital's review system, the payment of a particular persons bill, for example. Consumer activity around PSROs would be severely curtailed by statewide designations and efforts to focus power at the state level perhaps should be seen as a further attempt to minimize consumer impact on the program.

c. Consumer Rights

PSROs will conduct primary determinations and hearings on review of determinations with which beneficiaries are dissatisfied. (§ 1159 of the Social Security Act, 42 U.S.C. § 1320c–8) The mechanics of review—mustering an argument, gaining access to information necessary to a case, marshalling support from providers or practitioners, effective presentation of the case—are complicated and difficult. To conduct the review process on a centralized statewide basis rather than locally will be detrimental to consumer rights which have been guaranteed by the statute. It would place an unjust burden on Medicaid and Medicare beneficiaries forcing them to travel long distances at great difficulty and inconvenience to present their cases effectively. Making the process inaccessible by virtue of those state designations, will thwart attempts by consumers to avail themselves of their rights.

Medicaid recipients, have in the past enjoyed a fair hearing process which is highly localized (through County Assistance Offices or other similar entities). Although the rights of these recipients may already have been unconstitutionally impaired through jurisdictional amount restrictions on review and preemption of jurisdiction by federal courts (§ 1159 (b) and (c); 42 U.S.C. § 1320c–8 (b) and (c)), the further restrictions of their access to the hearing process by centralizing that activity in a statewide entity, would unduly discriminate against those who can least afford an adverse determination they may be precluded from effectively challenging.

The statute provides for no effective means of enforcing rotation requirements on physicians, although a principal assumption of the value of PSROs lies in the educational effect it can have if all physicians participate. Although rotation of participation is strongly expressed as a necessity and goal of the program (§ 1155(d); 42 U.S.C. § 1320c–4(d); see also, Sen. Fin. Committee Report (1972) at 259 and 262), the system is essentially voluntary. To centralize activities in a statewide PSRO would enhance the possibility of domination by an established group of physicians both politically and functionally, because of the additional burden it would impose on local physicians who might otherwise choose to participate in review activities. Mere remuneration for time spent in review will not be sufficient incentive to participate in the program. A statewide focus may alienate a few physicians active in state medical society activities, but more seriously, may actually discourage the participation of local physicians not interested in state society activities, who will not choose to take the time to go to a centralized location to render services which they may not be anxious to offer in the first instance.

The example of the interaction of centralized fiscal intermediaries and the Social Security Administration (SSA) illustrates enforcement difficulties presented by statewide designations which could hinder public accountability and accountability to the government. When SSA contracted with the Blue Cross Association (BCA) as the fiscal intermediary under the Medicare program, Blue

Cross subcontracted with local Blue Cross Plans. Until a new contract provision was added in 1970, SSA was required to channel all communications through the Chicago organization. Even after revision in the SSA–BCA prime contract to permit direct communication, no regulation or instruction could be prescribed by the Secretary without prior consultation with the BCA. (See, Hospital Insurance Benefits for the Aged, Agreement with Intermediary Pursuant to § 1816 of the Social Security Act (1970) Article VII, § B)

Although the analogy is not direct, it demonstrates the pitfalls in monitoring, enforcement and administration of a program where the actual day-to-day activities are conducted on a local level, but primary authority and administration is in a centralized structure. Even if statewide PSROs were designated in some of the larger states that seek such approval, by necessity day-to-day review will be conducted by various sub-groups. Enforcement and monitoring of local activities might have to be conducted through the statewide PSRO (otherwise there is no raison d'etre for them), and the insulation can, as was the case with fiscal intermediaries, destroy the accountability and effectiveness of the entire program.

c. General Comments

The basic issue in the area designation dispute involves a balancing test. We believe that statewide designations in other than the small, sparsely populated states, can seriously undermine the beneficial effects of this program and will result in a structure directly inimical to consumer interests and rights. By the same token, an organization that is too localized (institutional utilization review committees may be an example) can defeat the program as well because of cronyism factors—a hesitancy on the part of physicians to review strictly and sometimes levy sanctions on their friends.[1] The balance lies somewhere between the two.

If the professional associations which testified in the hearings on the Social Security Amendments of 1972 were correct in their assertions that peer review should be conducted by peers,[2] it would seem that the better mode for review would be a more localized organization. In some of the states which are seeking single state designations, the differences between urban and rural areas are so great that the difference becomes one of kind. The type of medicine practiced in the disparate areas is not equivalent and review by a single group, would not, for that reason, be performed by peers.

If PSROs will result in better quality medical care through an educational process that will involve substantial numbers of physicians actively participating day-to-day review on a rotating basis, a statewide designation will attenuate the process because of the number of physicians that will have to rotate through a single entity. Service by those physicians will be occasional and sporadic as attempts are made to include everyone. Unless rotation and widespread participation are sought, the program will be defeated by domination by a small group of physicians traditionally involved in state society affairs. Where a local organization serving a smaller area containing a smaller group of physicians is the focus of activity, more physicians can rotate through more often over a shorter period of time thereby enhancing the educational effects of the program.

5 Hearings and Review

Unlike the other areas already discussed which address the regulatory process, the statute itself may unconditionally condition the previously well-established hearing rights of Medicaid recipients. (§ 1159; 42 U.S.C. § 1320c–8) The Medicaid hearing process has been locally administered with judicial review available in state courts. These poor patients have never been subject to "amount in controversy" limitations, like those imposed by the PSRO statute. The very fact of their eligibility for the program is eloquent testimony to their inability to absorb adverse determinations on services costing up to $1,000 or

[1] See Derbyshire, Medical Licensure and Discipline in the United States, John Hopkins Press, 1969 at 77 demonstrating reluctance of physicians to discipline each other.

[2] See hearings of the Senate Finance Committee on H.R. 1 (92d Cong.) Social Security Amendments of 1971, and, for example, testimony of American Dental Association at 2415, American Nurses Association at 2421, American Podiatry Association at 3305, College of American Pathologists at 2885, and the Coalition of Independent Health Professionals at 3363.

even $100. See for example *Knickbocker Hospital* v. *Downing*, 317 NYS 2d 688 (1971), and *Society of New York Hospital* v. *Moyensen*, 165 NYLJ20 (#4, 1971).[3] The statute (§ 1902(a)(3); 42 U.S.C. § 1396a(a)(3)) and regulations applicable to Medicaid recipients provide for a hearing in accordance with standards established in *Goldberg* v. *Kelly*, 397 US 254 (1970), for "any recipient who is aggrieved by any agency action resulting in suspensions, reduction, discontinuance or terminations of assistance," (45 CFR § 205.10(a)(5)). Cases which have held that this provision includes level-of-care determinnation (like those PSROs will make) are *Bell* v. *Heim*, (No. 1989 D.N.M. Oct. 21, 1971, CCH Pov. L. Reporter § 14,406) and *Martinez* v. *Richardson*, 472E2d 112 (10th Cir. 1973).

In using language which essentially follows the Medicare hearings process, the statute does not adequately recognize the rights of the different groups of government beneficiaries over which the PSRO program will have jurisdiction.

Poor people who are weakened by illness manifest the "brutal need" for benefits to which they have established their eligibility. To deny them those benefits through an adverse determination by a PSRO without affording meaningful hearings rights, is truly to push the recipient against the wall. *Sniadach* v. *Family Finance Corp. of Bay View*, 395 US 337, (1969).

GUSTE, BARNETT & COLOMB,
ATTORNEYS AND COUNSELLORS AT LAW,
New Orleans, May 10, 1974.

Mr. MICHAEL STERN,
Staff Director, Senate Finance Committee, Dirksen Senate Office Building, Washington, D.C.

DEAR MR. STERN: It was a pleasure to be one of the witnesses at the Hearing of the Health Subcommittee on PSRO representing the Council of Medical Staffs yesterday on May 9, 1974.

One of the questions asked by Senator Bennett included the issue as to whether CMS was representing the views of a "minority" position. In view of the limitations of time this could not be properly addressed. American CMS would like to have this Statement enclosed as a written statement in addition to the verbal testimony as per the ruling that witness statements should be mailed by May 12, 1974 for inclusion in the record. We hereby submit the following additional statement:

Statement from American CMS (in addition to the verbal hearing): A question was asked during our oral testimony May 9th as to whether CMS represented the position of a minority. CMS believes that ours is a consensus position, as follows:

(1) The position of the Medical Professions of those States represented by those Senators present at the time of the CMS hearing were in a majority for *Repeal* of PSRO, as follows:

(a) The Hon. Senator Long from the State of Louisiana: the Louisiana State Medical Society has thoroughly debated the PSRO issue and unanimous'y voted on May 5, 1974 for the Repeal of PSRO by deletion of the entire amendment not by partial amendment. The entire Resolution #709 is, as follows, to be printed as part of this statement: (Resolution #709 attached.)

(b) The Chairman of the Subcommittee on Health, Hon. Senator Talmadge, represents the State of Georgia. The Medical Association of Georgia voted for the Repeal of PSRO, as follows:

"Our officers, counselors, and Executive Committee should be instructed to work for repeal and inform the AMA and all other state medical associations of our decision. (b) In addition, we should: (1) Urge the membership to work in a united way toward this end. (2) Notify our representatives in Congress of our position and request their help. (3) Ask the AMA for financial support and ask AMA to work with the Congress. (4) Communicate with those in health related

[3] CCH Medicare and Medicaid Guide, ¶26,237.

organizations and ask for support. (5) Encourage the membership to inform its patients about the disadvantages of the law and mount a letter campaign to Congress asking for repeal of the law.

It voted a statewide public information program for the Repeal of PSRO, and held a rally in Atlanta on April 7, 1974 for Repeal of PSRO.

The Georgia Legislature adopted a Resolution urging Repeal, as follows: (attached).

(c) The Hon. Senator Curtis, representing the State of Nebraska: The Nebraska Medical Society is on record for Repeal of PSRO.

Of the four senators who heard the CMS presentation, three had clear mandates from their respective states for the complete Repeal of PSRO. Only the Hon. Senator Bennett had support from his State Medical Society.

(d) The State of Indiana Medical Society and Legislature are on record for Repeal of PSRO. Senator Vance Hartke represents the State of Indiana in the Finance Committee.

(2) The list of State Medical Societies which have gone on record for Repeal of PSRO in 1973 and 1974 are, as follows: Oklahoma, Louisiana, Texas, Nebraska, Kentucky, Michigan, North Dakota, Virginia, Indiana, Tennessee, California, Illinois, Arizona, Missouri, Georgia.

(3) The State Legislatures of the following states have gone on record for Repeal of PSRO and have thus memoralized the United States Congress: Tennessee, Indiana, Illinois (Precertification Regulations), Kentucky, Georgia.

(4) The American Medical Association House of Delegates, the opinion-making body of organized medicine, is on record that the Repeal of PSRO is in the public interest. It is only the position of the Board of Trustees—which is not the policy-making body of the AMA—that they will accept "Repeal by substitution" of amendments.

(5) Civic organizations have gone on record in Louisiana, as follows:

New Orleans: (a) YMBC. The Resolution of the YMBC is hereby enclosed, to be printed on the record as part of this statement. This resolution of the 1300 member YMBC of New Orleans was written and voted by the assembly after six months of deliberations and open hearings. Representatives included the Regional HEW Director in Dallas, Texas, Dr. Kenneth Schneider, Honorable Congressman Rarick from Louisiana and Dr. James Mongan (representing Honorable Senator Long). Open hearings which were carried on extensively before the unanimous vote for the Repeal of PSRO. (b) The American Association of Retired People, New Orleans Chapter;

Slidell: (a) The American Association of Retired People, Slidell Chapter; (b) The Resolution of the Slidell City Council signed by Mayor Cusimano; (c) Veterans of Foreign Wars; (d) Priscilla Club.

(6) Enclosed for the Testimony is the editorial of the TIMES-PICAYUNE, April 20, 1974, called "Iron Fist" and the editorial of the ST. LOUIS GLOBE DISPATCH, April 23, 1974, and the editorial from the WALL STREET JOURNAL, December 6, 1973, are printed as examples of national press and opinion that PSRO Repeal should be considered.

(7) In November 28, 1973, 39 Congressmen signed this letter (attached) urging Repeal of PSRO as addressed to the American Medical Association Convention in Anaheim.

(8) At the time of writing, 67 Congressmen have introduced at least 20 bills for Repeal.

(9) Orther Louisiana Delegations. The following Congressmen from Louisiana are on record for repeal: F. Edward Hebert, Lindy Boggs, David C. Treen, Joe D. Waggonner, Jr., John R. Rarick, John B. Breaux and Senator J. Bennett Johnston, Jr.

(10) The Louisiana Medical Association (representing the black doctors of Louisiana) are also on record for Repeal of PSRO.

(11) The Association of American Physicians and Surgeons is on record for Repeal. They have filed a suit to the Federal District Court in the State of Illinois.

Repeal of PSRO, in toto, has overwhelming support from major segments of not only the medical profession, but also the State Legislatures, City Councils and Civic Organizations. In addition, American CMS has received thousands of letters from patients urging Repeal of PSRO which they have also sent to their Congressmen.

We respectfully submit that if Congress is to reflect the voice of the people the members of the Senate Committee on Finance would indeed vote for the Repeal of PSRO.

Respectfully submitted,

ROY F. GUSTE,
Legal Counsel, American CMS.

RESOLUTION No. 709

Introduced by: Shreveport Medical Society
Subject: To request the Congress of the United States to repeal Professional Standards Review, section 249F of Public Law 92-603

Whereas, Professional Standards Review, section 249F of Public Law 92-603, is detrimental to the delivery of quality health and medical care for the American people, therefore be it

Resolved, by the Louisiana State Medical Society in regular session May 5-7, 1974, in Lake Charles, Louisiana, that the Congress of the United States is hereby requested to repeal in its entirety Professional Standards Review, section 249F of Public Law 92-603, immediately.

Our officers, counselors, and Executive Committee should be instructed to work for repeal and inform the AMA and all other state medical associations of our decision.

(b) In addition, we should:

(1) Urge the membership to work in a united way toward this end.

(2) Notify our representatives in Congress of our position and request their help.

(3) Ask the AMA for financial support and ask AMA to work with the Congress.

(4) Communicate with those in health related organizations and ask for support.

(5) Encourage the membership to inform its patients about the disadvantages of the law and mount a letter campaign to Congress asking for repeal of the law.

GEORGIA GENERAL ASSEMBLY ADOPTS RESOLUTION URGING REPEAL

A RESOLUTION

Urging Congress to repeal the Professional Standard Review Organization Law; and for other purposes.

Whereas, Section 249-F, Title XI of the Social Security Act, Public Law 92-603, Professional Standard Review Organization (PSRO), was enacted by the Congress of the United States in 1972 without due consideration and careful deliberation by both its bodies; and

Whereas, operation of Professional Standard Review Organization will cause great harm and financial hardship to the elderly and poor people of our country because of its unrealistic requirements on physicians to practice their profession based on standards and norms approved by the Department of Health, Education, and Welfare; and

Whereas, these segments of our population will suffer greatly if denied medical care and hospitalization deemed necessary by their physician but not in conformance with HEW standards based on averages and medians rather than human needs; and

Whereas, this law may well inhibit the great advancement seen in American medicine during this century of progress in conquering many of man's dread diseases.

Now, therefore, be it resolved by the General Assembly of Georgia that this body notify the Congress of the United States that the Professional Standard Review Organization Law is ill-conceived legislation, harmful to the public and pernicious in its effect on the practice of medicine.

Be it further resolved that the Congress be urged to repeal the Professional Standard Review Organization Law as quickly as possible to prevent the damage it will cause to the public and the American health care system.

Be it further resolved, that this Assembly encourage Georgia physicians to continue the ethical practice of their profession, to maintain the privacy and confidentiality of their patient's records, to retain their right to make medical decisions based on their own professional judgement, and to support the existing system of peer and utilization review available in hospitals and nursing homes, medical societies and associations, and the Georgia Medical Care Foundation.

Be it further Resolved that the Secretary of State is hereby authorized and directed to transmit an appropriate copy of this Resolution to the Secretary of the Senate of the United States, to the Clerk of the House of Representatives of the United States, and to each member of the Georgia Congressional Delegation.

[From the Wall Street Journal, Dec. 6, 1973]

REVIEW AND OUTLOOK

NO TIME FOR PATIENTS?

We would never argue that any group should be exempt from accountability to the larger society, but we can understand why many doctors at an American Medical Association convention in Anaheim this week are up in arms over a new federal law purportedly designed to monitor the way doctors deal with federally insured patients.

The law, described elsewhere on this page today by Dr. Winsten, requires the establishment of "Professional Standards Review Organizations," all around the country starting Jan. 1. These PSROs which will be comprised mainly of doctors, will have the task of second-guessing decisions made by other doctors in treating patients under Medicare, Medicaid and maternal and child health problems.

Their findings will be used by a HEW bureaucracy to establish certain "norms" that doctors would be expected to follow in treating federally insured patients. Such questions as whether some doctors overprescribe or require unnecessary hospitalization will enter into the review and normsetting process.

While we favor a businesslike administration of federal social programs, the PSRO legislation raises some questions which didn't get adequately asked or answered by Congress. It was attached by Senator Bennett (R., Utah), as a rider onto last fall's big and controversial Social Security bill and somehow rode through with almost no public attention. The House did not even hold public hearings on the PSROs.

And yet the law empowers the government, through PSROs, to examine medical records in doctors' offices, not only of federally insured patients but private patients as well. The Association of American Physicians and Surgeons thinks this is an unconstitutional invasion of a private relationship.

Further, it can be doubted that Congress gave sufficient thought to the cost of all this monitoring and normsetting. There is no clear picture of how many PSROs there will be but a minimum of 150, and probably considerably more, is likely. The man-hours of doctors who serve on them will be that many fewer man-hours devoted to practicing medicine, not to mention the man-hours that will have to be devoted in doctors' offices to meeting demands for information or justifying decisions.

It might be noted that some 50 million patients and 10 million hospital admissions are potentially subject to monitoring and that the proposed norms cover some 350 procedures. It makes you wonder if doctors will have any time left to treat patients.

Finally, the law seems to ignore that a great deal of peer review already goes on in medicine, by state and local medical societies and hospital boards that review decisions to operate and the like. While peer review has been criticized as ineffective a lot of the criticism remains unproved. In Louisiana last December, it was the state medical society that blew the whistle on a HEW-financed private birth control scheme that now is under criminal investigation, which suggests that the public interest may fare at least as well under private peer review as through the good offices of HEW.

Many doctors claim that the PSRO sleeper actually was designed to open the medical profession up for full federal insurance, or, as the AMA once would have termed it, "socialized medicine." Interestingly, the AMA had a hand in the original conception of PSROs, apparently with some notion of displaying flexibility—thus avoiding the kind of pitched battle it lost over Medicare—and at the same time keeping PSROs in the hands of physicians. But a good many physicians are making it clear that they think that was a bad tactic.

It would seem that they have a point. Medicare and Medicaid were a product of the mid-1960s and there is no denying the public support that then existed. But this is 1973 and Americans have seen quite a lot they don't like about federal social programs. There is no certainty they are yet ready for national health insurance and they certainly aren't ready for sneaky approaches to that end through innocent-looking riders to complex bills in Congress. As to monitoring Medicare and Medicaid, HEW might do well, or so the Louisiana case would suggest, to get better control of its existing auditing system.

Rep. Rarick (D., La.) has introduced a bill to repeal PSROs. It may well be that the public has a bigger stake in repeal than it realizes. At any rate, the issue deserves a better hearing than it got when PSROs were so nimbly written into law last year.

YOUNG MEN'S BUSINESS CLUB OF
GREATER NEW ORLEANS, INC.,
New Orleans, La.

RESOLUTION

Whereas, Public Law 92-603 created the Professional Standards Review Organization (PSRO) which is intended to monitor the way physicians deal with patients that are provided healthcare insurance through federal funds, which at time of passage was limited essentially to Medicare and Medicaid patients;

Whereas, the recently enacted Health Maintenance Organization (HMO) Act of 1973, provides federal funds to aid in Development of HMO's which will further increase the number of patients receiving healthcare insurance through federal funds;

Whereas, all proposed National Health Insurance plans will include more individuals in federally insured health care programs;

Whereas, Public Law 92-603 empowers the government to examine medical records in doctors' offices, not only of federally insured patients but private patients as well;

Whereas, this law may conceivably reduce the quality of healthcare since the physicians serving on a PSRO will not be able to devote their full time to the

practice of medicine and all physicians will have to devote more of their time to meet demands for the information of justifying their medical decisions;

Whereas, it has yet to be proven that the creation of the PSRO will reduce healthcare costs and improve the healthcare delivery system;

Whereas, the government will spend millions of tax dollars on a project with unproven merit—$34,000,000 in 1974 alone to establish the PSRO;

Now therefore be it Resolved that the YMBC of Greater New Orleans, Inc. urge repeal of that section of Public Law 92-603 that created the Professional Standards Review Organization;

Be it further Resolved that copies of this resolution be forwarded to all members of the Louisiana Congressional Delegation, the News Media and Medical Authorities.

Approved by general membership of the YMBC of greater New Orleans, March 21, 1974.

ELLIS JAY PAILET, *President.*

[From the Times Picayune, Apr. 20, 1974]

THE IRON FIST

(Editorial in Indianapolis News)

When Medicare and Medicaid were adopted back in 1965, assurances were given that these programs would not lead on to government control of medicine.

That guarantee, indeed, was written into the legislation. The bill explicitly said nothing in its language "shall be construed to authorize any Federal officer or employe to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided." This had a pleasantly soothing sound, and people who warned against potential government takeover were dismissed as cranks.

Less than 10 years later, those early warnings of government coercion are all in the process of coming true. The bureaucrats of the Department of Health, Education, and Welfare are deploying a massive network of "Professional Standards Review Organizations" to control the private practice of medicine down to the last detail. And the pretext, exactly according to the crank scenario, is that such control has become essential because of Medicare and Medicaid.

As just about everyone knows by now, these programs have run far ahead of original estimates and are costing the nation billions of dollars in tax money. (Another warning which was blandly ignored back there in 1965.) And in an effort to get these costs under some kind of control, the Federal planners have come up with their PSRO scheme to regulate everything and everybody which is or "may be" financed with government medical dollars.

PSRO is a vast bureaucratic pyramid allegedly relying on doctors themselves but controlled by the Secretary of HEW. Among other things, it will maintain computerized files on doctors and patients, establish "norms" of standardized medical care, and hand out punishments to medical practitioners whose treatments vary from the lowest common denominator. HEW will also have access to medical records as it sees fit, thereby violating at its whim the confidential relationship between doctor and patient.

Justification for all this is simplicity itself. As the HEW official in charge of imposing the controls has put it: "The government is paying for a significant amount of medical care. It wants to see that the care being received is appropriate." Which is another way of saying that, within the velvet glove of federal subsidy, there always lurks the fist of federal control.

[From the St. Louis Globe-Democrat, Tuesday, April 23, 1974]

SMOKESCREEN HAZARD TO HEALTH

Your medical records—from general health history to psychiatric diagnoses—may now be examined by government bureaucrats.

You and your personal physician may no longer decide that you should be admitted to a hospital—the government can decide that. And the bureaucrats can throw you out of a hospital despite the advice of your physician.

Your doctor may be fined $5,000 for deviating from federal procedures which describe exactly what may and may not be done regarding your own, unique health situation.

You and your physician will be part of a computerized file system which will establish certain "norms."

These are among the consequences of a law—already in effect—that establishes a massive network of "Professional Standards Review Organizations" (PSROs). The PSROs are now being deployed by Big Brother as a result of a little-considered amendment tacked onto a bill in 1972.

PSROs were presented as a way for doctors to examine the services performed by other physicians and to determine that these conformed to regional standards of medical practice. Yet the boards are primarily window-dressing; the law repeatedly states that procedures will be conducted "in accordance with the regulations of the secretary" of the U.S. Department of Health, Education, and Welfare. The secretary's powers are listed 96 times in the law.

When HEW awarded its first PSRO's contract this month (the program took effect Jan. 1 and will not be fully implemented until 1976), the administrator of the program boasted, "PSROs is potentially the most important piece of health legislation ever enacted, here or anywhere in the world. . . . The program has the potential now to be the backbone of all care rendered in the country to all citizens in any setting—hospital inpatients, office outpatients, and nursing homes."

The idea of federal bureaucrats in Washington setting "standards" for physicians regarding patient care is not much different than if the bureaucrats set "standards" for parents regarding their children's care. Who is better able to supervise the persons they care for—Washington functionaries or the family physician, the paper-pusher or the parent?

One reason the government is so interested in PSROs is the scandalous bureaucratic mess that followed the adoption of Medicare and Medicaid in 1965. These programs were "sold" with the assurance that they would not lead to federal control of medicine; in fact, the legislation stated that nothing in its language "shall be construed to authorize any federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided."

But now the government is arguing that PSROs and controls are necessary because of Medicare and Medicaid—thus justifying the federal control denied by the earlier programs. "The government is paying for a significant amount of medical care," said the HEW official in charge of the controls. "It wants to see that the care being received is appropriate."

Notice how the velvet glove becomes the iron fist? As would be the case with impending national health insurance proposals, and has been the case with virtually every federal program, the government's involvement with funding programs becomes the rationale for controlling them. With PSROs, subsidizing medical care has led to controlling medical care.

The PSRO legislation surely is, as an article in the Wall Street Journal calls it, "the most radical health legislation in this country's history." There is no other way to describe a law that imposes federal controls, grants the right to inspect an individuals highly personal medical history, fines doctors $5,000 plus the loss of the right to treat Medicare and Medicaid patients for deviating from federal procedures, and allows PSROs the right to order patients out of a hospital or deny admission altogether. Again, is your care a function of Big Brother or of your own physician?

How could Congress pass such a bill? The answer is: Unknowingly. The PSROs section was Section 249F of the 1972 Social Security Act amendments, which lingered on for 160 pages. The section was inserted by the Senate after the House had passed the bill, and was passed by the House as part of a House-Senate compromise bill without hearings and without most members even knowing the section existed.

There are more than 40 bills submitted in this Congress calling for repeal of the embryonic program. Eighteen state medical associations have formally urged repeal, and an equal number will soon consider such a resolution.

Those who think that national health care would be a great thing should ponder the lesson that PSROs already demonstrate: When federal funds for medical care are involved, controls over that medical care are close behind. It's true of medicine just as much as it's true of highways, education, flood insurance, welfare or anything else.

CONGRESS OF THE UNITED STATES,
HOUSE OF REPRESENTATIVES,
Washington, D.C., November 28, 1973.

AN OPEN LETTER TO THE HOUSE OF DELEGATES OF THE AMERICAN MEDICAL ASSOCIATION

Last year, as part of a thick, complex bill amending the Social Security law, Congress adopted, almost without notice, a provision which will completely alter the practice of medicine in the United States.

That section, creating Professional Standards Review Organizations, will require you to practice according to computerized standards, rather than using your best medical judgment in treating your patients. It will deprive your patients of their right to privacy. It will impose severe fines for medical innovation.

Some of you have ured AMA participation in implementation of PSRO so you can control the administration of the law. But PSRO is the law of the land; it is the working of Conress and its implementation is the responsibility of the Department of Health, Education and Welfare. Even if you help implement the law, you will not control it. The only way to avoid the law's bad effects is to repeal it.

The PSRO section is bad law; it will be bad for the doctor and bad for the patient. It should be repealed. Unfortunately, although many of us in Congress want to work for the repeal of PSRO, we have been handicapped by the AMA's failure to continue its active opposition to the law. Some of us have already introduced bills to repeal PSRO, but if we are to be successful we need your help. We strongly urge the House of Delegates to pass a resolution specifically calling for the repeal of PSRO and committing the all-out efforts of the American Medical Association to that end.

Ben C. Blackburn (R-Ga.); Edward J. Derwinski (R-Ill.); Steven D. Symms (R-Idaho); John H. Rousselot (R-Calif.); David C. Treen (R-La.); Robert J. Huber (R-Mich.); Philip M. Crane (R-Ill.); Sam Steiger (R-Ariz.); Dan Kuykendall (R-Tenn.); Harold V. Froelich (R-Wisc.); Tom S. Gettys (D-S.C.); G. V. Montgomery (D-Miss.); Andrew J. Hinshaw (R-Calif.); H. R. Gross (R-Iowa); John E. Hunt (R-N.J.); L. A. Bafalis (R-Fla.); Jack Brinkley (D-Ga.); LaMar Baker (R-Tenn.); Earl F. Landgrebe (R-Ind.); E. G. (Bud) Shuster (R-Pa.); Roger H. Zion (R-Ind.); Clair W. Burgener (R-Calif.); Robin L. Beard (R-Tenn.); Joel T. Broyhill (R-Va.); William H. Hudnut III (R-Ind.); Louis C. Wyman (R-N.H.); David W. Dennis (R-Ind.); Floyd Spence (R-S.C.); William M. Ketchum (R-Calif.); John R. Rarick (D-La.); Charles Thone (R-Nebr.); Trent Lott (R-Miss.); James M. Collins (R-Tex.); William J. Scherle (R-Iowa).

AMERICAN SPEECH AND HEARING ASSOCIATION,
Washington, D.C., May 1, 1974.

Senator HERMAN E. TALMADGE,
Chairman, Subcommittee on Health, Senate Finance Committee, Dirksen Senate Office Building, Washington, D.C.

DEAR SENATOR TALMADGE: This letter presents the American Speech and Hearing Association's general view of the Professional Standards Review Organization concept embodied in sections 1151 through 1170 of the Social Security Act (as

amended). We ask that it be included in the record of the Subcommittee's May 8 and 9 oversight proceedings.

The American Speech and Hearing Association (ASHA) is a national scientific and professional society, made up of some 18,000 speech pathologists and audiologists. The speech pathology and audiology profession is the primary discipline concerned with the systems, structures, and functions that make human communication possible; with the causes and effects of delay, maldevelopment, and disturbance in human communication; and with the identification, evaluation, and habilitation of individuals with speech, language and hearing disorders. Speech pathologists and audiologists considered "qualified providers" under Medicare and Medicaid regulations must hold a Master's degree in their field of specialization and have completed a "fellowship year" of supervised clinical internship. These standards are also among those set by ASHA for the achievement, on the part of potential service providers, of the ASHA Certificate of Clinical Competence in speech pathology or audiology. Qualified speech pathology and audiology providers render their clinical services in such settings as hospital speech and hearing clinics, freestanding outpatient speech pathology and audiology clinics, university outpatient clinics, outpatient rehabilitation centers (e.g., Easter Seal agencies), Veterans Administration hospitals, Head Start programs, and private practice.

ASHA has commented twice previously on the general subject of peer review to the Senate Finance Committee: first, in February 8, 1972, testimony to the full committee (*Social Security Amendments of 1971: Hearings on H.R. 1*, pp. 2573–81), and again in a "Statement of the Coalition of Independent Health Professions on Peer Review Systems" (*ibid.*, pp. 3363–64).

In its 1972 testimony, ASHA said, at p. 2580, that it "supports the concept of accountability and believes that all providers of medical and health care services should be held accountable for services rendered." The Association's testimony went on to say the " 'peer review' should be just that. Local and regional peer review committees comprised of speech pathologists (or audiologists) should be established nationwide to review speech pathology (or audiology) services provided to Medicare recipients and other consumers. ASHA, however, does not support a peer review concept which incorporates evaluation by individuals who do not possess in-depth professional knowledge and skills of the speech pathology and audiology profession. Specifically, ASHA does not support a peer review system incorporating review of nonmedical, independent health care providers by physicians. Further concern is generated by peer review proposals that are one-sided: physician evaluation of nonmedical health care services with no provision for evaluation of medical services by nonmedical health care providers."

This position was echoed by the Coalition's statement, which questioned, at p. 3364, "how effectively and equitably one professional of a specialized background and education can evaluate the judgment and services of a practitioner engaged in another equally specialized field when the only common denominator is essentially the fact that both are providers of health care services?"

ASHA has long acknowledged the public's right to the assurance of quality in the delivery of speech and hearing services—its nationally recognized certification system for practitioners and accreditation systems for clinical service and graduate training programs are impressive measures of this acknowledgement, as is the Association's current push to expand its accountability program to create mechanisms for evaluation, review, and monitoring the effectiveness of clinical speech pathology and audiology service. With regard to this latter effort, a recently created Association task force, cooperating with state speech and hearing associations, is in the process of developing standards, criteria, and norms, applicable at the local level, for determining the necessity and appropriateness of speech and hearing services, and of designing the administrative models that will provide peer review, rather than physician review of these services.

Organizations representing other nonmedical health professions, such as those in the Coalition of Independent Health Professions, have undertaken similar efforts. We believe these efforts should be encouraged, principally because they represent attempts to achieve a system of true peer review, wherein each health care professional is evaluated by members of his own discipline.

I am enclosing a copy of section 730 of the recently published P.S.R.O. Program Manual [Office of Professional Standards Review, U.S. Department of Health, Education, and Welfare (March 15, 1974), Chapter VII, pp. 31–33], which appropriately reflects the involvement needs of "Non-physician Health Care Practitioners in PSRO Review." Aware as we are of the often transitory nature of federal regulations not based firmly in statute, we would hope that the thrust of this section (i.e., true peer review for nonphysician health practitioners) will be woven into the fabric of the PSRO law. We also believe that the PSRO needs and efforts of nonphysician health care providers—as well as the interests of the PSRO system generally—would be better served by a legislative mandate that brings direct nonphysician health practitioner input to both national and statewide professional standards review councils. Nonphysician membership on these councils constitutes a necessary step toward a national peer review system capable of objectively determining the appropriateness and necessity of all health care services.

The American Speech and Hearing Association appreciates this opportunity to express its views.

Sincerely,

RICHARD J. DOWLING,
Director of Governmental Affairs.

[From the PSRO Program Manual, Chapter VII, Page 31, Mar. 15, 1974]

Enclosure.

730 INVOLVEMENT OF NON-PHYSICIAN HEALTH CARE PRACTITIONERS IN PSRO REVIEW

Health care is provided by practitioners of a wide variety of health care disciplines. Review of care provided by non-physician health care practitioners should be performed by their peers. Thus, while the PSRO retains ultimate responsibility for the decisions made under its aegis, it should seek the participation of all health care practitioners in the development of criteria and standards and the selection of norms for their professions, in the establishment of mechanisms to review the care provided by each type of practitioner, and in the actual review of that care. The PSRO's formal plan shall contain a plan for the involvement of non-physician health care practitioners in the PSRO's review system.

730.2 Definition

Non-physician health care practitioners are those health professionals which (a) do not hold a Doctor of Medicine or Doctor of Osteopathy degree, (b) are qualified by education, experience and/or licensure to practice their profession, and (c) are involved in the delivery of direct patient care or services which are directly or indirectly reimbursed by the Medicare, Medicaid or Maternal and Child Health programs.

730.3 Development and On-going Modification of Norms, Criteria, and Standards

730.31 PSRO Responsibility. The PSRO is responsible for assuring, over time, that non-physician health care practitioners are involved in the establishment and on-going modification of norms, criteria and standards for their discipline. This is true both for PSRO direct development and when development is delegated to hospitals.

730.32 When care provided by non-physician health care practitioners will be assessed under any of the types of review to be performed by a PSRO or a hospital delegated PSRO review, non-physician health care practitioners of the appropriate discipline should work with committee(s) of the hospital or PSRO which are developing the criteria and standards and selecting the norms for these types of review.

730.33 Non-physician health care practitioners should work with the committee(s) of a hospital or PSRO fhich are responsible for on-going revision of norms, criteria or standards. This will assure the continual updating of the parameters as they relate to all involved health care disciplines.

730.4 Development of Review Mechanisms

730.41 PSRO Responsibility. The PSRO shall assure the active involvement of non-physician health care practitioners in all phases of the development and implementation of those review mechanisms which will be used to assess the performance of non-physician health care practitioners.

730.42 Hospital Responsibility. Any hospital which receives delegation of review activities from a PSRO is expected to involve non-physician health care practitioners in all phases of the development and implementation of those review mechanisms which will be used to assess the performance of non-physician health care practitioners.

730.5 Health Care Review

730.51 PSRO Responsibility. The PSRO is responsible for assuring that non-physician health care practitioners are involved in the actual review of care provided by their peers.

730.52 Hospital Responsibility. Any hospital which performs review under delegation from the PSRO is responsible for assuring that, where such review involves assessment of the care of non-physician health care practitioners, non-physician health care practitioners perform the assessment of their peers.

730.53 Where care is provided jointly by physician and non-physician health care practitioners, the assessment of such care will be performed jointly by peer physician and non-physician practitioners.

730.54 Where care is provided exclusively by one type of non-physician health care practitioners, the assessment of such care will be performed by peer non-physician practitioners. The decisions made during such review would be reported through the mechanisms established for review decisions related to physician care.

730.55 Only physicians will be allowed to make final decisions on the care provided by physicians.

730.7 Organization

Those types of non-physician health care practitioners whose care is being reviewed under the aegis of a PSRO are responsible for developing mechanisms by which the results of review are utilized in the continuing education of such practitioners.

730.7 Organization

Where appropriate, the organizational structure established to provide for involvement of non-physician health care practitioners in the activities listed above should be the same structure established for the performance of these activities by physicians. For example, committee(s) should include physician and non-physician practitioners.

730.8 PSROs must show evidence over time of adherence to the guidelines listed above.

STATUTE OF THE AMERICAN ACADEMY OF PEDIATRICS

Public Law 92-603 (HR 1) created the Professional Standards Review Organization Program, which mandates the establishment of organizations at the local level to review professional standards of medical care in the institutional setting.

The American Academy of Pediatrics has traditionally promoted standards of health care for all infants and children in the United States, Canada and Latin America through the various manuals and committee statements. Recently, it has been in a leadership role with other primary care physicians' organizations (American Medical Association, American Academy of Family Physicians, American Osteopathic Association, American Society of Internal Medicine, etc.) in a study of quality assurance of child health care in the ambulatory setting, to be completed in late 1974.

The Academy's Committee on Hospital Care has been engaged in the development of criteria for assessing quality care for infants and children in hospitals,

and has cooperated with the American Medical Association and norms and criteria for patient care, which can be modified to fit local situations.

The American Academy of Pediatrics has supported and will continue to support the concept of peer review as a method of assuring the delivery of an acceptable quality of pediatric care. This policy and the aforementioned activities are consistent with its objective to "foster measures and conduct activities directed toward establishing and maintaining the highest possible standards of quality and acceptability in the delivery of health care to children."

Professional Standards Review Organizations (PSRO) represent a method of accomplishing peer review of pediatric care. The Academy recognizes that varying opinions have been expressed regarding the acceptability of specific provisions in the law. With these in mind, however, the Academy feels that PSROs should be given every opportunity to prove their effectiveness in assuring better quality pediatric care through the cooperation of all physicians delivering child health care. As implementation of the law progresses, every effort should be made to maximize the acceptability of the PSRO system with both patients and providers through appropriate and timely changes in the system.

The American Academy of Pediatrics encourages all providers of child health care to cooperate in the implementation of the PSRO law through participation at the local level. The Academy will also continue to work cooperatively with all concerned organizations in the implementation of the law and also in seeking any changes that would maximize the acceptability of the PSRO system with both patients and providers of child health care.

AMERICAN ACADEMY OF PEDIATRICS.

AAP ISSUES PSRO STATEMENT

EVANSTON, ILL.—All providers of child health care should "cooperate in the implementation" of the federal law which establishes Professional Standards Review Organizations (PSROs), the American Academy of Pediatrics has urged in a policy statement.

The statement, approved by the AAP's Executive Board at its spring meeting in Bal Harbour, Fla., said the Academy as an association will "continue to work cooperatively with all concerned organizations in the implementation of the law and also in seeking any changes that would maximize the acceptability of the PSRO system with both patients and providers of child health care."

The PSRO law was passed by Congress to create local organizations to review the professional standards of medical care in the institutional setting. The PSRO law has been the subject of controversy within the medical profession.

The AAP statement noted that objections to the law had been made, but said that "PSROs should be given every opportunity to prove their effectiveness in assuring better quality pediatric care through the cooperation of all physicians delivering child health care."

The statement said the Academy has expressed similar interest in the quality of care through its work with the Joint Committee on Quality Assurance and the AAP's Committee on Hospital Care. The PSRO statement was drafted by the Academy's Council on Pediatric Practice and has been reviewed by its various District Committees.

AMERICAN NURSES' ASSOCIATION, INC.,
Kansas City, Mo., May 8, 1974.

Hon. HERMAN E. TALMADGE,
Chairman, Subcommittee on Health, Senate Committee on Finance, Old Senate Office Building, Washington, D.C.

DEAR SENATOR TALMADGE: The American Nurses' Association is the professional organization of registered nurses representing 200,000 registered nurses with constituent associations in fifty states and three territories of the United States. We are pleased to have this opportunity to express our support of the concept of peer review of health care services and respectfully request that this

statement be made part of the official record of the current hearings to evaluate present and proposed implementation of the professional standards review legislation.

The American Nurses' Association, since its inception in 1896, has consistently demonstrated its concern for the development and implementation of professional standards through: promoting state legislation to regulate the practice of nursing; developing standards for the preparation of individuals to enter the practice of nursing; establishing a code of ethical conduct for practitioners; developing Standards for Nursing Practice; standards for the organized delivery of nursing services; and stimulating research designed to enlarge the knowledge on which the practice of nursing is based.

As a result of more than a decade of diligent work by hundreds of nurses, in 1973, the American Nurses' Association issued general standards of practice and specialized standards in five areas of practice, namely, Medical-Surgical nursing, Maternal and Child Health nursing, Psychiatric and Mental Health nursing, Geriatric nursing and Community Health nursing. To our knowledge nursing is the only health profession to have voluntarily so moved beyond establishing a code of ethics to specify standards of practice. Currently, a major thrust of the Association is implementation of these standards. This is being accomplished through certification for excellence in practice, the development of out-come criteria and other tools to evaluate the quality of nursing care and promoting peer review mechanisms and the use of nursing audit.

The American Nurses' Association supports the basic principle of the accountability of all health care professionals to provide care which is of a high standard and which is available and accessible to all people at a reasonable cost. Furthermore, the ANA acknowledges the right of the public to be assured that the care received is of a high quality. We believe that it is the obligation of government as representing the people to insure that health care services meet professional standards. Providing support for the development of peer review systems is an appropriate mechanism to insure that professional standards are met.

The public would be better served if it were fully recognized that Health Care and Medical Care are not synonymous terms. Health Care Services encompass a wide range of activities designed to maintain the physical, mental and social well-being of people. Several health care disciplines must be involved in planning, providing and evaluating health care and each discipline must be accountable for the quality of its own practice. Health care to the population to be served under Title XVIII and XIX of P.L. 92-603 can be adequately evaluated only when the professional care provided by all disciplines are evaluated by members of the disciplines. This is a critical step in the direction of interdisciplinary review of all patient care provided.

Nursing is an essential component of health care. As the largest group of health professionals in the United States with 825,000 nurses actively engaged in practice, nursing as a profession has a significant role to play in any health care system. Physicians do not possess the knowledge and skills of the discipline of nursing. Peer review which incorporates the review of nursing care by physicians is, therefore, not in the best interest of the public. We urge that the legislation be amended to provide for true review of nursing care by nurses.

The recently published Program Manual by the Office of Professional Standards Review—Department of Health, Education and Welfare, in chapter VII, pages 31-33, makes reference to the involvement of "non-physician health care practitioners in PSRO Review." This section of the manual appears to reflect a genuine interest in the Department of Health, Education and Welfare to involve other health professionals in the mechanisms for review of care. However, in the absence of explicit provisions within the law to include representation from nursing and other health care disciplines as full partners within the councils and committees at the national and local levels, this regulation cannot be fully implemented.

The ANA urges your committee to give immediate attention to amending P.L. 92-603 to provide for the full participation of all health care disciplines in implementing a system of true peer review. While such amendments are under consideration, we urge provisions be made through appropriations to assist all

health care disciplines in developing appropriate norms and criteria to evaluate the quality of care they render.

The nursing profession recognizes that cost containment and reduction of over-utilization of costly services is a prime objective of the PSRO Program. If both cost containment and evaluation of quality are to receive appropriate attention, it might be well to consider two distinctive types of review: (1) utilization review, which would examine both over and under utilization, and (2) review of the quality of care provided. To be effective, utilization review must be an interdisciplinary undertaking.

In conclusion ANA commends the Finance Committee for its leadership evident in this legislation.

Respectfully submitted,

EILEEN M. JACOBI, Ed.D., R.N.,
Executive Director.

MR. MICHAEL STERN,
Staff Director, Senate Finance Committee, Dirksen Senate Office Building, Washington, D.C.

DEAR MR. STERN: Following "Statements for the Record" are submitted in response to the invitation soliciting views of various individuals on the PSRO issue. At the same time this writing may be considered as follow up to a correspondence which took place nearly two years ago between Senator Wallace Bennett and myself—copies of that dialogue are attached for reference. Summarizing what has taken place since that time, I believe;

(a) Intergovernment power struggle has temporarily subsided pending the implementation stage of PSRO.

(b) Insurance carriers, fiscal intermediaries, etc. have also suspended their opposition in hopes of deriving even more Federal funds for their services.

(c) Health Care professionals have intensified their effort in opposition to PSRO rapidly approaching a point of no return.

As you may have suspected by now, I AM ALL FOR PSRO. The people need it to obtain quality health care, the government needs it to help it monitor and direct its huge spendings, the insurance carriers need it to help them provide more precise coverage and health care professionals need it to help them provide better service to the public and modify patterns of care wherever and whenever necessary.

PSRO is needed to insure that administration of health care remains with the health care professionals and not government agencies. For the first time the professionals are afforded the opportunity to participate in administration of health care at the policy level. They owe it to themselves and to the public to take full advantage of this position by constructive contribution and wholehearted participation in the PSRO program.

With the National Health Insurance program around the corner, now is the time to start the mold that will produce the best form. Another Title XVII or Title XIX will surely result unless everyone interested and specially the health care professionals realize their obligations and support this program.

In summary I would like to state that PSRO is not perfect but it is here and it can be of great value to all of us. For any one wrong thing in the program, I can easily point out several more important benefits that we can all use, now.

I wish to thank you for your time and attention.

Sincerely,

M. ALI PARMOON.

JANUARY 24, 1973.

Hon. WALLACE BENNETT,
U.S. Senate,
Washington, D.C.

DEAR SENATOR: As a private citizen and one who is directly involved in the health care industry, I was indeed elated by the passage of Section 249F of HR-1 Act. Since that date in October, 1972, I have been expecting, exploring, and at

times even explaining the significant improvements that this legislation can bring about. However, it appears that passage of time is slowly but surely altering its direction away from the intended objectives. It seems apparent that unless immediate attention is given to the status of the Professional Standards Review organization effort, it may become totally neutralized and, in fact, further add to the heavy burden carried by the general public for maintenance of our existing inadequate health care delivery systems.

One can easily see the tremendous benefits that can be derived from an effective implementation of this section of the HR-1 legislation. Unfortunately, powerful factions in government and private sector have labeled the PSRO effort "An Enemy." They have reached the unspoken agreement to preclude its success. Established administrations within the Federal government see PSRO as a threat to their power structure. The insurance carriers visualize PSRO as a force interferring with their payment methods. While, worst of all, the powerful organizations representing health care professionals predict a time under PSRO when mythical sanctions can no longer replace professionalism and expertise. Since those who stand to benefit the most from PSRO's are the general population, and since these people have little to say in the day-to-day operation of the Federal government, unless this matter receives the direct and personal attention of a person of your position, its fate will be decided by those who desire it the least.

Any evaluation of our health care delivery system readily reveals the desperate need for an effective implementation of the PSRO program. You have realized this necessity for some time by first conceiving the PSRO concept and subsequently sponsoring its passage through the Congress. I hope and believe that you will bring the power and prestige of your office to insure its successful implementation as well.

I would welcome the opportunity to discuss any of the above in more detail with yourself or your representatives.

Very truly yours,

M. A. PARMOON.

U.S. SENATE,
Washington, D.C., February 5, 1973.

Mr. ALI PARMOON,
San Jose, Calif.

DEAR MR. PARMOON: I want to acknowledge my receipt of your recent letter in which you express your fears about the viability and effectiveness of PSRO.

I don't share your fears and at the moment there really isn't anything that needs to be done or that can be done. I am working closely with Secretary Designate Weinberger who will finally select the man to head the PSRO effort on the staff of the Department of Health, Education and Welfare, and I think that selection may be the key t othe over-all implementation of the program.

At the same time, you may be sure that we, on the Finance Committee who fought so hard and so long to get this concept built into our health care system, will be giving this very careful supervision, particularly during the formative months and years.

I appreciate your personal interest and if, as time goes on and the system actually gets into operation, your fears continue both the Finance Committee and I will be interested in any information you can give us.

Very truly yours,

WALLACE F. BENNETT.

EAST RANGE CLINICS LTD.,
April 9, 1974.

MICHAEL STERN,
Staff Director, Senate Committee on Finance, Dirksen Senate Office Building, Washington, D.C.

DEAR MR. STERN: As I understand it, Senator Talmadge's Senate Subcommittee on Health will be meeting to discuss implementation of PSRO legislation. Presently I practice in a 26 man clinic in Virginia, Minnesota. The Secretary of Health, Education, and Welfare has placed Northern Minnesota in a district by itself. That is, he has made three PSRO's in the State of Minnesota. Previously I had written to him giving him the reasons for my wishing and feeling that the entire State should be an entire PSRO.

However, for reasons that I cannot fathom, Minnesota is a three PSRO area. And, as I mentioned, Northern Minnesota is by itself. This encompasses an area greater than 250 by 250 miles. There is no administrative body that can come forward and form a PSRO in this very large area. It is impossible for the average or even the above average physician, such as myself, and any other physician in this area to spend the time required to organize any form of administrative body that might function as a PSRO in this area. For us to spend days traveling to the various communities located in this large, large area is impossible. There just is no way that any of us can take the time or have the finances to do it.

With a one PSRO area State we would have the organizational ability to set up a PSRO that could function on a local level, report to a higher authority, and accomplish what the PSRO legislation is all about. The reason that it could be done if there is one PSRO in the State is that there is an organization willing and able to take over the function of the PSRO. They have the organizational ability. They have the expertise. They have gone through all this. They have made all the mistakes. They have the opportunity to obtain funding to start this thing off.

One almost gets the feeling that the Secretary of HEW put three PSRO's in the State of Minnesota knowing full well that there is no organizational body that can function as a PSRO. Therefore, if the physicians themselves cannot come forth, and in this instance they cannot, then he, the Secretary, can appoint someone else. One gets the idea that this is exactly what he has in mind.

Very truly yours,

D. J. RICHTER, M.D.

STATEMENT OF THE AMERICAN OCCUPATIONAL THERAPY ASSOCIATION, SUBMITTED BY LEO C. FANNING, EXECUTIVE DIRECTOR

INTRODUCTION

The American Occupational Therapy Association, representing 17,000 members, fully supports the objectives of Professional Standards Review as provided in Public Law 92-603. These objectives are consistent with our own goals of assuring that occupational therapy provides effective and efficient service as well as the most economical care consistent with standards developed by the profession. AOTA has followed the implementation of the PSRO legislation with interest and approval, and will continue to do so.

In this statement, all non-physician health care professionals are frequently considered as a single group. Although we are familiar with the previous testimony and general viewpoint of these groups, we have not consulted with them and do not officially speak for the entire group. We refer to all non-physician health care professiona's because of our concern that this large group is about to be brought into the review procedures even though the PSRO amendment is ambiguous regarding the nature and process for their involvement.

Lack of a Clear Directive for Peer Review by Occupational Therapists and Other Non-Physician Health Care Professionals Reduces PSRO Effectiveness

According to the PSRO amendment, The Professional Standards Review Organization serving any area may, "to the extent necessary or appropriate . . . utilize the services of persons who are practitioners of or specialists in the various areas of medicine (including dentistry), or other types of health care, which persons shall, to the maximum extent practicable, be individuals engaged in the practice of their profession within the area served by such organization. . . ."

This statement does not provide a clear directive for self-assessment by non-physician health care professionals. Furthermore, the PSRO Program Manual reflects this fact in its interim guidelines. On the one hand, the Manual states, "Review of care provided by non-physician health care professionals should be performed by their peers" and, on the other hand, it comments, "Where care is provided jointly by physician and non-physician health care practitioners, the assessment of such care will be performed jointly by peer physician and non-physician practitioners."

This ambiguous posture regarding non-physician health care professionals can, we feel, lead to confusion and debate instead of constructive cooperation as the

PSROs plan how to include the non-physician professionals in review activities. Physician and non-physician professionals at the local level are left to struggle over the definition of "care provided jointly." They must devise a way to perform peer review with the active participation of a non-peer. And the local PSRO, already faced with the physicians' concern that review procedures may be too great a burden on their time, must find a way to involve physicians in a joint review of the numerous non-physician health care professionals. There are at least 30–40 groups that qualify as non-physician practitioners.

Effective Over-All Review of Health Care Can Be Met With the Non-Physician Health Care Practitioners Conducting True Peer Review

We agree with three concerns expressed by Senator Bennett during the 1972 HR 1 hearings. In answer to a recommendation from a non-physician health care professional that they review their own services, Senator Bennett pointed out that there could be 50 or 60 review mechanisms set up to operate in each area and it would be almost impossible to operate that from Washington. He also said, " . . . we don't want a series of protective unions; we don't want each group reviewing itself with no overview of the overall effect of the type of service that is being given to the patient."

Senator Bennett delineated three requirements a Professional Standards Review System must meet to be effective: (1) the administrative structure must be efficient and manageable; (2) the review procedures must be demonstrably effective; and (3) there is a need for an overall review of the total effect of the treatment program for those clients or patients requiring care from many different health care practitioners.

It is not inconsistent to agree with Senator Bennett's point of view and simultaneously to urge that occupational therapists and other non-physician health care professionals review their own services. The PSRO can be the single agency responsible for professional standards review in each area, thus providing efficient central administrative procedure. This satisfies the first requirement Senator Bennett mentioned. The PSRO can also evaluate the review procedure and the results of the review in the same way it will assess in-house review mechanisms of health care facilities. In this way, effective and manageable review can be assured.

If the PSRO is going to be the single agency charged with the proper utilization, as well as improvement of health care services, then the non-physician health care practitioners should have an assured way to provide input to the PSRO. The non-physician health care professionals have a unique viewpoint, ideas, needs and concerns that should be considered in order to improve the delivery of health care.

We see great potential in the PSRO amendment. As results of review are utilized to guide continuing education programs and as health care evaluation studies yield results the quality of health care should improve. But, if the occupational therapist and other non-physician health care professionals are to be an integral part of the total review process, including the feedback loop for continuing education and the use of collected data for health care studies, then they need an identifiable and uniform procedure for input and exchange of ideas at both the national and local PSRO levels.

Utah has provided us with an example of how to implement input from non-physician health care practitioners directly to a PSRO. In 1971, efforts to create a professional review organization were begun in Utah. Following the formation of a Board of Directors, but before the Utah Professional Review Organization (UPRO) was officially established, an advisory group of non-physician health

care practitioners was organized. The advisory group requested representation on the UPRO Board of Directors. This was granted and the president of the UPRO Board assured council members true peer review would prevail and charged the Advisory Council of Allied Health Professionals with the following responsibilities:

(1) A continuing public relations program should be implemented whereby the Allied Health Professionals will keep current on all activities of UPRO.

(2) The Advisory Council should be asked to react to any programs or policies adopted by UPRO.

(3) The Advisory Council should make recommendations to the UPRO Board of Directors based on their own observations of methods of improving the quality of medical care provided to the people of Utah.

(4) Preliminary discussions should be held regarding cooperative efforts in quality care review for all health professionals, specifically, as provided for in Public Law 92-603.

The current PSRO Program Manual states that a PSRO may, at its discretion, utilize an advisory group of non-physician health care professionals (see Page 18, Chapter V). Implementation of this law would be facilitated by stronger endorsement of non-physician health care professional advisory groups to all PSROs, similar to the Utah plan. This would coordinate physician and non-physician health care practitioners in the review procedures.

The third problem raised by Senator Bennett was fragmentation of care. Modern health care developed specialty services because of the information explosion. There was too much information for one person to command or utilize it all. Health care specialty services arose in order to provide the most effective care. Because of this, there are occupational therapists, speech pathologists, physical therapists, social workers, etc. There are pediatricians, neurologists and allergists—and even pediatric allergists and pediatric neurologists.

Fragmentation of care is one of the problems resulting from specialization. It needs to be solved in order to improve the quality of care. But to expect the physician to solve this problem by trying to know enough to jointly assess all the non-physician health care professionals is not, we feel, as likely to succeed as a team assessment procedure might.

Summary

The PSRO law has a great potential for improving the quality and delivery of health care. Our recommendations are made in an effort to enhance the likelihood of success. First, we recommend that the law state unequivocally that non-physician health care professionals shall review the services which their peer-practitioners provide, so long as the review is effective. The present ambiguity in the law will cause confusion and debate as the PSROs plan to involve the non-physician health care professionals in review procedure.

Second, the non-physician health care professionals should have a formal, assured method of interaction with an input into the administrative and operational aspects of the PSRO. This would facilitate coordination of services and integration of the non-physician health care professional in the review, research and educational aspects of the PSRO.

Third, we recommend that the non-physician health care practitioners have a formal method of input at the federal level of policy development to the Department of Health, Education, and Welfare. The process for this input should be planned with the combined efforts of the Department of Health, Education, and Welfare and non-physician health care professionals.

We should be happy to recommend specific amendments to the law to accomplish these goals.

Appendix B

Background Material Relating to Professional Standards Review Organizations (PSRO's) Prepared by the Staff of the Committee on Finance

Background Material Relating to PSRO's

CONTENTS

I. Summary of Legislative History

On July 1, 1970, Senator Wallace F. Bennett announced his intention to offer an amendment authorizing the estabishment of Professional Standards Review Organizations (PSRO) throughout the United States (Appendix A). In that speech Senator Bennett stated that the legislative oversight work of the Finance Committee and its Subcommittee on Medicare and Medicaid indicated urgent need for development of effective professional quality and utilization control mechanisms for the Federal health care financing programs. He noted that the American Medical Association had requested him to consider introducing legislation which they had prepared designed to establish peer review organizations throughout the country. Senator Bennett said that, although he agreed with the AMA that establishment of peer review organizations was necessary, he believed that the AMA proposal should be expanded and strengthened to assure comprehensiveness of review and public accountability.

In that announcement of his intent to introduce a review amendment, he stated that, "I believe that physicians, properly organized and with a proper mandate, are capable of conducting an ongoing effective review program which would eliminate much of the present criticism of the profession and help enhance their statute as honorable men in an honorable vocation willing to undertake necessary and broad responsibility for overseeing professional functions. If medicine accepts this role and fulfills its responsibility, then the Government would not need to devote its energies and resources to this area of concern. Make no mistake; the direction of the House-passed Social Security bill (H.R. 17550) is toward more—not less—review of the need for and quality of health care. I believe my amendment would provide the necessary means by which organized medicine could assume responsibility for that review."

Senator Bennett formally introduced his amendment on August 20, 1970 (Appendix B). The Committee on Finance considered the Bennett Amendment during its extensive work on H.R. 17550, the Social Security Amendments of 1970. The legislative proposal was approved by the Committee with some modifications in October, 1970. During Senate floor debate on H.R. 17550 a motion offered on December 18, 1970 to delete the Bennett Amendment from the Committee bill failed to carry by a vote of 18 yeas to 48 nays.

Although the Senate approved H.R. 17550, the House and Senate were unable to confer on the bill prior to the end of the 91st Congress.

Senator Bennett reintroduced his proposal on January 25, 1972 (see appendix B) as an amendment to H.R. 1, the Social Security Amendments of 1972.

Subsequent to further consideration, the Finance Committee announced its approval of the Bennett Amendment to H.R. 1 on March 2,

1972. The full Senate considered and approved H.R. 1, including the PSRO Amendment, in October, 1972.

Upon completion of Senate action on H.R. 1, a Conference was held with the House of Representatives to resolve differences between the House and Senate bills. The Bennett Amendment was, of course, subject to Conference consideration inasmuch as it had not been included in the House bill.

The House Conferees accepted the Senate PSRO Amendment after certain changes were agreed to by the Senate Conferees. Thereafter, the House of Representatives and the Senate approved the Conference bill on October 17, 1972. The President signed the bill into law on October 30, 1972 (Public Law 92-603).

II. Excerpts from Senate Finance Committee Report Concerning PSRO's

The Senate Finance Committee Report on H.R. 1, the Social Security Amendments of 1972, contained an extensive discussion of the PSRO provision which the Committee had approved.

The Committee Report described the need for an effective professional review mechanism to review the quality and utilization of health services provided through the Federal health programs, the failures of existent utilization review mechanisms and its intent with respect to the structure and operations of the PSRO program.

Excerpts from the Committee report appear below.

PROFESSIONAL STANDARDS REVIEW (SEC. 249F OF THE BILL)

According to recent estimates the costs of the medicare hospital insurance program will overrun the estimates made in 1967, by some $240 billion over a 25-year period. The monthly premium costs for part B of medicare—doctors' bills—rose from a total of $6 monthly per person on July 1, 1966, to $11.60 per person on July 1, 1972. Medicaid costs are also rising at precipitous rates.

The rapidly increasing costs of these programs are attributable to two factors. One of these is an increase in the unit cost of services such as physicians' visits, surgical procedures, and hospital days. H.R. 1, as reported, contains a number of desirable provisions which the committee believes should help to moderate these unit costs.

The second factor which is responsible for the increase in the costs of the medicare and medicaid programs is an increase in the number of services provided to beneficiaries. The Committee on Finance has, for several years, focused its attention on methods of assuring proper utilization of these services. That utilization controls are particularly important was extensively revealed in hearings conducted by the subcommittee on medicare and medicaid. Witnesses testified that a significant proportion of the health services provided under medicare and medicaid are probably not medically necessary. In view of the per diem costs of hospital and nursing facility care, and the costs of medical and surgical procedures, the economic impact of this overutilization becomes extremely significant. Aside from the economic impact the committee is most concerned about the effect of overutilization on the health of the aged and the poor. Unnecessary hospitalization and unnecessary surgery are not consistent with proper health care.

REVIEW OF PRESENT UTILIZATION CONTROLS

The committee has found that present utilization review requirements and activities are not adequate.

"Under present law, utilization review by physician staff committees in hospitals and extended care facilities and claims review by

medicare carriers and intermediaries are required. These processes have a number of inherent defects. Review activities are not coordinated between medicare and medicaid. Present processes do not provide for an integrated review of all covered institutional and noninstitutional services which a beneficiary may receive. The reviews are not based upon adequately and professionally developed norms of care. Additionally, there is insufficient professional participation in, and support of, claims review by carriers and intermediaries and consequently there is only limited acceptance of their review activities. With respect to the quality of care provided, only institutional services are subject to quality control under medicare, and then only indirectly through the application of conditions of participation. . . .

The detailed information which the committee has collected and developed as well as internal reports of the Social Security Administration indicate clearly that utilization review activities have, generally speaking, been of a token nature and ineffective as a curb to unnecessary use of institutional care and services. Utilization review in medicare can be characterized as more form than substance. The present situation has been aptly described by a State medical society in these words:

"Where hospital beds are in short supply, utilization review is fully effective. Where there is no pressure on the hospital beds, utilization review is less intense and often token."

The current statute places upon the intermediary as well as the State health agency responsibility for assuring that participating hospitals and extended-care facilities effectively perform utilization review.

Available data indicate that in many cases intermediaries have not been performing these functions satisfactorily despite the fact that the Secretary may not, under the law, make agreements with an intermediary who is unwilling, or unable, to assist providers of services with utilization review functions.

Apart from the problems experienced in connection with their determinations of "reasonable" charges, the performance of the carriers responsible for payment for physicians services under medicare has also varied widely in terms of evaluating the medical necessity and appropriateness of such services. Moreover, ever since medicare began, physicians have expressed resentment that their medical determinations are challenged by insurance company personnel. The committee has concluded that the present system of assuring proper utilization of institutional and physicians' services is basically inadequate. The blame must be shared between failings in the statutory requirements and the willingness and capacity of those responsible for implementing what is required by present law.

There is no question, however, that the Government has a responsibility to establish mechanisms capable of assuring effective utilization review. Its responsibility is to the millions of persons dependent upon medicare and medicaid, to the taxpayers who bear the burden of billions of dollars in annual program costs, and to the health care system.

In light of the shortcomings outlined above, the committee believes that the critically important utilization review process must be restructured and made more effective through substantially increased professional participation.

The committee believes the review process should be based upon the premise that only physicians are, in general, qualified to judge

whether services ordered by other physicians are necessary. The committee is aware of increasing instances of criticism directed at the use of insurance company personnel and Government employees in reviewing the medical necessity of services.

The committee generally agrees with the principles of "peer review" enunciated in the report of the President's Health Manpower Commission, issued in November 1967. That report stated:

"Peer review should be performed at the local level with professional societies acting as sponsors and supervisors.

"Assurance must be provided that the evaluation groups perform their tasks in an impartial and effective manner.

"Emphasis should be placed on assuring high quality of performance and on discovering and preventing unsatisfactory performance.

"The more objective the quality evaluation procedures, the more effective the review bodies can be. To enable greater objectivity, there should be a substantial program of research to develop improved criteria for evaluation, data collection methods, and techniques of analysis." [1]

The committee has therefore included an amendment, as it did in H.R. 17750, which authorizes the establishment of independent professional standards review organizations (PSRO's) by means of which practicing physicians would assume responsibility for reviewing the appropriateness and quality of the services provided under medicare and medicaid.

THE COMMITTEE PROVISION

The committee has provided for a review mechanism through which practicing physicians can assume full responsibility for reviewing the utilization of services. The committee's review mechanism at the same time contains numerous safeguards intended to fully protect the public interest.

The committee provision would establish broadly based review organizations with responsibility for the review of both institutional and outpatient services, as opposed to the present fragmented review responsibilities.

The new review organizations would be large enough to take full advantage of rapidly evolving computer technology, and to minimize the inherent conflicts of interest which have been partially responsible for the failure of the smaller institutionally based review organizations. The review process would be made more sophisticated through the use of professionally developed regional norms of diagnosis and care as guidelines for review activities, as opposed to the present usage of arbitrarily determined checkpoints. The present review process, without such norms, becomes a long series of episodic case-by-case analyses on a subjective basis which fail to take into account in a systematic fashion the experience gained through past reviews or to sufficiently emphasize general findings about the pattern of care provided. The committee believes that the goals of the review process can be better achieved through the use of norms which reflect prior review experience.

The committee's bill provides specifically for the establishment of independent professional standards review organizations (PSRO's)

[1] Report of the Health Manpower Commission, November 1967, p. 48.

formed by organizations representing substantial numbers of practicing physicians in local areas to assume responsibility for the review of service, (but not payments) provided through the medicare and medicaid programs.

Recognizing the problem, on their own, a number of medical societies and other health care organizations have already sponsored similar types of mechanisms for purposes of undertaking unified and coordinated review of the total range of health care provided patients. Additional medical societies are proceeding to set up such organizations.

In reaffirming its conviction that the establishment of PSRO's should result in important improvements to the medicare and medicaid programs, the committee has taken particular note of the progress which has been made by a number of prototype review organizations across the country. Experience by these organizations has provided the committee with convincing evidence that peer review can—and should—be implemented on an operational, rather than merely an experimental basis.

The committee expects that in developing the policies and regulations implementing the PSRO provision, the Secretary will seek the advice and counsel of physicians and administrators connected with existing successful review organizations.

However, in most parts of the country, new organizations would need to be developed.

The committee would stress that physicians—preferably through organizations sponsored by their local associations—should assume responsibility for the professional review activities. Medicine, as a profession, should accept the task of advising the individual physician where his pattern of practice indicates that he is overutilizing hospital or nursing home services, overtreating his patients, or performing unnecessary surgery.

It is preferable and appropriate that organizations of professionals undertake review of members of their profession rather than for Government to assume that role. The inquiry of the committee into medicare and medicaid indicates that Government is ill equipped to assure adequate utilization review. Indeed, in the committee's opinion, Government should not have to review medical determinations unless the medical profession evidences an unwillingness to properly assume the task.

But, the committee does not intend any abdication of public responsibility or accountability in recommending the professional standards review-organizations approach. While persuaded that comprehensive review through a unified mechanism is neecssary and that it should be done through usage, wherever possible and wherever feasible, of medical organizations, the committee would not preclude other arrangements being made by the Secretary where medical organizations are unwilling or unable to assume the required work or where such organizations function not as an effective professional effort to assure proper utilization and quality of care but rather as a token buffer designed to create an illusion of professional concern. . . .

Priority in designation as a PSRO would be given to organizations established at local levels representing substantial numbers of practicing physicians who are willing and believed capable of progressively assuming responsibility for overall continuing review of institutional

and outpatient care and services. Local sponsorship and operation should help engender confidence in the familiarity of the review group with norms of medical practice in the area as well as in their knowledge of available health care resources and facilities. Furthermore, to the extent that review is employed today, it is usually at the local level. To be approved, a PSRO applicant must provide for the broadest possible involvement, as reviewers on a rotating basis, of physicians engaged in all types of practice in an area such as solo, group, hospital, medical school, and so forth.

Participation in PSRO would be voluntary and open to every physician in the area. Existing organizations of physicians should be encouraged to take the lead in urging all their members to participate and no physician could be barred from participation because he is or is not a member of any organized medical group or be required to join any such group or pay dues or their equivalent for the privilege of becoming a member or officer of any PSRO nor should there be any discrimination in assignments to perform PSRO duties based on membership or nonmembership in any such organized group of physicians.

Physician organizations or groupings would be completely free to undertake or to decline assumption of the responsibilities of organizing a PSRO. If they decline, the Secretary would be empowered to seek alternative applicants from among other medical organizations, State and local health departments, medical schools, and failing all else, carriers and intermediaries or other health insurers. In no case, however, could any organization be designated as a PSRO which did not have professional medical competence. And, in no case could any final adverse determinations by a PSRO with respect to the conduct or provision of care by a physician be made by anyone except another qualified physician. . . .

The PSRO's responsibilities are confined to evaluating the appropriateness of medical determinations so that medicare and medicaid payments will be made only for medically necessary services which are provided in accordance with professional standards of care.

Where advance approval by the review organizations for institutional admission was required and provision of the services was approved by the PSRO, or where and to the extent the PSRO accepted "in-house" review, such approval woud provide the basis for a presumption of medical necessity for purposes of medicare and medicaid benefit payments. However, advance approval of institutional admission would not preclude a retroactive finding that ancillary services (not specifically approved in advance) provided during the covered stay were excessive.

The PSRO, where it has not accepted in-house review in a given hospital as adequate, would be responsible for reviewing attending physicians' certifications of need for continued hospital care beyond professionally determined regional norms directly related to patients' age and diagnoses, using criteria such as the types of data developed by the Commission on Professional and Hospital Activities, which is sponsored by the American Hospital Association, the American College of Physicians, and the American College of Surgeons. It is expected that such certification would generally be required not later than the point where 50 percent of patients with similar diagnoses and in the same age groups have usually been discharged. However, it is recognized that there are situations in which such stays for certain

diagnoses may be quite short in duration. In such situations the PSRO might decide against requiring certification at or before the expiration of the period of usual lengths of stay on the grounds that the certification would be unproductice; for example, when the usual duration of stay is two days or less. Certification on the first day of stay might yield no significant advantage in the review process. This professionally determined time of certification of need for continued care is a logical checkpoint for the attending physician and is not to be construed as a barrier to further necessary hospital care. Neither should the use of norms as checkpoints, nor any other activity of the PSRO, be used to stifle innovative medical practice or procedures. The intent is not conformism in medical practice—the objective is reasonableness.

PSRO disapproval of the medical necessity for continued hospital care beyond the norm for that diagnosis will not mean that the physician must discharge his patient. The physician's authority to decide the date of discharge as well as whether his patient should be admitted in the first place cannot be and are not taken from him by the PSRO. The review responsibility of the PSRO is to determine whether the care should be paid for by medicare and medicaid. By making this determination in advance, the patient, the institution, and the physician will all be forewarned of the desirability of making alternative plans for providing care or financing the care being contemplated.

Similarly, as feasible, out-of-institution norms would be developed and utilized based upon patterns of actual and proper practice by physicians. Such norms are available in many areas to an extent today. It is recognized that continuing efforts will need to be made to improve the scope and comprehensiveness of such norms.

Employees of the PSRO would be selected by the organizations and would not be Government employees. Where the Federal Government has paid for or supplied necessary equipment to the review organizations, title to such property would remain with the Government.

A PSRO agreement would include provision for orderly transfer of medicare and medicaid records, data and other materials developed during the trial period to the Secretary or such successor organization as he might designate in the event of termination of the initial agreement. Such transfer would involve only those records pertinent to medicare and medicaid patients and would be made solely for purposes of permitting orderly continuity of review activities by a successor PSRO.

Properly established and properly implemented throughout the Nation, professional standards review mechanisms can help relieve the tremendous strain which soaring health costs are placing upon the entire population. Emphasis, wherever possible, upon the provision of necessary care on an outpatient rather than inpatient basis could operate to reduce need for new construction of costly hospital facilities. Hospital bed need would be further reduced by reductions in lengths of hospital stay and avoidance of admission for unnecessary or avoidable hospitalization.

To be effective, the PSRO provisions will require full and forthright implementation. Equivocation, hesitance, and half-hearted compliance will negate the intended results from delegation, with appropriate public interest safeguards, of primary responsibility for professional review to nongovernmental physicians.

33-013 O - 74 - pt. 2 - 4

III. Current Status of Implementation of the PSRO Program

The Secretary of Health, Education, and Welfare assigned primary responsibility for implementation of the PSRO Program to the Assistant Secretary for Health who in turn established an Office of Professional Standards Review. Additional PSRO administrative functions are performed by the Bureau of Quality Assurance in the Health Services Administration and the Bureau of Health Insurance in the Social Security Administration.

The National Professional Standards Review Council, to be composed of non-Federal physicians of "recognized standing and distinction in the review of medical care," as called for in the legislation, was appointed on June 1, 1973. Initial members of the Council included the following:

Clement R. Brown, M.D., Director, Medical Education, Mercy Hospital and Medical Center, Chicago, Illinois

Ruth M. Covell, M.D., Assistant to the Dean, School of Medicine, University of California at San Diego, La Jolla, California

Merlin K. DuVal, M.D., Vice President for Health Sciences, University of Arizona, Tucson, Arizona

Thomas J. Greene, M.D., Surgeon, Detroit, Michigan

Robert J. Haggerty, M.D., Professor of Pediatrics, University of Rochester, School of Medicine and Dentistry, Rochester, New York

Donald C. Harrington, M.D., Obstetrician-Gynecologist and Medical Director, San Joaquin Foundation for Medical Care, Stockton, California

Robert B. Hunter, M.D., Family Physician, Sedro Woolley, Washington

Alan R. Nelson, M.D., Internist, Salt Lake City, Utah

Raymond J. Saloom, D.O., Osteopathic Physician, Harrisville, Pennsylvania

Ernest W. Saward, M.D., Professor of Social Medicine, University of Rochester School of Medicine and Dentistry, Rochester, New York*

William C. Scrivner, M.D., Obstetrician, Gynecologist, Belleville, Illinois

The duties of the Council are to:

"(1) advise the Secretary in the administration of this part;

"(2) provide for the development and distribution, among Statewide Professional Standards Review Councils and Professional Standards Review Organizations of information and data which will assist such review councils and organizations in carrying out their duties and functions;

*Chairman.

"(3) review the operations of Statewide Professional Standards Review Councils and Professional Standards Review Organizations with a view to determining the effectiveness and comparative performance of such review councils and organizations in carrying out the purposes of this part; and

"(4) make or arrange for the making of studies and investigations with a view to developing and recommending to the Secretary and to the Congress measures designed more effectively to accomplish the purposes and objectives of this part."

The PSRO Statute required designation of PSRO areas throughout the United States not later than December 31, 1973. Proposed areas were announced on December 20, 1973, with final designations made by the Secretary in March 1974.

Following final designation of areas the Department announced its intention to begin support of appropriate physician-sponsored organizations interested in developing or establishing PSRO's in each area. The Department announced that qualified groups of physicians may seek designation as conditional PSRO's or, alternatively, may request support from HEW for the purpose of conducting planning activities toward establishment of conditional PSRO's. The Department also announced that it would fund qualified Statewide organizations of physicians desirous and capable of serving as PSRO technical and administrative resource centers.

Finally, the Department announced that funds would be available to medical specialty societies for the purpose of developing suggested norms, criteria and standards for various diagnoses which might assist local PSRO's in the development of review plans and activities. Local PSRO's are at liberty to adopt, adapt or reject such recommendations. This function is assigned under Section 1163(e)(2) to the National Professional Standards Review Council.

IV. Physician-Sponsored Organizations Seeking To Participate in the PSRO Program

Following are local physicians' organizations, statewide physicians' organizations and medical specialty societies which as of May 1, 1974, have applied for designation as conditional PSRO's or Statewide resource centers, or to apply for funds to plan the establishment of conditional PSRO's or funds to develop norms, criteria or standards.

TOTAL PROPOSALS RECEIVED

HEW region [1]	Planning	Conditional	Support center
I	12	2	2
II	17	0	2
III	18	1	2
IV	12	2	1
V	17	1	3
VI	1	1	1
VII	6	0	1
VIII	1	4	0
IX	15	2	1
X	5	1	0
Total	104	14	13

[1] Regional offices: region I, Boston, Mass.; region II, New York, N.Y.; region III, Philadelphia, Pa.; region IV, Atlanta, Ga.; region V, Chicago, Ill.; region VI, Dallas, Tex.; region VII, Kansas City, Mo.; region VIII, Denver, Colo.; region IX, San Francisco, Calif.; and region X, Seattle, Wash.

PSRO area number	State	Name of applicant organization	Type of application
REGION I			
I	Massachusetts	Health Care Foundation for Western Massachusetts.	Planning.
II	do	Central Massachusetts Health Care Foundation	Do.
III [1]	do	Charles River Health Care Foundation	Do.
III [1]	do	do	Conditional.
IV	do	Bay State PSRO, Inc	Do.
V	do	Southeastern Massachusetts PSR	Planning.
State of Maine	Maine	Thayer Hospital (Pine Tree Organization for PSRO).	Do.
State of Vermont	Vermont	Health Care Foundation of Vermont, Inc	Do.
State of Rhode Island	Rhode Island	Rhode Island PSRO, Inc	Do.
State of New Hampshire.	New Hampshire	New Hampshire Foundation for Medical Care	Do.
I	Connecticut	PSRO of Fairfield County, Inc	Do.
II	do	Connecticut Area II PSRO, Inc	Do.
III	do	Hartford County PSRO, Inc	Do.
IV	do	Eastern Connecticut PSRO, Inc	Do.
State of Connecticut	do	Connecticut Medical Institute	Support center.
State of Massachusetts.	Massachusetts	Commonwealth Institute of Medicine	Do.

REGION II

State of Puerto Rico	Puerto Rico	Foundation for Medical Care of Puerto Rico	Planning.
I	New Jersey	Area I—PSRO Region II	Do.
II	do	Passaic Valley PSRO	Do.
IV	do	Essex Physician Review Organization, Inc	Do.
I	New York	Erie Region PSRO, Inc	Do.
II	do	Genessee Region PSRO, Inc	Do.
III	do	PSRO of Central New York, Inc	Do.
IV	do	Five-County Organization for Medical Care and PSR.	Do.
V	do	Adirondack Professional Standards Review Organization.	Do.
IX	do	Area 9 PSRO of New York, Inc	Do.
X	do	Professional Standards Review Organization of Rockland.	Do.
XI	do	New York County Health Services Review Organization.	Do.
XII	do	Richmond County, New York PSRO, Inc	Do.
XIII	do	Kings County Health Care Review Organization	Do.
XIV	do	Medical Society of County of Queens	Do.
XV	do	Nassau Physicians' Review Organization	Do.
XVI	do	Bronx Medical Services Foundation, Inc	Do.
State of New York	do	Medical Society of New York State	Support center.
State of New Jersey	New Jersey	New Jersey Foundation for Health Care Evaluation.	Do.

PSRO area number	State	Name of applicant organization	Type of application
REGION III			
State of Delaware	Delaware	Delaware Foundation for Medical Care	Planning.
II	Virginia	Northern Virginia Foundation for Medical Care	Do.
District of Columbia	District of Columbia	National Capital Medical Foundation, Inc	Do.
State of West Virginia.	West Virginia	West Virginia Medical Institute, Inc	Do.
II	Pennsylvania	Central Pennsylvania Area II PSRO	Do.
IV	do	Eastern Pennsylvania Health Care Foundation, Inc.	Do.
VI	do	Allegheny PSRO	Do.
VII	do	Southwestern Pennsylvania PSRO	Do.
VIII	do	PSRO Area VIII Steering Committee	Do.
IX	do	South Central Pennsylvania PSRO	Do.
XI	do	Montgomery/Bucks PSRO	Do.
XII	do	PSRO Area XII Executive Committee	Do.
II	Maryland	Baltimore City Professional Review Org., Inc	Do.
III	do	Montgomery County, Md. Medical Care Foundation, Inc.	Do.
IV [1]	do	Prince George's Foundation for Medical Care, Inc.	Do.
IV [1]	do	Prince George's Foundation	Conditional.
V	do	Central Maryland PSRO, Inc	Planning.
VI	do	Southern Maryland PSRO	Do.
VII	do	Delmarva Foundation for Medical Care	Do.
State of Maryland	do	Maryland Foundation for Health Care, Inc	Support center.
State of Virginia	Virginia	Medical Society of Virginia	Do.

REGION IV

I	Tennessee	Shelby County Foundation for Medical Care	Planning.
II	do	Tennessee Foundation for Medical Care, Inc	Conditional.
III	Florida	Jacksonville Area PSRO	Planning.
IV	do	Pinellas County PSR, Inc	Do.
VIII	do	Brevolco PSRO, Inc	Do.
XII	do	Dade-Monroe PSRO, Inc	Do.
State of Alabama	Alabama	Alabama Medical Review, Inc	Do.
State of Georgia	Georgia	PSRO of Georgia	Do.
State of Kentucky	Kentucky	Kentucky Peer Review Organization, Inc	Do.
State of South Carolina.	South Carolina	South Carolina Medical Care Foundation	Do.
I, II, III, IV, V, VI, VIII.[1]	North Carolina	Old North State PSRO	Do.
II[1]	do	Piedmont Medical Foundation, Inc	Do.
VII	do	North Carolina Area VII Peer Review Corp	Do.
State of Mississippi	Mississippi	Mississippi Foundation for Medical Care, Inc	Conditional.
State of North Carolina.	North Carolina	North Carolina Medical Peer Review Foundation, Inc.	Support center.

REGION V

I	Wisconsin	Wisconsin Professional Review Organization	Planning.
II	do	(The Foundation for Medical Care Evaluation of Southeastern Wisconsin, Inc.).	Do.
II	Minnesota	Foundation for Health Care Evaluation	Conditional.
III	do	Southern Minnesota PSRO	Planning.
III	Illinois	Chicago Foundation for Medical Care	Do.
IV	do	Quad River Foundation for Medical Care	Do.
I	Indiana	Calumet Professional Review Organization	Do.

PSRO area number	State	Name of applicant organization	Type of application
REGION V—Continued			
V	do	The Marion County Medical Society	Do.
I	Michigan	Upper Peninsula Medical Society Executive Committee.	Do.
V	do	Genessee Medical Corp	Do.
VIII [1]	do	Detroit Medical Foundation	Do.
VIII [1]	do	Federation of Physicians in Southeastern Michigan.	Do.
I	Ohio	Medco Peer Review, Inc	Do.
II	do	Western Ohio Foundation for Medical Care	Do.
IV	do	The Academy of Medicine of Toledo and Lucas County.	Do.
VI	do	Region Six Peer Review Corp	Do.
X	do	Academy of Medicine of Columbus and Franklin County.	Do.
XII	do	Physicians' Peer Review Organization	Do.
State of Ohio	Ohio	Medical Advances Institute	Support center.
State of Michigan	Michigan	Michigan State Medical Society	Do.
State of Indiana	Indiana	Indiana Physicians Support Agency	Do.

REGION VI AND VII

State of Arkansas	Arkansas	Arkansas Foundation for Medical Care	Planning.
State of Iowa	Iowa	Iowa Foundation for Medical Care	Do.
State of Kansas	Kansas	Kansas Foundation for Medical Care	Do.
I	Missouri	Northwest Missouri PSRO Foundation	Do.
II	do	Mid-Missouri Foundation	Do.
III	do	Central Eastern Missouri Professional Review Organization Committee.	Do.
V	do	Southeast Missouri Foundation for Medical Care	Do.
State of New Mexico	New Mexico	New Mexico Standards Review Organization	Conditional.
State of Missouri	Missouri	Health Care Foundation of Missouri	Support center.
State of Louisiana	Louisiana	Southeastern-Southwestern PSRO Statewide Support Center.	Do.

REGION VIII

State of South Dakota.	South Dakota	South Dakota Foundation for Medical Care	Planning.
State of Colorado	Colorado	Colorado Foundation for Medical Care	Conditional.
State of Montana	Montana	Montana Foundation for Medical Care	Do.
State of Utah	Utah	Utah Professional Review Organization	Do.
State of Wyoming	Wyoming	Wyoming Health Services, Co	Do.

REGION IX

State of Nevada	Nevada	Nevada PSRO	Planning.
State of Hawaii	Hawaii	Hawaii Foundation for Medical Care	Do.
II	Arizona	Pima Foundation for Medical Care, Inc	Do.
I	California	Redwood Coast Region PSRO	Do.
III	do	Marin Foundation for Medical Care, Inc	Do.

PSRO area number	State	Name of applicant organization	Type of application
IV	do	Medical Care Foundation of Sacramento	Conditional.
V	do	San Francisco Medical Society Health Plan, Inc	Planning.
VI	do	San Mateo County Medical Society	Do.
VIII	do	San Joaquin Area PSRO	Conditional.
IX	do	Foundation for Medical Care of Santa Clara County.	Planning.
X	do	Stanislaus Foundation for Medical Care	Do.
XII	do	Monterey Bay Area PSRO	Do.
XIV	do	Kern County Medical Society	Do.
XVI	do	Organization for Professional Standards Review of Santa Barbara.	Do.
XVII	do	Ventura Area PSRO, Inc	Do.
XXIV	do	East Central Los Angeles PSRO	Do.
XXVII	do	Riverside County	Planning.
State of California	do	United Foundations for Medical Care	Support center.
REGION X			
I	Oregon	Multnomah Foundation for Medical Care	Planning.
I	do	do	Conditional.
II	do	Greater Oregon PSRO	Planning.
State of Washington	Washington	Washington State Medical Association	Do.
State of Idaho	Idaho	Idaho Foundation for Medical Care Inc	Do.
State of Alaska	Alaska	Alaska Professional Review Organization	Do.

[1] Denotes 2 proposals from the same PSRO area.

V. Response of Senator Wallace Bennett to AMA Allegations Concerning the PSRO Program

On April 2, 1974 Senator Bennett responded, on the Senate floor, to the allegations contained in the material which the AMA had issued on the "deleterious effects of PSRO."

The speech prepared by the AMA had contained five general allegations concerning the PSRO program which Senator Bennett addressed in his speech.

Excerpts from Senator Bennett's speech follow:

[From the Congressional Record, Apr. 2, 1974]

* * * * * * *

I will try to respond to the principal allegations which have been raised by advocates of PSRO repeal. Before doing so, it might be helpful to note that all of the review activities which a PSRO is expected to undertake were generally authorized under the Social Security Act prior to the PSRO legislation. Our motive in enacting PSRO was to give practicing physicians priority in undertaking this activity rather than utilizing bureaucrats and insurance company personnel to review care provided under the $25 billion medicare and medicaid programs.

Mr. President, I now propose to lay the AMA's "devil" to rest. I trust that the Senate will bear with me during the course of my extensive response to the anti-PSRO allegations. A substantial amount of time and effort was devoted to the preparation of detailed and specific answers. It is my hope that Members of the Senate and others will find these remarks helpful in placing a vitally necessary and significant statute in proper perspective.

ALLEGATION

"A law of such consequence should have been written with a proportionate amount of forethought. But the forethought was meager. It is the law itself that was a creature of impulse—as its background makes clear."

ANSWER

The professional standards review legislation was the product of years of effort representing the input and testimony of many individuals and organizations. Its genesis was the American Medical Association's own PRO proposal which they asked me to consider introducing in early 1970.

In fact, this amendment was before the public from July 1970, when I first announced my intention to introduce the legislation, to October of 1972 when it became law. It was the subject of extensive public testimony in hearings before the Finance Committee in 1970 and 1971—including testimony from the American Medical Associa-

tion, the Council of Medical Staffs and the American Association of Physicians and Surgeons—and it was also testified to during the course of overall health insurance hearings before the House Ways and Means Committee in 1971. It was formally before the Committee on Ways and Means in the form of H.R. 7182, a bill "to amend the Social Security Act to provide for the establishment of Professional Standards Review Organizations." That bill, in many respects similar, and in others identical to mine, was sponsored by Congressmen DEVINE and Betts. Mr. Betts was a member of the Committee on Ways and Means. It was passed twice by the Finance Committee as an amendment to appropriate social security-medicare bills, twice by the full Senate—including Senate rejection by a vote of 18 to 48 of a specific amendment by Senator CURTIS of Nebraska to delete the PSRO provision—and it was considered and approved by a conference committee of both Houses and finally signed by the President into law was Public Law 92-603 on October 30, 1972.

In addition, the amendment was subject to much discussion in the health care field. It might be an interesting exercise to total up the column inches, in the AMA News—the weekly newspaper of the AMA—which were devoted to PSRO from August of 1970 to October of 1972.

The AMA's own "Medical Backgrounder" on PSRO's legislative history contains the following statements:

"Senator Wallace Bennett of Utah used the AMA concept as a base and developed the PSRO Program. A basic difference between the AMA and Bennett approaches was that under PSRO, a State medical society could not be the reviewing agency. Rather, a new organization must be created."

"AMA had other objections: The requirement for advance approval of admissions to hospitals for elective surgery, national 'norms' of health care, monetary fine for violations of certain provisions and Government ownership of the records of patients and physicians. *The Senate Finance Committee modified PSRO in each of these areas to at least some degree.*" (Emphasis supplied.)

Mr. President, the AMA's own words leave very little to the imagination. Basically, what they wanted they could not have—the formal and legal vesting of PSRO responsibilities with State medical societies. That would have been highly inappropriate in a public program utilizing public trust funds.

ALLEGATION

The law requires development and application of "norms of care" which would lead to "cookbook medicine."

ANSWER

Here is another area where private health insurers and the medicare and medicaid administrators had been applying their own criteria of care—almost always retrospectively—in determining whether to approve or disapprove a claim for payment. In contrast, the PSRO legislation seeks to substitute professionally developed norms and parameters of care which are the product of the work of practicing

physicians in the area. It seems a far more acceptable approach to have the community of physicians in an area determine these factors than for them to be the province of an anonymous insurance company or Government bureaucracy. Further, virtually all of these parameters will be known to the community of doctors—who have developed and approved them. The effect of this should be to virtually end the retroactive denials of payment under medicare and medicaid.

The statute does not speak to a single norm or way of treatment as the definitive and only type for which payment will be made. Rather, it refers to the "range of norms" acceptable to the PSRO for a given diagnosis. Section 1156(b) states:

> Such norms with respect to treatment of particular illnesses or health conditions shall include (in accordance with regulations of the Secretary)—(1) the types and extent of the health care services which, *taking into account differing but acceptable modes of treatment and methods of organizing and delivering care are considered within the range of appropriate diagnosis and treatment of such illness or health condition, consistent with professionally recognized and accepted patterns of care.* (Emphasis supplied)

This acceptable range may well include patterns of care which serve to decrease the concern with and incidence of "defensive medicine." Further, and of great importance, is the fact that these norms and parameters are only checkpoints—developed by the practitioners themselves—related to age and diagnosis which simply serve to establish reasonable points at which the attending doctor should indicate the need for continued care or service or why certain services were not provided. Assuming the PSRO approves care beyond these checkpoints, it would be paid by medicare and medicaid without each case being second-guessed by carriers, intermediaries, or State agencies. This would replace the use of arbitrary 7th day, 12th, or 18th day kind of review unrelated to age or diagnosis which has obtained in the programs heretofore. It allows a physician to explain to another practicing physician—rather than those same carriers or intermediaries—why his patient needs certain care and treatment.

The alternative to appropriate professionally developed checkpoints in determining reasonableness for payment with public funds is to have no reference points, which obviously is an untenable position. The PSRO manual, just released, has two sections which put this all in perspective:

> In each of its review activities the PSRO will use norms, criteria, and standards which are useful in identifying possible instances of misutilization of health care services or of the delivery of care of substandard quality. *The PSRO is responsible for the initial development and on-going modification of the criteria and standards and the selection of the norms to be used in its area.* While PSRO's will structure themselves in many ways to perform these duties, *the overall responsibility for the development, modification and content of norms, criteria and standards rests with the PSRO.* (Emphasis supplied)
>
> Norms, criteria, and standards should be used in each type of PSRO review. They should, at least, be used for the initial screening of cases to select those cases requiring more in-depth review. *In-depth review should be performed by peers using a combination of more detailed norms, criteria and standards and an assessment of a patient's individual clinical and social situation* and the resources of the institution in which care is provided. (Emphasis supplied)

And as the Finance Committee stated in its report on PSRO:

> Neither should the use of norms as checkpoints nor any other activity of the PSRO, be used to stifle innovative medical practices or procedures. The intent is not conformism in medical practice—the objective is reasonableness.

Resolution 56 approving the development of PSRO norms was adopted by the American Medical Association at its Clinical Convention in 1972. That resolution is as follows:

No. 56 SPECIFICATIONS FOR DEVELOPMENT OF NORMS FOR CARE, DIAGNOSES, AND TREATMENT

HOUSE ACTION: ADOPTED

Resolved, That the American Medical Association supports the development of "norms" for medical care as stated in Public Law 92-603 calling for the establishment of "professionally developed norms of care, diagnoses and treatment, based upon typical patterns of practice in its regions," provided such "norms":

1. Have a content which:
a. Recognizes the separate concern for cost and quality.
b. Recognizes that medical care often deals with patient problems rather than specific diagnoses.
c. Recognizes the frequent occurrence of multiple problems in a single patient.
d. Recognizes the uniqueness of individual patients.
e. Recognizes the fact of regional variations in medical care patterns, e.g., differences in availability of facilities and services.
2. Have a structure which:
a. Is developed by organized medicine.
b. Has major input from national and regional specialty societies.
c. Is acceptable to the practicing physician at the regional level.
3. Are applied so as to:
a. Be useful for assessment of professional performance.
b. Recognize deficiencies in medical care in order to identify appropriate areas for continuing education.
c. Assure continuing evaluation and amendment of the "norms" by the medical profession.

The AMA's resolution is completely in agreement with the language and intent of the PSRO statute and report.

ALLEGATION

The PSRO program would violate confidentiality of patient records.

ANSWER

Private health insurers, such as Blue Cross-Blue Shield, have been reviewing medical records for many years—long before PSRO and long before medicare. Granted that review has not always been done discretely nor confidentially. The PSRO legislation, however, in contrast, has specific statutory safeguards designed to safeguard patient identity and confidentiality. First, section 1155(a)(4) states that each PSRO shall utilize—

. . . to the greatest extent practicable in such patient profiles, methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation.

Second, section 1166 is entitled "Prohibition Against Disclosure of Information," and reads as follows:

(a) Any data or information acquired by any Professional Standards Review Organization, in the exercise of its duties and functions, *shall be held in confidence* and shall not be disclosed to any person except (1) to the extent that may be necessary to carry out the purposes of this part, or (2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners or providers of health care.

(b) *It shall be unlawful for any person to disclose any such information* other than for such purposes, and any person violating the provisions of this section shall, upon conviction, be fined not more than $1,000, and imprisoned for not more than six months, or both, together with the costs of prosecution. (Emphasis supplied)

PSRO was developed building upon the PRO proposal of the American Medical Association. The AMA's legislative proposal did not contain any specific provisions directed toward safeguarding confidentiality.

The PSRO statute—section 1155(a)(1) and section 1155(b)(3) specifically limit review activities and access to records to Social Security Act health care programs—namely, medicare and medicaid.

The provision authorizing access to medicare or medicaid patient records in a physician's office is a residual authority intended to be exercised only in highly unusual or exceptional situations—certainly not routinely. For example, a PSRO may have reason to believe that in a given case, substantial discrepancies may exist between the services indicated as provided on a claims form and those actually provided. It is my understanding that the Office of Professional Standards Review in Health, Education, and Welfare is developing extensive guidelines on the maintenance of confidentiality, including material spelling out the intent that this access to records in an office is limited to highly unusual or exceptional circumstances as delineated in the guideline.

ALLEGATION

The costs of PSRO review will outweigh any savings.

ANSWER

Appropriate professional review mechanisms do cost substantially. However, the experience with the operating PSRO prototypes—such as those in Colorado, New Mexico, Utah, and Sacramento and San Joaquin Counties in California—evidences substantial cost savings above the costs of the review process itself—apart from considerations of enhanced quality of care—as well as establishing the fact that the review activities do not require inordinate or unjustified requirements on physician time.

Of course, the Government is already spending a significant amount on review activities in medicare and medicaid. As the PSRO's assume full responsibility, those other review activities would terminate with commensurate cost offsets against PSRO expenses. Considering the $25 billion now spent on medicare and medicaid, the cost of PSRO review efforts will be relatively small.

ALLEGATION

Under the law, fines may be imposed upon a physician and these fines will have a stultifying effect on medical practice.

ANSWER

In actuality, the law does not contain any provision calling for fines. The original Bennett amendment did include a provision authorizing fines, but that was dropped subsequently. The PSRO statute does con-

tain a provision allowing the local doctors to recommend a series of sanctions on a physician who flagrantly or consistently orders or renders services which are either unnecessary or of improper quality. Under sections 1862 and 1903 of the Social Security Act—non-PSRO sections—the Secretary has the authority to suspend a physician from the programs. Under the PSRO provision, the local physicians themselves, rather than the Secretary, would have the authority to recommend appropriate sanctions. These sanctions could either be suspension or, if they decided a less severe sanction was called for, they could recommend repayment by the practitioner of the actual costs paid by the Government, not to exceed $5,000, if excessive services had been rendered. It would be difficult to construct an effective peer review law which had no sanctions—such as the recovery provision—since the local physicians would then have no way to deal with an improper situation.

Mr. President, I believe that I have dealt with the principal allegations of the PSRO opposition. During the next week or so, I shall have more to say to the Senate concerning additional positive developments with respect to professional standards review.

Mr. President, I ask unanimous consent that a listing of the principal review provisions in the Social Security Act—other than professional standards review—be printed in the RECORD.

There being no objection, the listing was ordered to be printed in the RECORD, as follows:

PRINCIPAL GENERAL AND SPECIFIC PROVISIONS OF SOCIAL SECURITY ACT (OTHER THAN PSRO PROVISIONS OF LAW) AUTHORIZING AND REQUIRING REVIEW ACTIVITIES

I. ACCESS TO RECORDS AND OTHER DATA

Medicare

Intermediaries—Section 1816(a)(2)(B) . . . "to make such audits of the records of providers as may be necessary to insure that proper payments are made under this part . . ."

Carriers—Section 1842(a)(1)(C) . . . "to make such audits of the records of providers of services as may be necessary to assure that proper payments are made under this part . . ."

Medicaid

Section 1902(a)(27) . . . "provide for agreements with very person or institution providing services under the State plan under which such institution or persons agrees (A) to keep such records as are necessary fully to disclose the extent of the services provided to individuals receiving assistance under the State plan, and (B) to furnish the State agency with such information, regarding any payments claimed by such person or institution for providing services under the State plan, as the State agency may from time to time request . . ."

II. GENERAL REVIEW REQUIREMENTS

Medicare

Section 1862(a)(1) . . . "Notwithstanding any other provisions of this title, no payment may be made under part A or part B for any expenses incurred for items or services—(1) which are not reasonable or necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member . . ."

Medicaid

Section 1902(a)(30) . . . "provide such methods and procedures relating to the utilization of, and the payment for, care and service available under the plan

33-013 O - 74 - pt. 2 - 5

(including but not limited to utilization review plans provided for in Section 1903(i)(4)) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payment (including payments for any drugs provided under the plan) are not in excess of reasonable charges consistent with efficiency, economy and quality of care . . ."

III. STATEWIDE PROGRAM REVIEW TEAMS

Medicare

Section 1862(d)(4) . . . "(4) For the purposes of paragraph (1)(B) and (C) of this subsection, and clause (F) of section 1866(b)(2), the Secretary shall, after consultation with appropriate State and local professional societies, the appropriate carriers and intermediaries utilized in the administration of this title, and consumer representatives familiar with the health needs of residents of the State, appoint one or more program review teams (composed of physicians, other professional personnel in the health care field, and the consumer representatives) in each State which shall, among other things—

(A) undertake to review such statistical data on program utilization as may be submitted by the Secretary.

(B) submit to the Secretary periodically, as may be prescribed in regulations, a report on the results of such review, together with recommendations with respect thereto.

(C) undertake to review particular cases where there is a likelihood that the person or persons furnishing services and supplies to individuals may come within the provisions of paragraph (1)(B) and (C) of this subsection or clause (F) of section 1866(b)(2)), and

(D) submit to the Secretary periodically, as may be prescribed in regulations, a report of cases reviewed pursuant to subparagraph (C) along with an analysis of, and recommendations with respect to, such cases."

IV. AUTHORITY TO SUSPEND PRACTITIONERS AND PROVIDERS

Medicare

Section 1862(d)(1) . . . "No payment may be made under this title with respect to any item or services furnished to an individual by a person where the Secretary determines under this subsection that such person— . . . (C) has furnished services or supplies which are determined by the Secretary, with the concurrence of the members of the appropriate program review team . . . who are physicians or other professional personnel in the health care field, to be substantially in excess of the needs of individuals or to be harmful to individuals or to be a grossly inferior quality.

(2) A determination made by the Secretary under this subsection shall be effective at such time and upon such reasonable notice to the public and to the person furnishing the services involved as may be specified in regulations. Such determination shall be effective with respect to services furnished to an individual on or after the effective date of such determination (except that in the case of inpatient hospital services, posthospital extended care services, and home health services such determination shall be effective in the manner provided in section 1866(b)(3) and (4) with respect to terminations of agreements), and shall remain in effect until the Secretary finds and gives reasonable notice to the public that the basis of such determination has been removed and that there is reasonable assurance that it will not recur."

Medicaid

Section 1903(i) . . . "Payment under the preceding provisions of this section shall not be made . . . (2) with respect to any amount paid for services furnished under the plan after December 31, 1972, by a provider or another person during any period of time, if payment may be made under title XVIII with respect to services furnished by such provider or person during such period of time solely by reason of a determination by the Secretary under section 1862(d)(1) or under clause (D), (E), or (F) of section 1866(b)(2) . . ."

GENERAL AUTHORITY OF SECRETARY TO ISSUE REGULATIONS AND ASSURE COMPLIANCE

Social security act programs

Section 1102 . . . "The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health, Education, and Welfare, respectively, shall make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which each is charged under this Act."

Medicare

Section 1871 . . . "The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this title . . ."

Appendix A

Statutory Language of the PSRO Provision

Statutory Language of the PSRO Provision

"TITLE XI—GENERAL PROVISIONS AND PROFESSIONAL STANDARDS REVIEW

"PART A—GENERAL PROVISIONS"

(b) Title XI of such Act is further amended by adding the following:

"PART B—PROFESSIONAL STANDARDS REVIEW

"DECLARATION OF PURPOSE

"SEC. 1151. In order to promote the effective, efficient, and economical delivery of health care services of proper quality for which payment may be made (in whole or in part) under this Act and in recognition of the interests of patients, the public, practitioners, and providers in improved health care services, it is the purpose of this part to assure, through the application of suitable procedures of professional standards review, that the services for which payment may be made under the Social Security Act will conform to appropriate professional standards for the provision of health care and that payment for such services will be made—

"(1) only when, and to the extent, medically necessary, as determined in the exercise of reasonable limits of professional discretion; and

"(2) in the case of services provided by a hospital or other health care facility on an inpatient basis, only when and for such period as such services cannot, consistent with professionally recognized health care standards, effectively be provided on an outpatient basis or more economically in an inpatient health care facility of a different type, as determined in the exercise of reasonable limits of professional discretion.

"DESIGNATION OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"SEC. 1152. (a) The Secretary shall (1) not later than January 1, 1974, establish throughout the United States appropriate areas with respect to which Professional Standards Review Organizations may be designated, and (2) at the earliest practicable date after designation of an area enter into an agreement with a qualified organization whereby such an organization shall be conditionally designated as the Professional Standards Review Organization for such area. If, on the basis of its performance during such period of conditional designation, the Secretary determines that such organization is capable of fulfilling, in a satisfactory manner, the obligations and requirements for a Professional Standards Review Organization under this part, he shall enter into an agreement with such organization designating it as the Professional Standards Review Organization for such area.

"Qualified organization."

"(b) For purposes of subsection (a), the term 'qualified organization' means—

"(1) when used in connection with any area—

"(A) an organization (i) which is a nonprofit professional association (or a component organization thereof), (ii) which is composed of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area, (iii) the membership of which includes a substantial proportion of all such physicians in such area, (iv) which is organized in a manner which makes available professional competence to review health care services of the types and kinds with respect to which Professional Standards Review Organizations have review responsibilities under this part, (v) the membership of which is voluntary and open to all doctors of medicine or osteopathy licensed to engage in the practice of medicine or surgery in such area without requirement of membership in or payment of dues to any organized medical society or association, and (vi) which does not restrict the eligibility of any member for service as an officer of the Professional Standards Review Organization or eligibility for and assignment to duties of such Professional Standards Review Organization, or, subject to subsection (c)(i),

"(B) such other public, nonprofit private, or other agency or organization, which the Secretary determines, in accordance with criteria prescribed by him in regulations, to be of professional competence and otherwise suitable; and

"(2) an organization which the Secretary, on the basis of his examination and evaluation of a formal plan submitted to him by the association, agency, or organization (as well as on the basis of other relevant data and information), finds to be willing to perform and capable of performing, in an effective, timely, and objective manner and at reasonable cost, the duties, functions, and

activities of a Professional Standards Review Organization required by or pursuant to this part.

"(c)(1) The Secretary shall not enter into any agreement under this part under which there is designated as the Professional Standards Review Organization for any area any organization other than an organization referred to in subsection (b)(1)(A) prior to January 1, 1976, nor after such date, unless, in such area, there is no organization referred to in subsection (b)(1)(A) which meets the conditions specified in subsection (b)(2).

"(2) Whenever the Secretary shall have entered into an agreement under this part under which there is designated as the Professional Standards Review Organization for any area any organization other than an organization referred to in subsection (b)(1)(A), he shall not renew such agreements with such organization if he determines that—

"(A) there is in such area an organization referred to in subsection (b)(1)(A) which (i) has not been previously designated as a Professional Standards Review Organization, and (ii) is willing to enter into an agreement under this part under which such organization would be designated as the Professional Standards Review Organization for such area;

"(B) such organization meets the conditions specified in subsection (b)(2); and

"(C) the designation of such organization as the Professional Standards Review Organization for such area is anticipated to result in substantial improvement in the performance in such area of the duties and functions required of such organizations under this part.

Agreement expiration, prior termination.

"(d) Any such agreement under this part with an organization (other than an agreement established pursuant to section 1154) shall be for a term of 12 months; except that, prior to the expiration of such term such agreement may be terminated—

Post, p. 1432.

"(1) by the organization at such time and upon such notice to the Secretary as may be prescribed in regulations (except that notice of more than 3 months may not be required); or

"(2) by the Secretary at such time and upon such reasonable notice to the organization as may be prescribed in regulations, but only after the Secretary has determined (after providing such organization with an opportunity for a formal hearing on the matter) that such organization is not substantially complying with or effectively carrying out the provisions of such agreement.

Waiver.

"(e) In order to avoid duplication of functions and unnecessary review and control activities, the Secretary is authorized to waive any or all of the review, certification, or similar activities otherwise required under or pursuant to any provision of this Act (other than this part) where he finds, on the basis of substantial evidence of the effective performance of review and control activities by Professional Standards Review Organizations, that the review, certification, and similar activities otherwise so required are not needed for the provision of adequate review and control.

Agreement notice.

"(f)(1) In the case of agreements entered into prior to January 1, 1976, under this part under which any organization is designated as the Professional Standards Review Organization for any area, the Secretary shall, prior to entering into any such agreement with any organization for any area, inform (under regulations of the Secretary) the doctors of medicine or osteopathy who are in active practice in such area of the Secretary's intention to enter into such an agreement with such organization.

"(2) If, within a reasonable period of time following the serving of such notice, more than 10 per centum of such doctors object to the Secretary's entering into such an agreement with such organization on the ground that such organization is not representative of doctors in such area, the Secretary shall conduct a poll of such doctors to determine whether or not such organization is representative of such doctors in such area. If more than 50 per centum of the doctors responding to such poll indicate that such organization is not representative of such doctors in such area the Secretary shall not enter into such an agreement with such organization.

"REVIEW PENDING DESIGNATION OF PROFESSIONAL STANDARDS REVIEW ORGANIZATION

"SEC. 1153. Pending the assumption by a Professional Standards Review Organization for any area, of full review responsibility, and pending a demonstration of capacity for improved review effort with respect to matters involving the provision of health care services in such area for which payment (in whole or in part) may be made, under this Act, any review with respect to such services which has not been designated by the Secretary as the full responsibility of such organization, shall be reviewed in the manner otherwise provided for under law.

"TRIAL PERIOD FOR PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"SEC. 1154. (a) The Secretary shall initially designate an organization as a Professional Standards Review Organization for any area on a conditional basis with a view to determining the capacity of such organization to perform the duties and functions imposed under this part on Professional Standards Review Organizations. Such designation may not be made prior to receipt from such organization and approval by the Secretary of a formal plan for the orderly assumption and implementation of the responsibilities of the Professional Standards Review Organization under this part.

Plan, approval.

Duties.

"(b) During any such trial period (which may not exceed 24 months), the Secretary may require a Professional Standards Review Organization to perform only such of the duties and functions required under this part of Professional Standards Review Organization as he determines such organization to be capable of performing. The number and type of such duties shall, during the trial period, be progressively increased as the organization becomes capable of added responsibility so that, by the end of such period, such organization shall be considered a qualified organization only if the Secretary finds that it is substantially carrying out in a satisfactory manner, the activities and functions required of Professional Standards Review Organizations under this part with respect to the review of health care services provided or ordered by physicians and other practitioners and institutional and other health care facilities, agencies, and organizations. Any of such duties and functions not performed by such organization during such period shall be performed in the manner and to the extent otherwise provided for under law.

Termination, notice.

"(c) Any agreement under which any organization is conditionally designated as the Professional Standards Review Organization for any area may be terminated by such organization upon 90 days notice to the Secretary or by the Secretary upon 90 days notice to such organization.

"DUTIES AND FUNCTIONS OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"SEC. 1155. (a) (1) Notwithstanding any other provision of law, but consistent with the provisions of this part, it shall (subject to the provisions of subsection (g)) be the duty and function of each Professional Standards Review Organization for any area to assume, at the earliest date practicable, responsibility for the review of the professional activities in such area of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under this Act for the purpose of determining whether—

"(A) such services and items are or were medically necessary;

"(B) the quality of such services meets professionally recognized standards of health care; and

"(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type.

"(2) Each Professional Standards Review Organization shall have the authority to determine, in advance, in the case of—

"(A) any elective admission to a hospital, or other health care facility, or

"(B) any other health care service which will consist of extended or costly courses of treatment,

whether such service, if provided, or if provided by a particular health care practitioner or by a particular hospital or other health care facility, organization, or agency, would meet the criteria specified in clauses (A) and (C) of paragraph (1).

Case criteria, publication.

"(3) Each Professional Standards Review Organization shall, in accordance with regulations of the Secretary, determine and publish, from time to time, the types and kinds of cases (whether by type of health care or diagnosis involved, or whether in terms of other relevant criteria relating to the provision of health care services) with respect to which such organization will, in order most effectively to carry out the purposes of this part, exercise the authority conferred upon it under paragraph (2).

Patient profiles, maintenance and review.

"(4) Each Professional Standards Review Organization shall be responsible for the arranging for the maintenance of and the regular review of profiles of care and services received and provided with respect to patients, utilizing to the greatest extent practicable in such patient profiles, methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation consistent with the purposes of this part. Profiles shall also be regularly reviewed on an ongoing basis with respect to each health care practitioner and provider to determine whether the care and services ordered or rendered are consistent with the criteria specified in clauses (A), (B), and (C) of paragraph (1).

Hospital care, physician review.

"(5) Physicians assigned responsibility for the review of hospital care may be only those having active hospital staff privileges in at least one of the participating hospitals in the area served by the Professional Standards Review Organization and (except as may be otherwise provided under subsection (e) (1) of this section) such physicians ordinarily should not be responsible for, but may participate in the review of care and services provided in any hospital in which such physicians have active staff privileges.

"(6) No physician shall be permitted to review—

"(A) health care services provided to a patient if he was directly or indirectly involved in providing such services, or

"(B) health care services provided in or by an institution, organization, or agency, if he or any member of his family has, directly or indirectly, any financial interest in such institution, organization, or agency.

Physician's family.

For purposes of this paragraph, a physician's family includes only his spouse (other than a spouse who is legally separated from him under a decree of divorce or separate maintenance), children (including legally adopted children), grandchildren, parents, and grandparents.

"(b) To the extent necessary or appropriate for the proper performance of its duties and functions, the Professional Standards Review Organization serving any area is authorized in accordance with regulations prescribed by the Secretary to—

"(1) make arrangements to utilize the services of persons who are practitioners of or specialists in the various areas of medicine (including dentistry), or other types of health care, which persons shall, to the maximum extent practicable, be individuals engaged in the practice of their profession within the area served by such organization;

"(2) undertake such professional inquiry either before or after, or both before and after, the provision of services with respect to which such organization has a responsibility for review under subsection (a)(1);

"(3) examine the pertinent records of any practitioner or provider of health care services providing services with respect to which such organization has a responsibility for review under subsection (a)(1); and

"(4) inspect the facilities in which care is rendered or services provided (which are located in such area) of any practitioner or provider.

"(c) No Professional Standards Review Organization shall utilize the services of any individual who is not a duly licensed doctor of medicine or osteopathy to make final determinations in accordance with its duties and functions under this part with respect to the professional conduct of any other duly licensed doctor of medicine or osteopathy, or any act performed by any duly licensed doctor of medicine or osteopathy in the exercise of his profession.

"(d) In order to familiarize physicians with the review functions and activities of Professional Standards Review Organizations and to promote acceptance of such functions and activities by physicians, patients, and other persons, each Professional Standards Review Organization, in carrying out its review responsibilities, shall (to the maximum extent consistent with the effective and timely performance of its duties and functions)—

"(1) encourage all physicians practicing their profession in the area served by such Organization to participate as reviewers in the review activities of such Organizations;

"(2) provide rotating physician membership of review committees on an extensive and continuing basis;

"(3) assure that membership on review committees have the broadest representation feasible in terms of the various types of practice in which physicians engage in the area served by such Organization; and

"(4) utilize, whenever appropriate, medical periodicals and similar publications to publicize the functions and activities of Professional Standards Review Organizations.

"(e)(1) Each Professional Standards Review Organization shall utilize the services of, and accept the findings of, the review committees of a hospital or other operating health care facility or organization located in the area served by such organization, but only when and only to the extent and only for such time that such committees in such hospital or other operating health care facility or organization have demonstrated to the satisfaction of such organization their capacity effectively and in timely fashion to review activities in such hospital or other operating health care facility or organization (including the medical necessity of admissions, types and extent of services ordered, and lengths of stay) so as to aid in accomplishing the purposes and responsibilities described in subsection (a)(1), except where the Secretary disapproves, for good cause, such acceptance. Review committees.

"(2) The Secretary may prescribe regulations to carry out the provisions of this subsection. Regulations.

"(f)(1) An agreement entered into under this part between the Secretary and any organization under which such organization is designated as the Professional Standards Review Organization for any area shall provide that such organization will— Agreement requirements.

"(A) perform such duties and functions and assume such responsibilities and comply with such other requirements as may be required by this part or under regulations of the Secretary promulgated to carry out the provisions of this part; and

"(B) collect such data relevant to its functions and such information and keep and maintain such records in such form as the Secretary may require to carry out the purposes of this part and to permit access to and use of any such records as the Secretary may require for such purposes.

"(2) Any such agreement with an organization under this part shall provide that the Secretary make payments to such organization equal to the amount of expenses reasonably and necessarily incurred, as determined by the Secretary, by such organization in carrying out or preparing to carry out the duties and functions required by such agreement.

"(g) Notwithstanding any other provision of this part, the responsibility for review of health care services of any Professional Standards Review Organization shall be the review of health care services provided by or in institutions, unless such Organization shall have made a request to the Secretary that it be charged with the duty and function of reviewing other health care services and the Secretary shall have approved such request.

"NORMS OF HEALTH CARE SERVICES FOR VARIOUS ILLNESSES OR HEALTH CONDITIONS

"SEC. 1156. (a) Each Professional Standards Review Organization shall apply professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice in its regions (including typical lengths-of-stay for institutional care by age and diagnosis) as principal points of evaluation and review. The National Professional Standards Review Council and the Secretary shall provide such technical assistance to the organization as will be helpful in utilizing and applying such norms of care, diagnosis, and treatment. Where the actual norms of care, diagnosis, and treatment in a Professional Standards Review Organization area are significantly different from professionally developed regional norms of care, diagnosis, and

treatment approved for comparable conditions, the Professional Standards Review Organization concerned shall be so informed, and in the event that appropriate consultation and discussion indicate reasonable basis for usage of other norms in the area concerned, the Professional Standards Review Organization may apply such norms in such area as are approved by the National Professional Standards Review Council.

"(b) Such norms with respect to treatment for particular illnesses or health conditions shall include (in accordance with regulations of the Secretary)—

"(1) the types and extent of the health care services which, taking into account differing, but acceptable, modes of treatment and methods of organizing and delivering care are considered within the range of appropriate diagnosis and treatment of such illness or health condition, consistent with professionally recognized and accepted patterns of care;

"(2) the type of health care facility which is considered, consistent with such standards, to be the type in which health care services which are medically appropriate for such illness or condition can most economically be provided.

Preparation and distribution of data.

"(c)(1) The National Professional Standards Review Council shall provide for the preparation and distribution, to each Professional Standards Review Organization and to each other agency or person performing review functions with respect to the provision of health care services under this Act, of appropriate materials indicating the regional norms to be utilized pursuant to this part. Such data concerning norms shall be reviewed and revised from time to time. The approval of the National Professional Standards Review Council of norms of care, diagnosis, and treatment shall be based on its analysis of appropriate and adequate data.

"(2) Each review organization, agency, or person referred to in paragraph (1) shall utilize the norms developed under this section as a principal point of evaluation and review for determining, with respect to any health care services which have been or are proposed to be provided, whether such care and services are consistent with the criteria specified in section 1155(a)(1).

Ante, p. 1433.

"(d)(1) Each Professional Standards Review Organization shall—

"(A) in accordance with regulations of the Secretary, specify the appropriate points in time after the admission of a patient for inpatient care in a health care institution, at which the physician attending such patient shall execute a certification stating that further inpatient care in such institution will be medically necessary effectively to meet the health care needs of such patient; and

"(B) require that there be included in any such certification with respect to any patient such information as may be necessary to enable such organization properly to evaluate the medical necessity of the further institutional health care recommended by the physician executing such certification.

"(2) The points in time at which any such certification will be required (usually, not later than the 50th percentile of lengths-of-stay for patients in similar age groups with similar diagnoses) shall be consistent with and based on professionally developed norms of care and treatment and data developed with respect to length of stay in health care institutions of patients having various illnesses, injuries, or health conditions, and requiring various types of health care services or procedures.

"SUBMISSION OF REPORTS BY PROFESIONAL STANDARDS REVIEW ORGANIZATIONS

"SEC. 1157. If, in discharging its duties and functions under this part, any Professional Standards Review Organization determines that any health care practitioner or any hospital, or other health care facility, agency, or organization has violated any of the obligations imposed by section 1160, such organization shall report the matter to the Statewide Professional Standards Review Council for the State in which such organization is located together with the recommendations of such Organization as to the action which should be taken with respect to the matter. Any Statewide Professional Standards Review Council receiving any such report and recommendation shall review the same and promptly transmit such report and recommendation to the Secretary together with any additional comments or recommendations thereon as it deems appropriate. The Secretary may utilize a Professional Standards Review Organization, in lieu of a program review team as specified in sections 1862 and 1866, for purposes of subparagraph (C) of section 1862(d)(1) and subparagraph (F) of section 1866(b)(2). Post, p. 1438. 79 Stat. 325; 81 Stat. 846. 42 USC 1395y, 1395oo. Ante, p. 1406.

"REQUIREMENT OF REVIEW APPROVAL AS CONDITION OF PAYMENT OF CLAIMS Ante, p. 1409.

"SEC. 1158. (a) Except as provided for in section 1159, no Federal funds appropriated under any title of this Act (other than title V) for the provision of health care services or items shall be used (directly or indirectly) for the payment, under such title or any program established pursuant thereto, of any claim for the provision of such services or items, unless the Secretary, pursuant to regulation determines that the claimant is without fault if— 81 Stat. 921. 42 USC 701.

"(1) the provision of such services or items is subject to review under this part by any Professional Standards Review Organization, or other agency; and

"(2) such organization or other agency has, in the proper exercise of its duties and functions under or consistent with the purposes of this part, disapproved of the services or items giving rise to such claim, and has notified the practitioner or provider who provided or proposed to provide such services or items and the individual who would receive or was proposed to receive such services or items of its disapproval of the provision of such services or items.

"(b) Whenever any Professional Standards Review Organization, in the discharge of its duties and functions as specified by or pursuant to this part, disapproves of any health care services or items furnished or to be furnished by any practitioner or provider, such organization shall, after notifying the practitioner, provider, or other organization or agency of its disapproval in accordance with subsection (a), promptly notify the agency or organization having responsibility for acting upon claims for payment for or on account of such services or items.

"HEARINGS AND REVIEW BY SECRETARY

"SEC. 1159. (a) Any beneficiary or recipient who is entitled to benefits under this Act (other than title V) or a provider or practitioner who is dissatisfied with a determination with respect to a claim made by a Professional Standards Review Organization in carrying out its responsibilities for the review of professional activities in accordance with paragraphs (1) and (2) of section 1155(a) shall, after being Ante, p. 1433.

notified of such determination, be entitled to a reconsideration thereof by the Professional Standards Review Organization and, where the Professional Standards Review Organization reaffirms such determination in a State which has established a Statewide Professional Standards Review Council, and where the matter in controversy is $100 or more, such determination shall be reviewed by professional members of such Council and, if the Council so determined, revised.

"(b) Where the determination of the Statewide Professional Standards Review Council is adverse to the beneficiary or recipient (or, in the absence of such Council in a State and where the matter in controversy is $100 or more), such beneficiary or recipient shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 205(b), and, where the amount in controversy is $1,000 or more, to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g). The Secretary will render a decision only after appropriate professional consultation on the matter.

53 Stat. 1368, 42 USC 405.

"(c) Any review or appeals provided under this section shall be in lieu of any review, hearing, or appeal under this Act with respect to the same issue.

"OBLIGATIONS OF HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES; SANCTIONS AND PENALTIES; HEARINGS AND REVIEW

"SEC. 1160. (a)(1) It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this Act, to assure that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this Act—

"(A) will be provided only when, and to the extent, medically necessary; and

"(B) will be of a quality which meets professionally recognized standards of health care; and

"(C) will be supported by evidence of such medical necessity and quality in such form and fashion and at such time as may reasonably be required by the Professional Standards Review Organization in the exercise of its duties and responsibilities:

and it shall be the obligation of any health care practitioner in ordering, authorizing, directing, or arranging for the provision by any other person (including a hospital or other health care facility, organization, or agency), of health care services for any patient of such practitioner, to exercise his professional responsibility with a view to assuring (to the extent of his influence or control over such patient, such person, or the provision of such services) that such services or items will be provided—

"(D) only when, and to the extent, medically necessary; and

"(E) will be of a quality which meets professionally recognized standards of health care.

"(2) Each health care practitioner, and each hospital or other provider of health care services, shall have an obligation, within reasonable limits of professional discretion, not to take any action, in the exercise of his profession (in the case of any health care practitioner), or in the conduct of its business (in the case of any hospital or other such provider), which would authorize any individual to be admitted as an inpatient in or to continue as an inpatient in any hospital or other health care facility unless—

"(A) inpatient care is determined by such practitioner and by such hospital or other provider, consistent with professionally recognized health care standards, to be medically necessary for the proper care of such individual; and

"(B)(i) the inpatient care required by such individual cannot, consistent with such standards, be provided more economically in a health care facility of a different type; or

"(ii) (in the case of a patient who requires care which can, consistent with such standards, be provided more economically in a health care facility of a different type) there is, in the area in which such individual is located, no such facility or no such facility which is available to provide care to such individual at the time when care is needed by him.

"(b)(1) If after reasonable notice and opportunity for discussion with the practitioner or provider concerned, any Professional Standards Review Organization submits a report and recommendations to the Secretary pursuant to section 1157 (which report and recommendations shall be submitted through the Statewide Professional Standards Review Council, if such Council has been established, which shall promptly transmit such report and recommendations together with any additional comments and recommendations thereon as it deems appropriate) and if the Secretary determines that such practitioner or provider, in providing health care services over which such organization has review responsibility and for which payment (in whole or in part) may be made under this Act has— Report and recommendations. Ante, p. 1437.

"(A) by failing, in a substantial number of cases, substantially to comply with any obligation imposed on him under subsection (a), or

"(B) by grossly and flagrantly violating any such obligation in one or more instances,

demonstrated an unwillingness or a lack of ability substantially to comply with such obligations, he (in addition to any other sanction provided under law) may exclude (permanently for such period as the Secretary may prescribe) such practitioner or provider from eligibility to provide such services on a reimbursable basis.

"(2) A determination made by the Secretary under this subsection shall be effective at such time and upon such reasonable notice to the public and to the person furnishing the services involved as may be specified in regulations. Such determination shall be effective with respect to services furnished to an individual on or after the effective date of such determination (except that in the case of institutional health care services such determination shall be effective in the manner provided in title XVIII with respect to terminations of provider agreements), and shall remain in effect until the Secretary finds and gives reasonable notice to the public that the basis for such determination has been removed and that there is reasonable assurance that it will not recur. 79 Stat. 291. 42 USC 1395.

"(3) In lieu of the sanction authorized by paragraph (1), the Secretary may require that (as a condition to the continued eligibility of such practitioner or provider to provide such health care services on a reimbursable basis) such practitioner or provider pay to the United States, in case such acts or conduct involved the provision or ordering by such practitioner or provider of health care services which were medically improper or unnecessary, an amount not in excess of the actual or estimated cost of the medically improper or unnecessary services so provided, or (if less) $5,000. Such amount may be deducted from any sums owing by the United States (or any instrumentality thereof) to the person from whom such amount is claimed.

"(4) Any person furnishing services described in paragraph (1) who is dissatisfied with a determination made by the Secretary under this subsection shall be entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g).

53 Stat. 1368, 42 USC 405.

"(c) It shall be the duty of each Professional Standards Review Organization and each Statewide Professional Standards Review Council to use such authority or influence it may possess as a professional organization, and to enlist the support of any other professional or governmental organization having influence or authority over health care practitioners and any other person (including a hospital or other health care facility, organization, or agency) providing health care services in the area served by such review organization, in assuring that each practitioner or provider (referred to in subsection (a)) providing health care services in such area shall comply with all obligations imposed on him under subsection (a).

"NOTICE TO PRACTITIONER OR PROVIDER

"SEC. 1161. Whenever any Professional Standards Review Organization takes any action or makes any determination—

"(a) which denies any request, by a health care practitioner or other provider of health care services, for approval of a health care service or item proposed to be ordered or provided by such practitioner or provider; or

"(b) that any such practitioner or provider has violated any obligation imposed on such practitioner or provider under section 1160,

such organization shall, immediately after taking such action or making such determination, give notice to such practitioner or provider of such determination and the basis therefor, and shall provide him with appropriate opportunity for discussion and review of the matter.

"STATEWIDE PROFESSIONAL STANDARDS REVIEW COUNCILS; ADVISORY GROUPS TO SUCH COUNCILS

Establishment.

"SEC. 1162. (a) In any State in which there are located three or more Professional Standards Review Organizations, the Secretary shall establish a Statewide Professional Standards Review Council.

Membership.

"(b) The membership of any such Council for any State shall be appointed by the Secretary and shall consist of—

"(1) one representative from and designated by each Professional Standards Review Organization in the State;

"(2) four physicians, two of whom may be designated by the State medical society and two of whom may be designated by the State hospital association of such State to serve as members on such Council; and

"(3) four persons knowledgeable in health care from such State whom the Secretary shall have selected as representatives of the public in such State (at least two of whom shall have been recommended for membership on the Council by the Governor of such State).

Duties.

"(c) It shall be the duty and function of the Statewide Professional Standards Review Council for any State, in accordance with regulations of the Secretary, (1) to coordinate the activities of, and disseminate information and data among the various Professional Standards Review Organizations within such State including assisting the Secre-

tary in development of uniform data gathering procedures and operating procedures applicable to the several areas in a State (including, where appropriate, common data processing operations serving several or all areas) to assure efficient operation and objective evaluation of comparative performance of the several areas and, (2) to assist the Secretary in evaluating the performance of each Professional Standards Review Organization, and (3) where the Secretary finds it necessary to replace a Professional Standards Review Organization, to assist him in developing and arranging for a qualified replacement Professional Standards Review Organization.

"(d) The Secretary is authorized to enter into an agreement with any such Council under which the Secretary shall make payments to such Council equal to the amount of expenses reasonably and necessarily incurred, as determined by the Secretary, by such Council in carrying out the duties and functions provided in this section. Payments.

"(e)(1) The Statewide Professional Standards Review Council for any State (or in a State which does not have such Council, the Professional Standards Review Organizations in such State which have agreements with the Secretary) shall be advised and assisted in carrying out its functions by an advisory group (of not less than seven nor more than eleven members) which shall be made up of representatives of health care practitioners (other than physicians) and hospitals and other health care facilities which provide within the State health care services for which payment (in whole or in part) may be made under any program established by or pursuant to this Act.

"(2) The Secretary shall by regulations provide the manner in which members of such advisory group shall be selected by the Statewide Professional Standards Review Council (or Professional Standards Review Organizations in States without such Councils). Member selection, regulations.

"(3) The expenses reasonably and necessarily incurred, as determined by the Secretary, by such group in carrying out it duties and functions under this subsection shall be considered to be expenses necessarily incurred by the Statewide Professional Standards Review Council served by such group. Expenses.

"NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

"SEC. 1163. (a)(1) There shall be established a National Professional Standards Review Council (hereinafter in this section referred to as the 'Council') which shall consist of eleven physicians, not otherwise in the employ of the United States, appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service. Establishment; membership. 5 USC 101 et seq.

"(2) Members of the Council shall be appointed for a term of three years and shall be eligible for reappointment. Term of membership.

"(3) The Secretary shall from time to time designate one of the members of the Council to serve as Chairman thereof.

"(b) Members of the Council shall consist of physicians of recognized standing and distinction in the appraisal of medical practice. A majority of such members shall be physicians who have been recommended by the Secretary to serve on the Council by national organizations recognized by the Secretary as representing practicing physicians. The membership of the Council shall include physicians who have been recommended for membership on the Council by consumer groups and other health care interests. Qualifications.

"(c) The Council is authorized to utilize, and the Secretary shall make available, or arrange for, such technical and professional consultative assistance as may be required to carry out its functions, and the Consultants.

33-013 O - 74 - pt. 2 - 6

Secretary shall, in addition, make available to the Council such secretarial, clerical and other assistance and such pertinent data prepared by, for, or otherwise available to, the Department of Health, Education, and Welfare as the Council may require to carry out its functions.

Compensation.

"(d) Members of the Council, while serving on business of the Council, shall be entitled to receive compensation at a rate fixed by the Secretary (but not in excess of the daily rate paid under GS-18 of the General Schedule under section 5332 of title 5, United States Code), including traveltime; and while so serving away from their homes or regular places of business, they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in Government service employed intermittently.

5 USC 5332 note.

Duties.

"(e) It shall be the duty of the Council to—

"(1) advise the Secretary in the administration of this part;

"(2) provide for the development and distribution, among Statewide Professional Standards Review Councils and Professional Standards Review Organizations of information and data which will assist such review councils and organizations in carrying out their duties and functions;

"(3) review the operations of Statewide Professional Standards Review Councils and Professional Standards Review Organizations with a view to determining the effectiveness and comparative performance of such review councils and organizations in carrying out the purposes of this part; and

"(4) make or arrange for the making of studies and investigations with a view to developing and recommending to the Secretary and to the Congress measures designed more effectively to accomplish the purposes and objectives of this part.

Report to Secretary and Congress.

"(f) The National Professional Standards Review Council shall from time to time, but not less often than annually, submit to the Secretary and to the Congress a report on its activities and shall include in such report the findings of its studies and investigations together with any recommendations it may have with respect to the more effective accomplishment of the purposes and objectives of this part. Such report shall also contain comparative data indicating the results of review activities, conducted pursuant to this part, in each State and in each of the various areas thereof.

"APPLICATION OF THIS PART TO CERTAIN STATE PROGRAMS RECEIVING FEDERAL FINANCIAL ASSISTANCE

"SEC. 1164. (a) In addition to the requirements imposed by law as a condition of approval of a State plan approved under any title of this Act under which health care services are paid for in whole or part, with Federal funds, there is hereby imposed the requirement that provisions of this part shall apply to the operation of such plan or program.

"(b) The requirement imposed by subsection (a) with respect to such State plans approved under this Act shall apply—

"(1) in the case of any such plan where legislative action by the State legislature is not necessary to meet such requirement, on and after January 1, 1974; and

"(2) in the case of any such plan where legislative action by the State legislature is necessary to meet such requirement, whichever of the following is earlier—

"(A) on and after July 1, 1974, or

"(B) on and after the first day of the calendar month which first commences more than ninety days after the close of the first regular session of the legislature of such State which begins after December 31, 1973.

"CORRELATION OF FUNCTIONS BETWEEN PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS AND ADMINISTRATIVE INSTRUMENTALITIES

"SEC. 1165. The Secretary shall by regulations provide for such correlation of activities, such interchange of data and information, and such other cooperation consistent with economical, efficient, coordinated, and comprehensive implementation of this part (including, but not limited to, usage of existing mechanical and other data-gathering capacity) between and among—

"(a) (1) agencies and organizations which are parties to agreements entered into pursuant to section 1816, (2) carriers which are parties to contracts entered into pursuant to section 1842, and (3) any other public or private agency (other than a Professional Standards Review Organization) having review or control functions, or proved relevant data-gathering procedures and experience, and 79 Stat. 297. 42 USC 1395h. 42 USC 1395u.

"(b) Professional Standards Review Organizations, as may be necessary or appropriate for the effective administration of title XVIII, or State plans approved under this Act. 42 USC 1395.

"PROHIBITION AGAINST DISCLOSURE OF INFORMATION

"SEC. 1166. (a) Any data or information acquired by any Professional Standards Review Organization, in the exercise of its duties and functions, shall be held in confidence and shall not be disclosed to any person except (1) to the extent that may be necessary to carry out the purposes of this part or (2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care.

"(b) It shall be unlawful for any person to disclose any such information other than for such purposes, and any person violating the provisions of this section shall, upon conviction, be fined not more than $1,000, and imprisoned for not more than six months, or both, together with the costs of prosecution. Penalty.

"LIMITATION ON LIABILITY FOR PERSONS PROVIDING INFORMATION, AND FOR MEMBERS AND EMPLOYEES OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS, AND FOR HEALTH CARE PRACTITIONERS AND PROVIDERS

"SEC. 1167. (a) Notwithstanding any other provision of law, no person providing information to any Professional Standards Review Organization shall be held, by reason of having provided such information, to have violated any criminal law, or to be civilly liable under any law, of the United States or of any State (or political subdivision thereof) unless—

"(1) such information is unrelated to the performance of the duties and functions of such Organization, or

"(2) such information is false and the person providing such information knew, or had reason to believe, that such information was false.

"(b) (1) No individual who, as a member or employee of any Professional Standards Review Organization or who furnishes profes-

sional counsel or services to such organization, shall be held by reason of the performance by him of any duty, function, or activity authorized or required of Professional Standards Review Organizations under this part, to have violated any criminal law, or to be civilly liable under any law, of the United States or of any State (or political subdivision thereof) provided he has exercised due care.

"(2) The provisions of paragraph (1) shall not apply with respect to any action taken by any individual if such individual, in taking such action, was motivated by malice toward any person affected by such action.

"(c) No doctor of medicine or osteopathy and no provider (including directors, trustees, employees, or officials thereof) of health care services shall be civilly liable to any person under any law of the United States or of any State (or political subdivision thereof) on account of any action taken by him in compliance with or reliance upon professionally developed norms of care and treatment applied by a Professional Standards Review Organization (which has been designated in accordance with section 1152(b)(1)(A)) operating in the area where such doctor of medicine or osteopathy or provider took such action but only if—

Ante, p. 1430.

"(1) he takes such action (in the case of a health care practitioner) in the exercise of his profession as a doctor of medicine or osteopathy (or in the case of a provider of health care services) in the exercise of his functions as a provider of health care services, and

"(2) he exercised due care in all professional conduct taken or directed by him and reasonably related to, and resulting from, the actions taken in compliance with or reliance upon such professionally accepted norms of care and treatment.

"AUTHORIZATION FOR USE OF CERTAIN FUNDS TO ADMINISTER THE PROVISIONS OF THIS PART

"SEC. 1168. Expenses incurred in the administration of this part shall be payable from—

"(a) funds in the Federal Hospital Insurance Trust Fund;

"(b) funds in the Federal Supplementary Medical Insurance Trust Fund; and

"(c) funds appropriated to carry out the health care provisions of the several titles of this Act;

in such amounts from each of the sources of funds (referred to in subsections (a), (b), and (c)) as the Secretary shall deem to be fair and equitable after taking into consideration the costs attributable to the administration of this part with respect to each of such plans and programs.

"TECHNICAL ASSISTANCE TO ORGANIZATIONS DESIRING TO BE DESIGNATED AS PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"SEC. 1169. The Secretary is authorized to provide all necessary technical and other assistance (including the preparation of prototype plans of organization and operation) to organizations described in section 1152(b)(1) which—

"(a) express a desire to be designated as a Professional Standards Review Organization; and

"(b) the Secretary determines have a potential for meeting the requirements of a Professional Standards Review Organization;

to assist such organizations in developing a proper plan to be submitted to the Secretary and otherwise in preparing to meet the requirements of this part for designation as a Professional Standards Review Organization.

"EXEMPTIONS OF CHRISTIAN SCIENCE SANATORIUMS

"SEC. 1170. The provisions of this part shall not apply with respect to a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts."

Appendix B

Selected Speeches by Senator Bennett Concerning the PSRO Provision

Selected Speeches By Senator Bennett

[From the Congressional Record, July 1, 1970]

Professional Standards Review Organization Act of 1970

Mr. Bennett. Mr. President, in the near future, I intend to offer an amendment to the social security bill now before the Finance Committee, which would require, over a period of time, establishment of medical professional standards review organizations throughout the country.

All of us are deeply concerned over the multi-billion-dollar cost overruns in medicare and medicaid. In good part, those excessive costs resulted from an enormous infusion of new money into an already overburdened health care system with fragmented organization and control mechanisms. In fact, those same factors are inflating the costs of care for the total population.

I believe the American people are justifiably concerned over the tremendous costs of health care. Much of that concern, it seems to me, is a product of a very real feeling that we are not getting what we are paying for. I believe, equally, that much of the apprehension, anxiety, and suspicion now prevalent—for better or worse—with respect to those responsible for health care would disappear if professional standards review organizations were established and functioned effectively. It seems to me that the American people are entitled to know that American medicine shares their concern—and more importantly—proposes to do something substantial about it through means of professional standards review organizations.

It was in that spirit of genuine concern and a genuine desire to assume a personal responsibility in developing an effective review program that organized medicine through the American Medical Association began to dig into this problem.

Eventually, in mid-May, I was contacted by staff members of the AMA who asked me to consider introducing a proposal that they were developing to establish "peer review organizations" in each State to review doctors' services and charges under Part B of medicare.

I welcomed very much this thoughtful approach by the professionals involved and I forwarded their proposal to the Finance Committee staff for comment and analysis in terms of their experience with the medicare and medicaid programs and in light of hearings and other review activities.

The committee staff advised me that the AMA draft was "definitely a step in the right direction" and that the staff also welcomed this opportunity to dig into the entire question from a peer review standpoint.

We did find, however, that the Finance Committee staff felt that, in its opinion, the AMA plan was unduly limited and a number of suggestions, modifications, and extensions were recommended to me that the staff believed would reflect the attitude in their recent report on medicare and medicaid that: "The key to making the present system workable and acceptable is the physician and his medical society."

Mr. President, the AMA draft as modified by the suggestions of the Finance Committee staff provides the basis of this proposed amendment which I shall later propose.

Now it is very easy to speak of recognizing the entire health care system in the Nation through Federal control and financing. Some of us who have been engaged since the beginning in extensive evaluation of medicare and medicaid know full well that those objectives of many well-intentioned persons are far more easily talked about than reached. But Government control is not the answer, because there is potentially a better, more effective, and more suitable answer available.

As a matter of fact, careful and detailed study has indicated that the Federal Government and its agents do not presently have the capacity to properly administer medicare and medicaid—let alone to cope with the health care needs of millions of additional persons and reorganize the American medical care system.

I believe that physicians, properly organized and with a proper mandate, are capable of conducting an ongoing effective review program which would eliminate much of the present criticism of the profession and help enhance their stature as honorable men in an honorable vocation willing to undertake necessary and broad responsibility for overseeing professional functions. If medicine accepts this role and fulfills its responsibility, then the Government would not need to devote its energies and resources to this area of concern. Make no mistake; the direction of the House-passed social security bill is toward more—not less—review of the need for and quality of health care. I believe my amendment would provide the necessary means by which organized medicine could assume responsibility for that review.

In my opinion, if ultimately enacted, the "Professional Standards Review" proposal now being drafted would provide physicians with an imaginative and exciting opportunity to assume basic responsibility for reviewing health care as a whole. It would scrap the piecemeal review activities of varying effectiveness which have prevailed since 1966.

My thought in having the amendment prepared at this time is that it will benefit from thorough discussion and evaluation during the course of hearings in the Finance Committee on the social security bill. I would urge all Senators and other interested parties carefully to study and to comment on it. Undoubtedly, it will gain from the "light of day" and be modified and improved. Nonetheless, as will be readily understood from the outline which follows, I think the direction is clear.

As I have noted the American Medical Association has indicated its concern with a need for expanded review activities. The staff of the Finance Committee, in its report, reached the same conclusion. However, in essence, the AMA proposal would limit review activities to services directly rendered by physicians. In my opinion, to be effective we have to go considerably further.

Now let me explain the principal features and rationale of my proposal. First, utilization of all health care services, both inpatient and outpatient, is after all determined by the physician. Physicians' direct services account for a relatively small proportion of the Federal health care dollar costs. The bulk of those dollar costs go for institu-

tional care—hospital and nursing home—which is ordered by physicians. Since the physician determines the usage of institutional care it seems appropriate to charge him with the responsibility for its review, as well as for the review of those services directly provided by his peers—other physicians. This sort of unified review approach avoids the fragmented methods employed today. The hearings which the Finance Committee has held have shown that very substantial savings have resulted where medical societies and related organizations—such as medical care foundations—have assumed responsibility for prior approval and review of need for medical, hosiptal, and nursing home care.

Thus, my proposal would include in the review groups' mandate, responsibility for reviewing the totality of care provided patients—including all institutional care. Commensurate with that responsibility, cooperation with professional standards review organizations would be a contractual obligation of insurance carriers, intermediaries, fiscal agents, and all providers, as well as being required of all public agencies involved.

Second, under my amendment basic responsibility for the necessary review work would be lodged, wherever possible and wherever feasible, at the local community level. Local emphasis is necessary because the practice of medicine may vary, within reasonable limits, from area to area, and local review assures greater familiarity with the physicians involved and ready access to necessary data. Priority should be given to arrangements with local medical societies—of suitable size—which are willing and capable of undertaking comprehensive professional standards review. Other organizations—such as the Kaiser Foundation and similar foundations—should also be employed where they are representative of a substantial proportion of health care practitioners in a given geographic or medical service area, provided they are doing a good job.

Of course, the Secretary of Health, Education, and Welfare—who would contract for the review work—could also contract with a State medical society in a State where for reasons of size, population, or choice of local medical societies, that approach would work out best. Thus, in a small or sparsely populated State it might be that the State medical society would provide the most effective means for review.

Under the amendment, the Secretary could use State or local health departments or employ other suitable means of undertaking professional standards review only where the medical societies were unwilling or unable to do the necessary work, or where their efforts were only pro forma or token. Let me emphasize as strongly as possible that the thrust of this proposal is to have physicians, as a group, evaluate physicians and the services they provide and order as individuals.

Now that I have described some of the structure and some of the responsibility in my amendment, let me indicate what the professional standards review should encompass, and the assurances it should provide to the profession and to the public. It should determine that only medically necessary services are provided by physicians, hospitals, nursing homes, pharmacies, and so forth. Further, it should determine that the medically necessary care and services meet, within reasonable limits of professional standards. Finally, where medically appropriate, it should make certain that less costly alternative modes and sites of

treatment are brought to the attention of the physician, and that he is encouraged to employ them.

The regular review of all care for all medicare and medicaid patients should include regular examination of patient, practitioner and other health care provider services and charges profiles; independent medical audits; on-site audits; and other professional review procedures. The Professional Standards Review Organization should apply norms of care and treatment by diagnosis, age, and other medically relevant factors for inpatient and outpatient care. These norms of care and treatment should be used as checkpoints in evaluating the appropriateness of treatment, and the Professional Standards Review Organization should routinely secure, review, and approve written justification from physicians for departures from these norms.

Under the proposal, a statewide professional review council would be established consisting of one representative from each of the local professional standards review organizations, two physicians designated by the State medical society, and two physicians from the State designated by the Secretary as public representatives. The statewide council could help coordinate review activities within the State and could regularly review and report to the Secretary on the work of the local organizations within the State. A statewide advisory group to the State review council could also be established, which could consist of representatives of major types of health care providers and practitioners such as hospitals, nursing homes, dentists, pharmacists, and so forth. This group would serve as a liaison and advisory body to the State review council. Additionally, it would be expected that the local Professional Standards Review Organizations would subcontract or retain consultants, such as pharmacists, dentists, or medical specialists, to provide specialized professional counsel and assistance in making their reviews.

Completing the structure, the Secretary of Health, Education, and Welfare would establish a national advisory council to collect and distribute data and other information—for example, comparisons of differences in norms of care in different geographic areas—which would be helpful to State and local review bodies. The national council would also report regularly to the Secretary and Congress on the overall and area-by-area effectiveness of the professional standards review program. A majority of the members of the national council would be selected from nominees of organizatins representing physicians, with the balance consisting of representatives of the related services—pharmacy, dentistry, hospitals, nursing homes, and so forth.

Where a professional standards review organization finds that voluntary and educational efforts fail to correct or remedy an improper situation, it would hold a formal hearing and then transmit its recommendations to the Secretary and other professional or governmental organizations concerned. Protective appeals procedures would be afforded practitioners with respect to whom sanctions have been recommended.

Disciplinary recommendations by the Professional Standards Review Organization would be in proportion to the offense and may include:

First. Monetary penalties.

Second. Suspension from Federal programs.

Third. Exclusion from Federal programs.

Fourth. Civil or criminal prosecution.

Fifth. Movement leading to the suspension or revocation of professional licensure.

The records of the local Professional Standard Review Organization would be generally confidential.

The recommendation of the Professional Standards Review Organization would go to the Secretary through the Statewide Review Council, which would be free to offer the Secretary its own comments and advice with respect to the local organization's recommended sanction. The actual imposition of sanctions would be ordered by the Secretary, who, under the amendment in considering that order, would give great weight to the recommendations of the physician organization.

To protect conscientious members of review panels, they would not be liable for damages with respect to the discharge of their review duties, nor would an action lie against a person providing information without malice and believing it to be accurate.

The costs of establishing and operating the Professional Standards Review Organizations and the various statewide and advisory councils would be borne by the Federal Government. To the greatest extent possible, I would expect that existing computer and other resources would be utilized and that operations would be consolidated wherever feasible. However, the review activity and responsibility must in every instance rest with the Professional Standards Review Organization. In other words, Blue Cross and Blue Shield and private health insurers would not be allowed to assume the basic responsibilities for the physicians. Such organizations could be employed to provide computer and similar data to the Professional Standards Review Organization but no middlemen should do the job for professional medicine.

The professional standards review organizations would also have the potential of serving as a means of assuring professional control in health care for the non-medicare and medicaid population. There is demonstrated capacity in such organization to moderate the rising costs of health care and to improve the quality of medical service for all Americans.

I recognize that the proposed amendments, if adopted, would effect changes in the traditional relationship of medical societies and hospitals. Under the proposal, professional standards review organizations would be quite directly concerned with hospitalization—its need, its duration, and the types and extent of services provided in the hospital. But hospitals, after all, are settings designed to enhance and improve the practice of medicine under suitable circumstances. Only physicians practice medicine. They should assume responsibility for its proper practice—wherever the location, in office, in hospital, or in home.

Again, Mr. President, I will offer this amendment within the next few weeks. Hopefully, it will be received in the spirit in which it will be offered—as a stimulus for development of an appropriate professional mechanism for assuring protection of the legitimate interests of patients, physicians, and the Government.

To that end, this bill is offered not as a definitive solution, but basically as a substantial point of departure to give all concerned an oppor-

tunity to help us work out the foundation for what I believe may well be the major step in bringing order and commonsense into what is rapidly becoming a more and more chaotic and costly situation.

With that in mind, Mr. President, I ask unanimous consent to have printed at this point in the RECORD an article published in today's Washington Post, under the headline "Two Hospitals Raise Room Rates."

There being no objection, the article was ordered to be printed in the Record, as follows:

TWO HOSPITALS RAISE ROOM RATES

(By Stuart Auerbach)

Two Washington hospitals today will increase their room charges, signaling the start of another upward swing in the already high cost of hospital care in the area.

Georgetown University Hospital, which cares for more than 12,000 patients a year, will increase the cost of its semiprivate rooms by $5 a day—to $67.

The daily cost of semiprivate rooms at the Washington Hospital Center, the largest private health facility in the area with more than 35,000 admissions a year will go up by $7—to $62.

In addition, George Washington University Hospital officials said yesterday, they are planning to raise room rates soon by a still undetermined amount.

Georgetown, George Washington and the Hospital Center are the most influential hospitals in the area and generally set the pace for the other institutions.

The increases at those hospitals come on top of an averaging 15 per cent jump in the cost of rooms at all hospitals in the area during the past 16 months.

The total cost of hospitalization in the Washington area—including room charges—already is far above the national average, Group Hospitalization Inc., the local Blue Cross plan, reported in June.

GHI officials said this is because both salaries and the cost of living in the Washington area are among the highest in the nation.

Nationally, the American Hospital Association reported that the total cost of being in a hospital for a day averaged $67.59 last year, an increase of $7 a day. The cost of hospitalization in Washington was more than $80 a day.

The Hospital Center's increase in the price of a semi-private room amounts to 13 per cent. Private rooms also will go up—from $68 to $75 a day.

The Georgetown Hospital rate increase amounts to 8 percent. Small private rooms will go up from $75 to $80 a day, and large private room rates will increase from $80 to $85 a day.

While George Washington Hospital has not decided by how much and when it will raise its room rates, officials announced increased prices starting today for such facilities as the operating, recovery and delivery rooms, and the nursery and for medical supplies.

All three hospitals cited rising labor costs as the prime reason for the increases. In addition, George Washington said it loses money caring for indigent patients from Washington since the city only reimburses it $38 a day—less than half its total medical costs, per patient.

Joseph Curl, Georgetown's administrator, said the increased costs of the new medical equipment also is driving up the cost of hospitalization.

Wages account for at least 60 per cent of hospital costs. But GHI officials said they have noted that cost of new equipment is taking an increasingly large percentage of a hospital's budget.

This especially is true of teaching hospitals such as Georgetown, George Washington and the Hospital Center, which like to have the most modern equipment possible to train their medical students.

A GHI survey published in June showed that the 21 largest private hospitals in the area raised their room rates by an average of 14.6 per cent between February, 1968, and February, 1969. Since then, Prince Georges County Hospital raised its rates.

The individual hospital increases ranged from 7.7 per cent to 30 per cent. Some increases for semiprivate rooms were $4 a day, but Doctors Hospital raised its charges $15.

There are no signs the cost of hospitalization will level off. The American Hospital Association says that the average daily cost in the nation probably will rise to $74.24 this year and $98.37 in 1973.

[From the Congressional Record, Aug. 20, 1970]

Social Security Amendments of 1970—Amendment

Mr. Bennett. Mr. President, on July 1, I informed the Senate of my intention to offer an amendment to the social security bill now pending in the Finance Committee to provide a new system of professional review of health services provided under our Federal health plans. The proposal was outlined in substantial detail in my speech. At that time, I indicated that its genesis was in a draft given me by the American Medical Association. My amendment, however, is more comprehensive and more positive. In addition, it shifts the primary emphasis for review from State and medical societies to local societies. The amendment also contains a number of provisions assuring public accountability and responsibility.

That amendment, which I am submitting today, would authorize the establishment of professional standards review organizations, generally at local levels, as the primary mechanism to control and moderate the soaring costs of medicare and medicaid.

We have learned from long, hard, and costly experience that the Federal Government and its various public and private agents generally have been unable effectively to monitor and assure economical and efficient use of properly provided health care services in medicare and medicaid. What we must have are assurances that, in medicare and medicaid, only services necessary to proper health care are provided; that those services are provided on a basis consistent with professional standards; and that where medically appropriate, less costly alternative modes and sites of health care are called to the attention of the attending physician.

Unquestionably, those necessary determinations can best be made by health care professionals who recognize and accept the need to provide those assurances as a legitimate responsibility and concern of their profession.

Thus, my amendment provides that Professional Standards Review Organizations would be established in each area of the country, with the Secretary of Health, Education, and Welfare giving priority to designating qualified local medical societies as those review organizations.

Let me explain what is meant by a "qualified" medical society. In some cases, it would involve groupings of local societies, or possibly multicounty organizations. In other areas, State medical societies might be designated as the Professional Standards Review Organization. In any event, however, a medical society must be willing and capable of assuming responsibility for the on-going review and approval of all health care services rendered or ordered by physicians and of making suitable arrangements for the review of other health care services rendered by nonphysicians. All of this would be under-

taken in accordance with a formal plan for progressive assumption of review responsibilities which would be approved by the Secretary of Health, Education, and Welfare.

Where organized medicine is unwilling or unable to assume the responsibilities of a Professional Standards Review Organization, or where the performance of a particular organization is only pro forma or token, the amendment contemplates that the Secretary would arrange for the designation of another private or public organization or agency which has the professional competence to undertake the necessary functions.

All Professional Standards Review Organizations initially will be approved on a conditional basis—not to exceed a period of 2 years. During that trial period, all existing review mechanisms would continue to function until such time as the Professional Standards Review Organization effectively and satisfactorily has demonstrated its capacity to perform an equivalent or superior review. The amendment would give up none of the review mechanisms we now have until there is solid proof that the new organization can do better.

The on-going review would involve maintenance and, regular examination of patient, practitioner, and provider profiles of care and service. Additionally, the Professional Standards Review Organization would be responsible for approval in advance of all elective admissions to hospitals and nursing homes. Emergency admissions obviously should not require prior approval, and under my amendment they would not. There would be a subsequent review and a need for further approval by the Professional Standards Review Organization where a physician desires that his patient remain in the hospital beyond the average stay for patients of a given age and condition.

I would stress at this point the fact that objective and impartial review must be provided by a Professional Standards Review Organization. Malice and vendettas by members of the review group against other practitioners are by definition "nonprofessional" and in the unlikely event of such occurrences, I would expect that the Secretary of Health, Education, and Welfare, in the absence of immediate voluntary corrective action by the organization would promptly act to terminate the contract with that organization.

Following my July 1 speech, I have talked with a number of groups representing several health professions and medical specialty organizations. All stressed their interest in peer review. Most expressed concern that review activities be performed by actual peers. In other words, they feel that any review of a medical specialist such as a neurosurgeon should be performed by other neurosurgeons. Others stated that review of health services such as physical therapy should be the responsibility of other physical therapists.

The amendment, I believe, essentially and effectively deals with these concerns. Responsibility for review is placed with physicians, since it is the physician who is ultimately responsible for ordering or providing virtually all health care services. However, the local Professional Standards Review Organizations would have authority to engage and would be expected to utilize medical specialists such as neurosurgeons for specialty review. Similar arrangements could be made with those qualified to review physical therapy and other health services.

Under the amendment Professional Standards Review Organizations are to apply professionally developed regional norms of care and treatment in their review process. There is a large body of readily available data on length of hospital stay by age and diagnosis in all areas of the country. For example, the Committee on Professional and Hospital Activities, an organization sponsored by the American Hospital Association, the American College of Physicians, and the American College of Surgeons has developed comprehensive published data based upon many millions of hospital discharges—which indicate average lengths of stay by age, diagnosis and areas of the country.

This type of data would be used by the National Professional Standards Review Council in publishing norms of care by regions for use by the Local Professional Standards Review Organizations.

During work on the amendment, it became obvious that the present system of medicare recertification of need for hospital care makes little sense from a professional standpoint. Currently, a physician must recertify as to continuing need for hospitalization at the 12th hospital day. This point was selected arbitrarily, and bears no relation to whether the patient's age and illness would usually warrant a longer or shorter hospital stay.

With professionally developed data available, it would be far more sensible, and efficient, for the Professional Standards Review Organizations to apply the average length of stay for a given diagnosis as a checkpoint for review of continued need for hospitalization, and this is what my amendment proposes.

The professionally developed and published norms of care which would be applied under the proposed amendment are intended to be review checkpoints. They are not proposed as barriers to any additional care that may be needed beyond the predetermined checkpoint.

There is no intention either in the operation of the Professional Standards Review Organizations or in the application of norms of care and treatment to stifle innovative medical practice or procedure or to inhibit the exercise of reasonable professional discretion. The objectives of the proposal are reasonableness—not conformism in medical practice.

Any information acquired by a review organization in discharging its responsibilities would in general be confidential and available only for program purposes or to protect the rights of patients, practitioners, and providers. Violation of confidentiality would be punishable by up to 6 months imprisonment and a fine of up to $1,000.

Many of the provisions in the amendment are patterned after medical society sponsored foundations, such as the San Joaquin and Sacramento Foundations in California.

Spokesmen for these foundations testified before the Finance Committee that it would be easier for them to do an effective job of review if they could also assume responsibility and risk with respect to the review and payment of claims.

I have included in my amendment a provision authorizing demonstration programs so that the Secretary can contract with Professional Standards Review Organizations on an insured basis. This would permit comparison of results between Professional Standards Review Organizations where risk is assumed and those where no risk is undertaken.

Mr. President, the intent, substance, and safeguards of my amendment may be determined through a reading of the amendment itself and a section-by-section summary of its provisions. I, therefore, ask unanimous consent that both the amendment [1] and the summary be printed in the Record at the conclusion of my remarks.

I do not contend that the amendment is incapable of improvement. It is, however, the product of a great deal of effort and consultation. Hopefully, during the course of the next several weeks and during public hearings on the social security bill in September, the amendment can be refined and further improved on the basis of the informed and thoughtful comments and suggestions of concerned and interested citizens and organizations.

All of us, Mr. President, share a common concern with the need to assure reasonable professional controls in medicare and medicaid—in fact, in our entire health care system.

The amendment which I submit today was prepared and is offered in a spirit of meeting the legitimate concerns of millions of citizens who depend upon medicare and medicaid, the professions concerned with providing health care, and the public interest in general. I invite all of my colleagues to join with me in sponsoring this amendment.

The summary, presented by Mr. Bennett, is as follows:

PROFESSIONAL STANDARDS REVIEW—MEDICARE AND MEDICAID

SECTION-BY-SECTION SUMMARY OF AMENDMENT

Declaration of purpose

SEC. 1151. Purpose of the subtitle is to promote effective, efficient and economical delivery of health services for which payment may be made under the Social Security Act, through application of professional standards review procedures which would assure that such services are of appropriate quality, and are provided only when necessary and then in the most economical fashion consistent with professional recognized health care standards.

Designation of Professional Standards Review Organization (PSRO)

SEC. 1152. The Secretary of Health, Education, and Welfare shall at the earliest practicable date, but prior to January 1, 1972, enter into agreements in each area of the United States with qualified organizations to serve as Professional Standards Review Organizations (PSRO).

In making such agreements, the Secretary would give first priority to local medical societies or subsidiary organizations which represent a substantial portion of physicians in the area. Where such groups are unable or unwilling to enter into agreements, the Secretary would make such agreements with other private nonprofit, public, or other agency or organization with professional competence.

The agreement shall provide that the designated organization will perform the duties and functions of a PSRO and that the Secretary shall pay for reasonable and necessary expenses. Agreements shall be for periods of 12 months, and may be terminated by the organization upon reasonable notice, or by the Secretary after a formal hearing.

Review pending designation of Professional Standards Review Organizations

SEC. 1153. Pending assumption of responsibility, and demonstration of capacity for improved review efforts by a PSRO, presently authorized review and audit activities shall be continued.

Trial period for Professional Standards Review Organizations

SEC. 1154 (from the PSRO). The Secretary shall, after recipt and approval of a formal plan for progressive assumption of full responsibility, initially desig-

[1] The amendment is not reproduced in this document.

nate an organization as a PSRO on a conditional basis. During the trial period (not to exceed 24 months) the Secretary may require the PSRO to perform only such duties and functions as he deems them capable of performing. Assumption of responsibility for duties should proceed in accordance with the approved plan, so that at the end of the trial period, the PSRO is performing all required duties and functions.

An agreement by which an organization is *conditionally* designated as a PSRO may be terminated by either party on 90 days' notice.

Any duties and functions not performed by a PSRO during the trial period shall continue to be performed as presently authorized. The Secretary is authorized to waive any other review requirements where he finds, based on substantial evidence, that the PSRO meets or exceeds those requirements.

Duties and functions of Professional Standards Review Organization

SEC. 1155. It shall be the duty and function of each PSRO to assume responsibility for review of the professional activities of health care practitioners and providers with respect to health care services for which payment may be made under the Social Security Act. Such review shall be for the purpose of determining whether the services are necessary to proper health care; meet recognized professional standards of health care; and are provided in the most economical fashion consistent with recognized standards of care.

Each PSRO shall also determine, in advance, that elective inpatient admissions of extended, costly out-patient courses of therapy meet the above criteria. Hospital admissions shall be approved for periods certain related to patient age and diagnosis; and recertification by the attending physician shall be necessary for extensions of the period initially approved.

Each PSRO shall be responsible for the development, maintenance and review of practitioner, patient, and provider service profiles.

Each PSRO is authorized to: utilize specialists as needed in the review process; undertake necessary professional inquiries; and examine pertinent records and sites of care.

Norms of health care services for various illnesses or health conditions

SEC. 1156. Each PSRO shall apply professionally-developed and published norms of care and treatment based upon patterns of practice in the region as principal points of evaluation and review in determining quality and medical necessity of services.

Where actual norms is an area differ significantly from regional norms, the PSRO can, with approval of the National Professional Standards Review Council, apply such norms in its geographic area. The National Review Council shall prepare and distribute to each PSRO appropriate materials concerning the regional and national norms to be utilized as initial checkpoints.

Submission of reports by professional standards review organizations

SEC. 1157. If a PSRO determines that a practitioner or provider has violated any obligation imposed by Sec. 1160, the PSRO shall transmit a report of findings and recommendation to the Secretary through the Statewide Professional Standards Review Council, which shall transmit the report and recommendations along with such comments as the Statewide Council deems appropriate.

Requirement of review approval as condition of payment of claims

SEC. 1158. Where a PSRO has reviewed and disapproved a proposed health care service, and has prior to the provision of such service, notified the practitioner and provider and the patient of the disapproval, no Federal funds appropriated under the Social Security Act shall be used for the payment of any claim for the provision of such disapproved services.

Notice to payor of disapproved claim

SEC. 1159. The PSRO, upon disapproval of a proposed service, shall promptly notify any claims payment agency concerned of such disapproval.

33-013 O - 74 - pt. 2 - 7

Obligation of Health Care Practitioner and Providers of Health Care Services—Sanctions and Penalties

SEC. 1160. It shall be the obligation of any health care practitioner or provider to assure that the services they provide, for which payment may be made under the Social Security Act will be provided: only when medically necessary; will meet recognized professional standards of health care; and in the case of inpatient services will be provided in the most economical facility consistent with professionally recognized health care standards.

If after reasonable notice and opportunity for discussion, a PSRO finds that a practitioner or provider has consistently failed to comply or has flagrantly failed to comply with his obligations, the PSRO may then recommend to the Secretary (and he may require) that such practitioners or providers pay a monetary penalty not to exceed $5,000 (as a condition of remaining eligible for program payments for his services) or the Secretary may temporarily or permanently exclude such practitioner or provider from the program.

Hearings and Review

SEC. 1161. Whenever a PSRO takes any action which denies approval of a proposed service, or indicates that a practitioner or provide has violated the obligation imposed upon him, the PSRO shall give notice to the practitioner or provider, and provide an appropriate opportunity for discussion and review.

Following such discussion and review any practitioner or provider who remains dissatisfied shall, upon request to the Secretary, be entitled to a hearing by the Secretary. Within 30 days after hearing the Secretary shall make a final determination on the matter.

A practitioner or provider who is dissatisfied with this final determination may within 60 days appeal such determination to the courts.

Statewide Professional Standards Review Councils: Advisory groups to such Councils

SEC. 1162. In each State with two or more Professional Standards Review Organizations the Secretary shall appoint a Statewide Professional Standards Review Council consisting of one representative from each PSRO, two physicians designated by the State Medical Society and two physicians from the State selected by the Secretary as public representatives.

It shall be the function of each council to coordinate the activities of and disseminate data among the various PSROs and promptly to transmit to the Secretary reports and recommendations received from the PSROs.

The Secretary shall make payments to cover reasonable and necessary expenses.

Each Statewide Council shall be advised and assisted by an Advisory Group consisting of representatives of the various types of health care practitioners (other than physicians) and providers, providing covered health care services in a State which it shall select in accordance with regulations prescribed by the Secretary.

National Professional Standards Review Council

SEC. 1163. There shall be established a National Professional Standards Review Council consisting of eleven physicians appointed by the Secretary for three-year terms. A majority of the members of the Council shall consist of physicians of recognized standing and distinction in the appraisal of medical practice nominated by one or more national organizations representing practicing physicians. The Secretary shall provide such personnel and other assistance as may be necessary for the Council to carry out its functions.

The Council shall advise the Secretary in the administration of this part; distribute among Statewide Councils and PSROs pertinent information and data; review the operation of PSROs with a view to determining their comparative effectiveness and performance; and approve or disapprove requests of PSROs for usage of other than regional norms. The National Council shall, at least annually, submit to the Secretary and the Congress a report on its activities, and comparative data indicating the results of review activities in each State and area.

Application of this amendment to certain State programs receiving Federal financial assistance

SEC. 1164. Provisions of this amendment shall apply to the operation of any State plan approved under the maternal and Child Health, Medicaid, Intermediate Care, and any other health care or health care related programs.

Correlation of functions between Professional Standards Review Organizations and administrative instrumentalities

SEC. 1165. The Secretary shall by regulation provide for correlation and cooperation between carriers, intermediaries, government agencies and PSROs. Such cooperation shall include usage of existing mechanical and other data gathering capacity.

Prohibition against disclosure of information

SEC. 1166. Any information acquired by a PSRO in the discharge of its functions shall be held in confidence, except as may be necessary to carry out the purposes of this part or to assure adequate protection of the rights of patients, practitioners or providers. Disclosures of information other than for such authorized purposes shall be unlawful and shall upon conviction be punishable by a fine of up to $1,000 and imprisonment for up to 6 months.

Limitation on liability for persons providing information and for members and employees of PSROs

SEC. 1167. Persons providing information and members or employees of PSROs shall in general not be liable if such information were genuine, and if any actions taken are not motivated by malice. An action shall be deemed to be motivated by malice if the individual or PSRO has consistently failed impartially to take similar action in similar circumstances involving other persons or providers.

Federal ownership of files, records and material

SEC. 1168. All files, records and materials of a PSRO or a Statewide Council shall be the property of the United States.

Authorization for use of certain funds to administer the provisions of the part

SEC. 1169. Expenses incurred in the administration of this part shall be payable from the Hospital Insurance Trust Fund, the Supplementary Medical Trust Fund, and funds appropriated for other Titles of the Social Security Act in such proportion as the Secretary deems to be equitable.

Authorization of demonstration projects

SEC. 1170. The Secretary is authorized to enter into agreements (ending not later than 1975) with such number of PSRO's as are necessary to permit a comparison of results where a PSRO assumes a financial risk for the payment of Medicare claims in contrast to areas where a PSRO does not assume financial risk.

Where a PSRO indicates a willingness and capacity to assume financial responsibility for the review and payment of all claims, reimbursement to such PSROs may be made on a capitation, prepayment, insured or related basis for renewable contract periods not exceeding one year. Such amounts may not exceed per capita beneficiary costs in the area concerned during the preceding 12-month period.

Where such agreements are negotiated provision shall be made for the PSRO to assume a risk by making payments for physicians' services at a rate not in excess of 80% of otherwise allowable amounts for such services.

Any sums remaining at the end of the agreement period shall be divided so that the Government receives 50% of the savings. The Government shall also receive amounts, if any, remaining after the PSROs have received the 20 percent or other risk factor withheld and an incentive payment not in excess of 25% of 100% of the physicians' allowable program charges during the agreement period.

Renewable agreements shall be at the base or initial year rate of payments adjusted for appropriate increases, if any, in the unit costs of covered services during the prior year.

[From the Congressional Record, Jan. 5, 1972]

PROFESSIONAL STANDARDS REVIEW FOR MEDICARE AND MEDICAID

Mr. BENNETT. Mr. President, today I offer an amendment to H.R. 1 authorizing the establishment of Professional Standards Review Organizations throughout the United States.

This amendment is virtually identical with the Professional Standards Review provision supported by the Department of Health, Education, and Welfare, and approved by the Finance Committee and the full Senate as part of H.R. 17550, the "Social Security Amendments of 1970." What few changes I have made in the amendment are essentially of a technical and conforming nature, apart from incorporation into the amendment itself of language and intent expressed in the Finance Committee report on the PSRO provisions. The principal change—section 1159—involves the addition of specific language assuring and safeguarding the right of a patient to appeal an adverse decision of a PSRO.

The Professional Standards Review Organizations would be formed by practicing physicians themselves who would assume responsibility for reviewing the care and services provided under medicare and medicaid, in order to assure that such services are medically necessary and meet proper quality standards. The review activity would be a sophisticated process which would encompass the use of provider, patient, and practitioner profiles, and professionally developed norms as review checkpoints.

The amendment is so structured that practicing physicians rather than Government agencies or insurance company personnel will decide whether care was necessary and of proper quality. At the same time, I have built numerous safeguards into the amendment to assure public accountability and proper and professional monitoring of the review organizations. These safeguards, while realistic and substantial, are designed so as not to hamper effective day-to-day decisionmaking at the local levels.

Mr. President, all of us in this Congress are familiar with the problem of the rapidly rising costs of health care. These rising costs affect all citizens through increased taxes, insurance premiums and medical bills. In addition, rising health care costs fall disproportionately on those who have the greatest need for health services—the chronically ill, the aged, and the poor. Many of us are all too familiar with the fact that increasing health care costs have resulted in a projected deficit totaling at least $242 billion in the medicare program over the next 25 years. It is less well known that the increase in health care costs has also resulted in the aged paying about as much now for medical care per year as they were paying prior to the enactment of medicare.

In addition to the rapidly rising cost of health care, a problem exists with respect to the quality of that care. The Committee on Finance held two extensive series of hearings on health care in 1970. In the spring of 1970, we held oversight hearings on medicare and medicaid and, in the fall, we held hearings on the social security amendments which contained many medicare changes. During the course of those hearings, disturbing testimony was heard bearing on the quality of

health care. We heard practicing physicians testify to the effect that in many areas of the country a good deal of unnecessary and avoidable surgery was being performed and excessive and inappropriate health care services provided. We learned of significant variations between sections of the country in the lengths of hospitalization for similar patients having a given illness.

As these problems of rising costs, unnecessary services and uneven quality became apparent, the most disturbing fact was that in most areas of the country no effective review mechanism exists whereby practicing physicians can in organized and publicly accountable fashion, determine on a comprehensive and ongoing basis if services are medically necessary and if they meet quality standards. This amendment would go a long way toward correcting that intolerable situation.

Mr. President, I ask unanimous consent that the section of the Finance Committee Press Release No. 66, dated September 30, 1970, describing the Professional Standards Review Organization amendment, as approved by the Committee, appear at this point in my remarks.

There being no objection, the summary was ordered to be printed in the RECORD, as follows:

SUMMARY OF THE AMENDMENT

The professional standards review mechanism would take effect along the following lines:

The Secretary of Health, Education, and Welfare would, after consultation with national and local health professions and agencies, designate appropriate PSRO areas throughout the Nation. This would be done by January 1, 1973. Area may cover an entire State (particularly those with smaller populations) or parts of a State, but generally a minimum of three hundred practicing doctors would be included within one PSRO area. Tentative area designations could be modified if, as the system was placed into practice, changes seemed desirable. The Secretary would also, in consultation with professional and other concerned organizations and interests, develop prototype review plans and would aid in the development of such plans with the view to securing acceptable arrangements for PSRO's in all areas and to gain experience with several patterns.

Organizations representing substantial numbers of physicians in an area, such as medical foundations and medical societies, would be invited and encouraged to submit plans meeting the requirements of the programs. Where the Secretary finds that such organizations are not willing or cannot reasonably be expected to develop capabilities to carry out PSRO functions in an effective, economical and timely manner, he may then enter into PSRO agreements with each other agencies or organizations with professional competence as he finds are willing and capable of carrying out PSRO functions. Formal plans would specify the extent and nature of cooperating arrangements with all agencies necessary to proper administration of the program.

It is expected that an acceptable plan will be one which encompasses in its proposed activities and responsibilities to the greatest extent possible physicians engaged in all types of practices in the PSRO area, i.e. solo, group, hospital and medical school-based practice, etc.

The Secretary would approve those plans which can reasonably be expected to improve and expand the professional review process. The initial approval is to be made on a conditional basis, not to exceed two years, with the review organizations operating concurrently with the present review system. During the transitional period, carriers and intermediaries (in the case of Medicare) are expected to abide by the decision of the PSRO where the PSRO has acted. This reliance will permit a more complete appraisal of the effectiveness of the conditionally-approved PSRO.

In areas where no adequate plan was initially submitted, the Secretary will seek to aid in the improvement and expansion of plans offered and to develop

plans through his own efforts, based upon organizations with professional competence such as State or local health agencies or claims paying organizations such as carriers and intermediaries if necessary.

Once an organization is accepted, the Secretary with the assistance of the Statewide organization and the National Advisory Council would monitor the performance of the PSRO plans using statistical and other appropriate means of evaluation. Where performance of an organization was determined unsatisfactory, and his efforts to bring about prompt necessary improvement fail, he could terminate its participation, after appropriate notice and opportunity for administrative hearing by the Secretary, if requested.

Provider, physician and patient profiles and other relevant data would be collected and reviewed on an ongoing basis to the maximum extent feasible to identify persons and institutions that provide services requiring more extensive review. Regional norms of care would be used in the review process as routine checkpoints in determining when excessive services may have been provided. The norms would be used in determining the point at which physician certification of need for continued institutional care would be made and reviewed. The physician, provider and patient profiles and other data would be collected in ways determined by the Secretary to be most efficient. The initial priority in assembling and using data and profiles would be assigned to those areas most productive in pinpointing problems so as to conserve physician time and maximize the productivity of physician review. The PSRO would be permitted to employ the services of qualified personnel, such as registered nurses who could, under the direction and control of physicians, aid in assuring effective and timely review.

Where advance approval by the review organizations for institutional admission is required, such approval would provide the basis for a presumption of medical necessity for purposes of Medicare and Medicaid benefit payments. However, if the review organization finds that ancillary services provided subsequent to its approval are excessive, payment under Medicare and Medicaid would be denied with respect to such excessive services.

Failure of a physician, institution or other health care supplier to seek advance approval where required may be considered cause for disallowance of affected claims.

In addition to acting on its own initiative, the review organization would report on matters referred to it by the Secretary. It would also recommend appropriate action against persons responsible for gross or continued overuse of services, use of services in an unnecessarily costly manner, or for inadequate quality of services; and would act to the extent of its authority or influence to correct improper activities.

The Secretary would be authorized upon recommendation of the PSRO to recover cost of excessive services—up to $5,000—from the practitioner, supplier or institution at fault.

A National Professional Standards Review Council—composed of physicians with a majority selected from nominees of national organizations representing practicing physicians, and in addition physcians recommended by consumers and other health care interests—would be established by the Secretary to review the operations of the local area review organizations, advise the Secretary on their effectiveness and make recommendations for their improvement.

Those persons engaged in review activities would be exempt from liability for actions taken in the proper performance of these duties. In addition, physicians, providers and others involved in the delivery of care would be exempted from liability arising from conformity to the recommendations of such review organizations.

Mr. BENNETT. Mr. President, I would like to again point out that organized medicine has also recognized the need for an effective formal cost and quality review mechanism for health care.

As I stated on July 1, 1970, in my first speech on the Professional Standards Review Organization proposal, I welcomed the opportunity to review the American Medical Association's own peer review proposal. As I considered it, it became clear to me that to be effective, the AMA peer review proposal would have to be substantially strengthened and expanded and public interest safeguards should be

added. An appropriate amendment incorporating such necessary changes was developed and introduced by me on August 20, 1970.

Mr. President, I think it would be helpful to briefly review events of the past year or so, in relation to the PSRO amendment. Following introduction of the amendment, the Committee on Finance held public hearings on social security amendments—including the PSRO proposal. During the course of those hearings, constructive suggestions were received from a variety of interested organizations and individuals, including hospital and medical organizations. The amendment was then considered in executive session, by the Finance Committee. The committee modified the amendment so as to include the constructive changes proposed during the hearings. As modified, the committee approved the amendment.

During floor consideration of the social security amendments in the Senate late in 1970, a motion was offered to strike the PSRO provisions. That move was overwhelmingly defeated. As Senators are aware, we were unable to arrange a conference with the House on the social security amendments due to the late date in the congressional session, so that the amendments did not become law.

I have been pleased that, as time has passed, the Professional Review amendment has gained increased support from those who have studied the proposal, including many medical societies and organizations.

Most recently, during initial hearings by the Finance Committee in July 1971 on H.R. 1, Secretary Richardson reiterated his support for the professional standards review approach and requested authority to proceed with formal implementation of these mechanisms.

In addition to gaining official support over the past year or so, the PSRO concept has become a working reality in States such as New Mexico, Colorado, and Georgia.

In New Mexico, for example, the State has turned over complete responsibility for medicaid medical review to an organization established by the physicians of the State. That organization was consciously structured along the lines of the PSRO amendment. It has effectively and equitably moderated medicaid costs which had previously soared out of hand. It has provided assurances that care of proper quality is being provided. As one of their first functions, the New Mexico doctors undertook a complete evaluation of each and every skilled nursing home patient. They determined, among other findings, that some 35 percent of the medicaid population in nursing homes were not in need of institutional care. This, to me, is dramatic evidence of the PSRO potential. Additionally, they are finding and acting to correct cases of under-utilization such as maternity patients who receive no prenatal care. They are also having an impact on the quality of care. For example, they have found instances where major abdominal surgery is performed without any X-rays prior to surgery. They are taking positive action to correct this type of deficiency and similar situation in the future.

In Colorado, the PSRO has reduced medicaid average lengths of hospital stay by more than 1 full day. Admissions to hospitals have been reduced by approximately 10 percent as well.

These are the kinds of results which PSRO can be expected to achieve.

Mr. President, the establishment of Professional Standards Review Organizations throughout the country would mean that each physician, as an integral part of his own professional responsibilities, would formally assume a shared responsibility for reviewing the quality of medical practice in his community.

In closing, I would like to make two points. First, I believe that the PSRO proposal becomes increasingly important in view of current legislative trends in health care. Any expansion of Federal health insurance obviously increases the need for a cost and quality review mechanism. Additionally, any emphasis on the use of Health Maintenance Organizations as a cost control mechanism demands the existence of an effective quality review mechanism capable of monitoring underservicing as well as overutilization of services.

Second, I want to reiterate that my amendment is firmly based on the principle that only physicians are capable of deciding whether a service is medically necessary or meets proper quality standards. Therefore, peer review must mean just that—only physicians should review physicians. As Chairman Wilbur Mills stated succinctly in a recent speech in Atlanta, Ga., favorably discussing PSRO: "Physicians represent the master key; there are no copies." Public agents and fiscal intermediaries should not second-guess individual determinations made in the course of peer review. Obviously, the public interest must be safeguarded. However, while only peers can review peers if my amendment becomes law, the Government, the public, and the professions can and should audit the review process itself to determine what review activities are occurring. Additionally, we can and should review aggregate statistics from each review organization in order to determine the overall effectiveness of the review process.

Mr. President, I believe that the relationship between the patient, the physician, and the Government is at a crossroads in America today.

The pressures for increased governmental involvement in the day-to-day practice of medicine are increasing continually as we move toward expanded governmental financing of health care. Economics, commonsense, and morality each demand that the Government take an increasingly active role in dealing with the cost and the quality of medical care.

I sincerely believe that the amendment I now send to the desk represents the best and perhaps the last opportunity to fully safeguard the public's concern with respect to the cost and quality of medical care while, at the same time, leaving the actual control of medical practice in the hands of those best qualified—America's physicians.

Mr. President, I ask unanimous consent that a section-by-section analysis and the text of the amendment itself appear at this point in the Record.

There being no objection, the analysis and amendment were ordered to be printed in the Record, as follows:

The summary, presented by Mr. Bennett, is as follows:

PROFESSIONAL STANDARDS REVIEW—MEDICARE AND MEDICAID

SECTION-BY-SECTION SUMMARY OF AMENDMENT

Declaration of purpose

SEC. 1151. Purpose of the subtitle is to promote effective, efficient and economical delivery of health services for which payment may be made under the

Social Security Act, through application of professional standards review procedures which would assure that such services are of appropriate quality, and are provided only when necessary and then in the most economical fashion consistent with professional recognized health care standards.

Designation of Professional Standards Review Organization (PSRO)

SEC. 1152. The Secretary of Health, Education, and Welfare shall at the earliest practicable date, but prior to January 1, 1973, enter into agreements in each area of the United States with qualified organizations to serve as Professional Standards Review Organizations (PSRO).

In making such agreements, the Secretary would give first priority to local medical organizations which represent a substantial portion of physicians in the area. Where such groups are unable or unwilling to enter into agreements, the Secretary would make such agreements with other private nonprofit, public, or other agency or organization with professional competence.

The agreement shall provide that the designated organization will perform the duties and functions of a PSRO and that the Secretary shall pay for reasonable and necessary expenses. Agreements shall be for periods of 12 months, and may be terminated by the organization upon reasonable notice, or by the Secretary after a formal hearing.

Review pending designation of Professional Standards Review Organization

SEC. 1153. Pending assumption of responsibility, and demonstration of capacity for improved review efforts by a PSRO, presently authorized review and audit activities shall be continued.

Trial period for Professional Standards Review Organization

SEC. 1154. The Secretary shall, after receipt and approval of a formal plan for progressive assumption of full responsibility, initially designate an organization as a PSRO on a conditional basis. During the trial period (not to exceed 24 months) the Secretary may require the PSRO to perform only such duties and functions as he deems them capable of performing. Assumption of responsibility for duties should proceed in accordance with the approval plan, so that at the end of the trial period, the PSRO is performing all required duties and functions.

An agreement by which an organization is *conditionally* designated as a PSRO may be terminated by either party on 90 days' notice.

Any duties and functions not performed by a PSRO during the trial period shall continue to be performed as presently authorized. The Secretary is authorized to waive any other review requirements where he finds, based on substantial evidence, that the PSRO meets or exceeds those requirements.

Duties and functions of Professional Standards Review Organization

SEC. 1155. It shall be the duty and function of each PSRO to assume responsibility for review of the professional activities of health care practitioners and providers with respect to health care services and items for which payment may be made under the Social Security Act. Such review shall be for the purpose of determining whether the services are necessary to proper health care; meet recognized professional standards of health care; and are provided in the most economical fashion consistent with recognized standards of care.

Each PSRO may also determine, in advance, that elective inpatient admissions or extended, costly out-patient courses of therapy meet the above criteria. Hospital admissions shall be approved for certain periods related to patient age and diagnosis; and recertification by the attending physician shall be necessary for extensions of the period initially approved.

A PSRO is authorized to accept "in-house" hospital review to the extent it meets the requirements and responsibilities of the PSRO.

Each PSRO shall be responsible for the development, maintenance and review of practitioner, patient, and provider service profiles.

Each PSRO is authorized to: utilize specialists as needed in the review process; undertake necessary professional inquiries; and examine pertinent records and sites of care.

Norms of health care services for various illnesses or health conditions

SEC. 1156. Each PSRO shall apply professionally-developed and published norms of care and treatment based upon patterns of practice in the region as principal points of evaluation and review in determining quality and medical necessity of services.

Where actual norms in an area differ significantly from regional norms, the PSRO can, with approval of the National Professional Standards Review Council, apply such norms in its geographic area. The National Review Council shall prepare and distribute to each PSRO appropriate materials concerning the regional and national norms to be utilized as initial checkpoints.

Submission of reports by Professional Standards Review Organization

Sec. 1157. If a PSRO determines that a practitioner or provider has violated any obligation imposed by Sec. 1160, the PSRO shall transmit a report of findings and recommendation to the Secretary through the Statewide Professional Standards Review Council, which shall transmit the report and recommendations along with such comments as the Statewide Council deems appropriate.

Requirement of review approval as condition of payment of claims

SEC. 1158. Where a PSRO has reviewed and disapproved a health care service, and has notified the practitioner and provider and the patient of the disapproval, no Federal funds appropriated under the Social Security Act shall be used for the payment of any claim for the provision of such disapproved services.

The PSRO, upon disapproval of a proposed service, shall promptly notify any claims payment agency concerned of such disapproval.

SEC. 1159. Provides beneficiaries and recipients with right to appeal adverse PSRO decisions to Statewide PSRO Councils and Secretary of HEW where amount involved is $100 or more.

Obligation of Health Care Practitioner and Providers of Health Care Services—Sanctions and Penalties

SEC. 1160. It shall be the obligation of any health care practitioner or provider to assure that the services they provide, for which payment may be made under the Social Security Act, will be provided: only when medically necessary; will meet recognized professional standards of health care; and in the case of inpatient services will be provided in the most economical facility consistent with professionally recognized health care standards.

If after reasonable notice and opportunity for discussion, a PSRO finds that a practitioner or provider has consistently failed to comply or has flagrantly failed to comply with his obligations, the PSRO may then recommend to the Secretary (and he may require that such practitioners or providers pay an amount related to the cost of unnecessary or excessive services not to exceed $5,000 (as a condition of remaining eligible for program payments for his services) or the Secretary may temporarily or permanently exclude such practitioner or provider from the program).

Notice to Practitioner or Provider

SEC. 1161. Whenever a PSRO takes any action which denies approval of a proposed service, or indicates that a practitioner or provider has violated the obligations imposed upon him, the PSRO shall give notice to the practitioner or provider, and provide an appropriate opportunity for discussion and review.

Statewide Professional Standards Review Councils: Advisory groups to such Councils

SEC. 1162. In each State with three or more Professional Standards Review Organizations the Secretary shall appoint a Statewide Professional Standards Review Council consisting of one representative from each PSRO, two physicians designated by the State Medical Society, two physicians nominated by the State Hospital Association and four public members knowledgeable in health care from the State selected by the Secretary as public representatives.

It shall be the function of each council to coordinate the activities of and disseminate data among the various PSROs and promptly to transmit to the Secretary reports and recommendations received from the PSROs and to otherwise assist the Secretary.

The Secretary shall make payments to cover reasonable and necessary expenses.

Each Statewide Council shall be advised and assisted by an Advisory Group consisting of representatives of the various types of health care practitioners (other than physicians) and providers, providing covered health care services in a State which it shall select in accordance with regulations prescribed by the Secretary.

National Professional Standards Review Council

SEC. 1163. There shall be established a National Professional Standards Review Council consisting of eleven physicians appointed by the Secretary for three-year terms. A majority of the members of the Council shall consist of physicians or recognized standing and distinction in the appraisal of medical practice nominated by one or more national organizations representing practicing physicians. The Secretary shall provide such personnel and other assistance as may be necessary for the Council to carry out its functions.

The Council shall advise the Secretary in the administration of this part; distribute among Statewide Councils and PSROs pertinent information and data; review the operation of PSROs with a view to determining their comparative effectiveness and performance; and approve or disapprove requests of PSROs for usage of other than regional norms. The National Council shall, at least annually, submit to the Secretary and the Congress a report on its activities, and comparative data indicating the results of review activities in each State and area.

Application of this amendment to certain State programs receiving Federal financial assistance

SEC. 1164. Provisions of this amendment shall apply to the operation of any State plan approved under the Social Security Act as health care programs.

Correlation of functions between Professional Standards Review Organizations and administrative instrumentalities

SEC. 1165. The Secretary shall by regulation provide for correlation and cooperation between carriers, intermediaries, government agencies and PSROs. Such cooperation shall include usage of existing mechanical and other data gathering capacity where appropriate.

Prohibition against disclosure of information

SEC. 1166. Any information acquired by a PSRO in the discharge of its functions shall be held in confidence, expect as may be necessary to carry out the purposes of this part or to assure adequate protection of the rights of patients, practitioners or providers. Disclosures of information other than for such authorized purposes shall be unlawful and shall upon conviction be punishable by a fine of up to $1,000 and imprisonment for up to 6 months.

Limitation on liability for persons providing information and for members and employees of PSROs

SEC. 1167. Persons providing information and members or employees of PSROs shall in general not be liable if such information were genuine, and if any actions taken are not motivated by malice. An action shall be deemed to be motivated by malice if the individual or PSRO has consistently failed impartially to take similar action in similar circumstances involving other persons or providers.

Authorization for use of certain funds to administer the provisions of the part

SEC. 1168. Expenses incurred in the administration of this part shall be payable from the Hospital Insurance Trust Fund, the Supplementary Medical Trust

Fund, and funds appropriated for other Titles of the Social Security Act in such proportion as the Secretary deems to be equitable.

SEC. 1160. The Secretary is authorized to provide all necessary technical assistance to appropriate organizations in developing a plan for designation of such organizations as PSRO's.

Authorization of demonstration projects

SEC. 1170. The Secretary is authorized to enter into agreements (ending not later than 1975) with such number of PSROs as are necessary to permit a comparison of results where a PSRO assumes a financial risk for the payment of Medicare claims in contrast to areas where a PSRO does not assume financial risk.

Where a PSRO indicates a willingness and capacity to assume financial responsibility for the review and payment of all claims, reimbursement to such PSROs may be made on a capitation, prepayment, insured or related basis for renewable contract periods not exceeding one year. Such amounts may not exceed per capita beneficiary costs in the area concerned during the preceding 12-month period.

Where such agreements are negotiated provision shall be made for the PSRO to assume a risk by making payments for physicians' services at a rate not in excess of 80% of otherwise allowable amounts for such services.

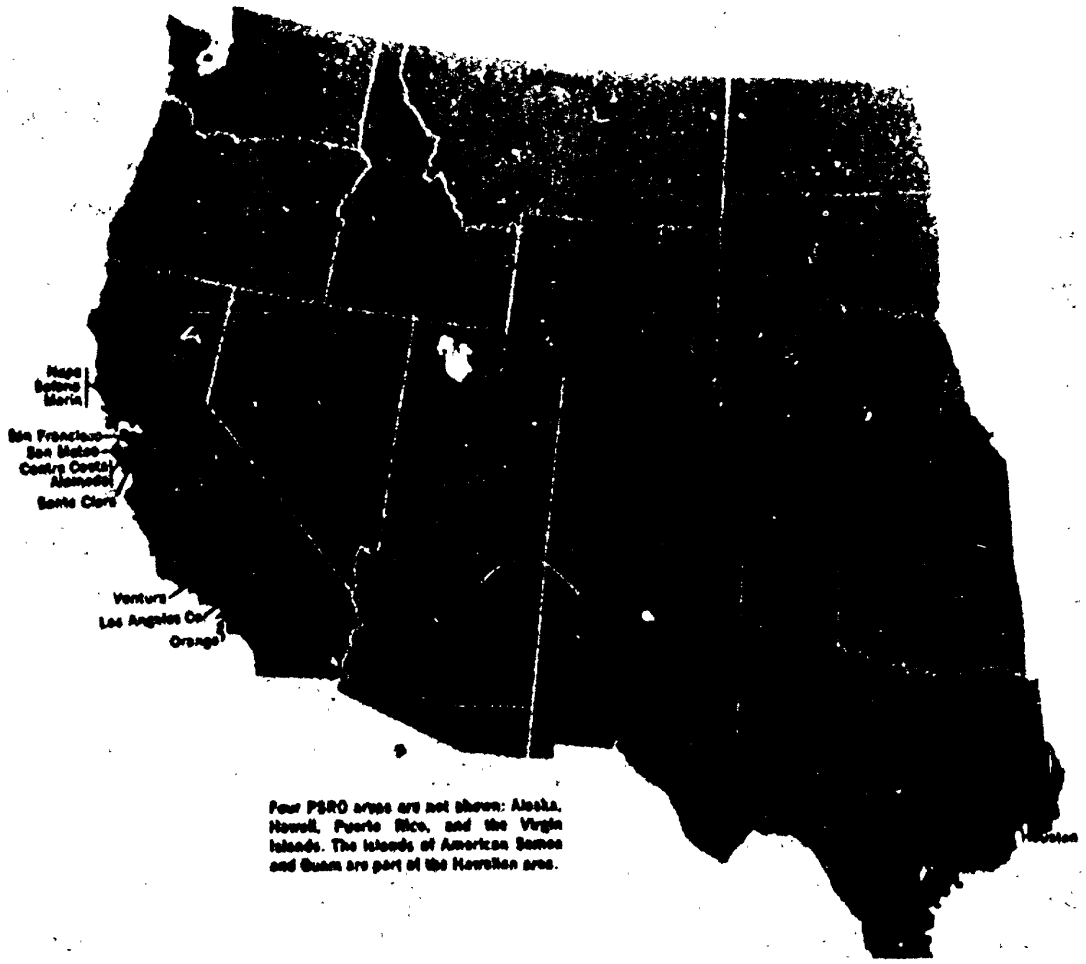
Any sums remaining at the end of the agreement period shall be divided so that the Government receives 50% of the savings. The Government shall also receive amounts, if any, remaining after the PSROs have received the 20 percent or other risk factor withheld and an incentive payment not in excess of 25% of 100% of the physicians' allowable program charges during the agreement period.

Renewable agreements shall be at the base or initial year rate of payment adjusted for appropriate increases, if any, in the unit costs of covered services during the prior year.

Appendix C

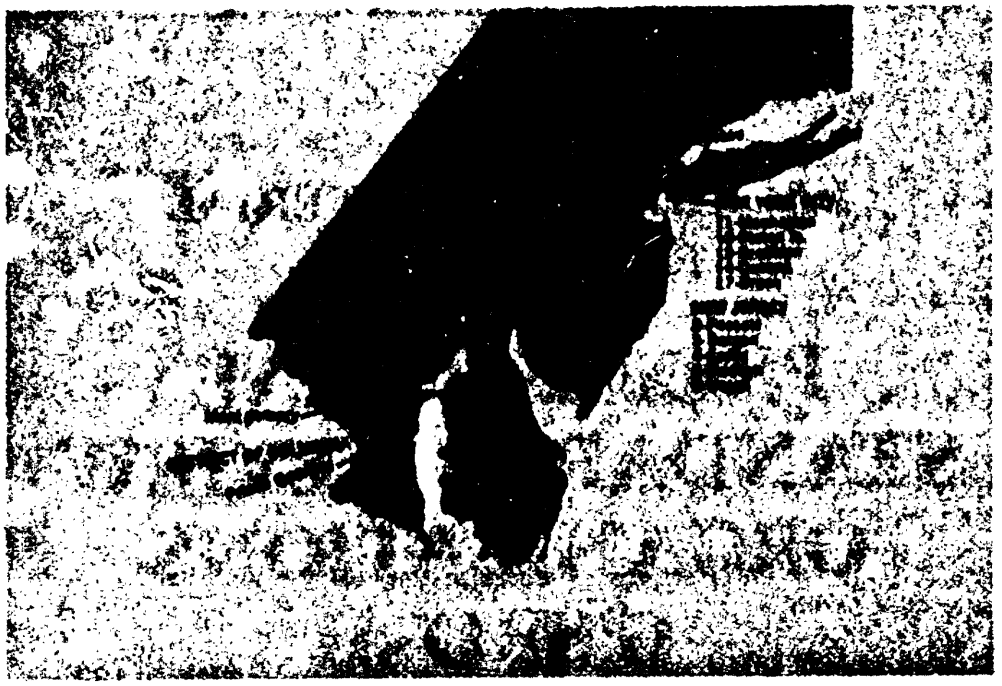
PSRO Regional Map

PSRO



Four PSRO areas are not shown: Alaska, Hawaii, Puerto Rico, and the Virgin Islands. The islands of American Samoa and Guam are part of the Hawaiian area.

REGIONS



72

Appendix C

National Professional Standards Review Council Meeting Reports

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

Meeting Report

March 4, 1974
1:00 p.m.-5:00 p.m.

March 5, 1974
9:00 a.m.-11:30 a.m.

Conference Room 5051
DHEW North Building
Washington, D. C.

Attendance

Members Present

Clement R. Brown, M.D.
Ruth M. Covell, M.D.
Merlin K. DuVal, M.D.
Thomas J. Greene, M.D.
Robert J. Haggerty, M.D.
Donald C. Harrington, M.D.
Robert B. Hunter, M.D.
Alan R. Nelson, M.D.
Raymond J. Saloom, D.O.
Ernest W. Saward, M.D.
Willard C. Scrivner, M.D.

Staff and Program Participants

Rhoda Abrams
Royal Crystal
Sidney Edelman
John R. Farrell, M.D.
Jonathan Fielding, M.D.
Michael J. Goran, M.D.
Erwin Hytner
Howard Newman
James Roberts, M.D.
Dale Schumacher, M.D.
Henry Simmons, M.D., M.P.H.
Keith Weikel, Ph.D.
David Weinman

Call to Order

Dr. Ernest Saward, Chairman, opened the sixth meeting of the National Professional Standards Review Council at 1:00 p.m., March 4, 1974.

The Council approved the minutes of the January 21-22, 1974 meeting (with modification) and the agenda for the present meeting of the Council.

Report of the Director

Dr. Henry Simmons, Deputy Assistant Secretary for Health and Director of the Office of Professional Standards Review, presented the Director's report. He announced the PSRO program had reached an extremely important milestone--that of becoming operational. The Commerce Business Daily of March 5 published an announcement that requests for support of three types of

organizations could be submitted, e.g., planning contracts for conditional PSROs; contracts for conditional PSROs; and contracts for development of Statewide Professional Standards Review Organization Support Centers.

The final PSRO geographic area designations and other information on PSRO will be announced in the very near future in a major press conference.

The Statewide PSRO Support Center concept was developed due to the interest of organized medicine and other physician groups at the statewide level in assisting the development of PSROs in their States. These organizations will help get PSROs started at the "grass-roots" level and continue throughout the operational phase of the PSROs. They will assume an important role in the PSRO program by providing common technical and administrative leadership services to PSROs. A contract resulting from an unsolicited proposal by the Pennsylvania Medical Society may be regarded as the first prototype for a Statewide PSRO Support Center. Hopefully, some of the other medical organizations in large States will become interested in forming Statewide Support Centers.

The first training program has been completed. Approximately 60 regional personnel at SSA, SRS, and H levels have received training on the contents of the PSRO Manual and were brought up to date in the program. The Regional Offices are now becoming ready to implement the program.

In addition, training contract proposals will be accepted from interested outside organizations to develop various kinds of professionals needed to run the PSRO program.

With the PSRO Manual due to be available for mailing throughout the country in the very near future, the program is ready to become operational. The PSRO budget for next fiscal year is $55 million, and the program now has 130 employees. In addition, the President has announced the quality assurance aspects of his Comprehensive Health Insurance Proposal would be founded on PSRO. Therefore, the need to get this program "off and running" is even more important in behalf of both the medical profession and the public.

There is a noticeable change in the awareness of how the PSRO program can become a very strong and contructive force in medicine. This is evidenced by the numbers and types of articles appearing in magazines, journals, etc. For example:

1. A recent New England Journal of Medicine published an editorial entitled "Operation Rates, Mortality Statistics, and the Quality of Life." It stated there are large quantitative differences in the surgical care received by different populations, and it is reasonable to assume, a priori, there are also differences in quality.

2. Another issue of the New England Journal of Medicine reviewed the differences in the rates at which operations are performed on either side of the Atlantic. Nearly twice as many operations are performed in Canada as in England and Wales. The question of the quality of surgery is still left largely unanswered but excess mortality may conceivably be attributed to increased surgery.

3. It was recently reported that appendectomy rates in Germany are two to three times higher than those in other countries, with mortality three times as great. Of the appendices removed, three-quarters were reported to be normal. The authors imply that when appendectomy is done at higher rates for increasingly tenuous indications, the risk of operation eventually exceeds the risk of the disease.

In the past, the individual surgeon has had the sole responsibility for deciding what is best for the individual patient. In the future, it will be groups of physicians acting together, perhaps in PSROs, who will examine and monitor the risks and benefits of specific operations and their application to the problems of individual patients.

In addition to the articles mentioned above, the March 4 edition of the Journal of the American Medical Association published an article by Drs. Paul Stolley and Henry Simmons on antibiotic use. There appears to be an inappropriate use of antibiotics and massive overuse. They recommend the initiation of antibiotic usage review programs in hospitals. It was pointed out in this article where PSRO-like organizations could contribute greatly.

In the March 4 edition of Time magazine, there was a major article on coronary bypass surgery pointing out that there are about 25,000 such operations performed each year. There has been no study that shows there is a difference in the mortality rate on the basis of having or not having that operation.

It is necessary that standards be developed for which such an expensive and hazardous operation would be performed. This same kind of thing will be coming up in total hip operations and a number of other areas. In the past, people have thought of utilization review as being the major responsibility of a PSRO. However, PSRO can be the intact mechanism that has the legitimacy and resources to study quality questions like those mentioned above and bring order where order is needed. In addition, PSRO could be one of the real mechanisms which could help bring about a control of a very wasteful, hazardous practice of defensive medicine and of the malpractice issue.

In 1971, the University of Washington published an article about skull x-rays and trauma which concluded that about 40 percent of all skull x-rays done

were wasted because they did not contribute to the diagnosis but added radiological hazard, cost and unnecessary procedures. The authors recommended development of standards for this procedure. No standards have yet been developed.

PSRO is the mechanism which can move into areas where problems have been identified and can do something about them. For this reason, the Department has held and will continue to hold meetings with the appropriate organizations to deal with standard setting in such areas as antibiotics, use of skull x-rays in trauma, mental health, etc. In addition, the Department will be contracting with the AMA which is developing model screening criteria in approximately 75 disease categories.

Meetings have been held with the American Dental Association, American Nurses Association, and the American Academy of Family Practice. The requests for speakers and information on PSROs continue on a steady basis.

Preliminary meetings have been held with the Joint Commission on Accreditation of Hospitals and will be held with AHA to bring together the QAP, TAP, and PSRO programs.

In response to the question of the notification process to be utilized in informing everyone that RFPs will be available for the three types of contracts, Dr. Simmons announced the PSRO Memo will be mailed to approximately 3,000 associations in addition to use of the AMA News and a press conference to be held by DHEW.

Review of Draft PSRO Program Manual

Organizational Requirements of a PSRO

The major areas of concern as voiced by the Chairman of the Subcommittee on Policy Development centered around the following:

1. Clarification of the term "Active staff privileges." The definition of the term was changed to include those individuals involved in the care of patients, such as radiologists, although they may not be involved in admitting or treating these patients.

2. Clarification of the term "physician professional activities." The definition of the term was left unchanged after explanation that membership of the PSRO should be as broad as possible. If restrictions are necessary, they would take place at the time of determining who would be eligible for different types of review.

3. Clarification of the term "practicing physician." A suggestion was made that wording be changed to indicate those people who reside within the State and hold an unrestricted license to practice medicine in that State.

4. Number of directors on the Governing Body. The Subcommittee recommended the maximum number of directors not be specified.

5. Non-physician voting. The Subcommittee recommended changing of the wording to indicate non-physician members could not vote on physicians' practice of medicine.

6. Executive Director of the PSRO. The draft Manual described the Executive Director as an ex officio member of all committees. The Subcommittee suggested he/she also provide technical support to the committees. In addition, it was suggested that the Chairman of the Governing Body serve as an ex officio member of all committees.

The Application Process

The Subcommittee members, during their earlier session, had no major suggestions for change in this chapter of the draft Manual as written. Therefore, there was no discussion on this item during the Council meeting.

Statewide Professional Standards Review Councils

The topics of major concern in this chapter of the draft Manual included the following:

1. More than 15 days should be allowed between the time the council members are appointed and the first meeting.

2. The qualifiers (geographic area, minority groups, etc.) should be eliminated as far as the composition and qualifications of these council members are concerned.

3. It was the general feeling of the members that one nomination per "slot" be solicited for membership on the Statewide Councils.

4. The request was made to change the wording in the Manual to clarify the fact that four physicians shall be appointed including one from AMA, one from AOA, or two from AMA if there are not a significant number of osteopathic physicians in the State.

5. The Subcommittee felt it inappropriate for the Statewide Council to submit a list of nominees for public members of the Statewide Council.

6. The draft Manual identified a representative from CHP as being on the DHEW Regional Office in-house advisory group to assist in the nomination process. The decision was made to eliminate reference to representatives other than those persons involved in the Medicare, Medicaid, and Maternal and Child Health programs in the Regional Offices.

7. Recommendation was made to have the Manual state that the Statewide Councils are to provide a coordination/liaison function and not one of management. Also, they should not have authority over PSROs concerning criteria. Nor should they be involved with contracting for education and training of local PSROs.

8. A particular concern of the Subcommittee was that Statewide PSR Councils should not in any way be a barrier between the local PSRO and any other organization.

Advisory Groups

The general feeling expressed by Council members was that the chapter should be flexible to allow PSROs and Statewide Councils latitude in designating their Advisory Groups. Specifically, general members objected to requiring the Advisory Group to have 1/4 of its membership represent hospitals and 1/4 represent other health care facilities.

PSRO Health Care Review Responsibilities

Discussion focused on items presented as a result of the joint meeting of the Subcommittee on Evaluation and Subcommittee on Data and Norms which included:

1. The guidelines for initial screening of patients by the PSROs were considered too restrictive, and the guidelines for the final decision of medical necessity of admission were thought to be too loose.

2. The concept of certification of all elective admissions was discussed. Initially, concurrent certification of all elective admissions would be performed. However, some types of cases could eventually be identified as not requiring this certification. Some of the members expressed opinions of this concept not being possible in many diagnostic categories.

3. The Council requested changing the portion of the Manual regarding references to pre-admission certification to indicate the PSRO may suggest appropriate medical consultation in certain instances to certify admissions when concurrent certification of elective admissions failed to prevent medically unnecessary admissions.

4. In order to protect confidentiality of patients, the Council requested the Manual be changed to indicate "coded identification of the patient" in lieu of "identification of the patient."

5. The members discussed, in great detail, the procedure to be utilized in making PSRO developed norms, criteria, and standards available and to whom. The consensus of the members was to have this information published and available to anyone who requested copies.

6. The next item in the Manual which was discussed was the monitoring of a hospital by a PSRO. It was agreed the monitoring would be accomplished with retrospective profile or aggregate information. In the near future, a set of guidelines relating to the development, content, and use of retrospective aggregate information will be prepared. The chapter regarding profiles--what they are, how they will be reviewed, their output, and when and where they will be available to the PSROs--is being prepared.

7. The Council members expressed concern over the Manual presenting the idea of individual PSROs or the Council itself developing inflexible criteria and giving them to practitioners. Dr. Simmons explained that there is a development of model criteria under the AMA umbrella and other groups. They will be offered through the Council to PSROs for modification and adoption. The PSRO can also develop their own criteria.

Baseline Data

Most of the changes recommended during the joint meeting of the two Subcommittees were of an editorial nature, i.e., expansion of the category of medical specialists; a reclassification of these categories; rewording of the material regarding the census of Medicaid recipients; and an expansion of the list of potential sources for community baseline information.

Federal Reporting Requirements

The changes recommended during the joint meeting of the two Subcommittees were of an editorial nature, i.e., redefinition of the term "evaluation," a change in reporting requirements from "quarterly (monthly)" to "timely," expansion of reporting channels to include State and National PSR Councils, and expansion and clarification of the purpose and function of the information to be collected. The need for exception reporting by type of service, length of stay, and other factors was expressed. This information will be published in the next edition of the Manual.

Major Objectives of the National PSRO Program

The recommendation from the joint meeting was to change the wording of the objective relating to quality of service from "assure a minimum standard of quality for health services" to "assure an acceptable standard of quality for health services."

The Council discussed, in great detail, the matter of assuring minimum or acceptable standards of quality care and what constitutes minimum or acceptable standards. After this discussion, the consensus of the Council was in agreement with the recommendation.

Update on the PSRO Program

Dr. Michael Goran, Acting Director of the Bureau of Quality Assurance, outlined the projected accomplishments for the remainder of the fiscal year as being two major activities: (1) implementation of the PSRO program and (2) issuance of planning and conditional contracts. Other activities include PSRO program support, i.e., support of criteria development, development of a training program to train PSRO staffs, continued effort in the Department to improve utilization review to make it consistent with and supportive of a PSRO, special evaluation activities to attempt to determine whether the program is succeeding, and expansion of the PSRO with new methodology outside the short-term hospital setting into the long-term care and eventually into the ambulatory care sector. These program implementation activities are viewed in five stages--educational, planning, conditional, operational, and replacement.

DHEW staff will be providing direct technical assistance to all potential and actual PSROs. In addition to this staff, Statewide PSRO Support Centers will provide assistance in the educational stage. Support centers will assist in the planning stage. State PSR Councils will assist in the conditional and operational stages. Statewide PSR Councils will also assist the Secretary in finding an adequate replacement for a local PSRO.

In order to quality as a Support Center, an organization must meet the following requirements: be composed primarily of practicing physicians, have continuing relationships with State medical and other health professional societies, demonstrate that physicians in the State desire assistance, demonstrate knowledge and expertise in conduct of PSRO-like peer review activities, and demonstrate that the proposed workload of the Center will be sufficient to require a direct contract with DHEW. (The workload would be reflected primarily in terms of the number of potential PSROs to be served.)

The purpose of the Support Centers is to stimulate and support the development and operation of the PSRO program by providing professional, technical, and administrative support to assist local PSROs in carrying out their standard-setting and peer-review responsibilities. These Centers will be established through competitive contracts with the Department.

As PSROs or State PSR Councils are established in each State, they would be able to sub-contract with Support Centers to provide continuing services.

There are currently three options open to the potential PSRO for requesting assistance during the planning stage: (1) direct assistance from DHEW; (2) assistance from the Support Center (if one exists); and (3) a combination of the first two options.

In the conditional and operational stages, the first alternative is a fundamental agreement between DHEW and the Conditional PSRO with DHEW responsible for reimbursing the PSRO for administrative-operational costs. The PSRO would be performing all services in an autonomous manner and would not sub-contract for support. The second alternative is to have the Department enter into an agreement with the PSRO and that PSRO could sub-contract with the Support Center for some supportive services.

The question was raised as to the possibility of a Support Center sub-contracting with fiscal intermediaries or computer organizations to do the computer work under the guidance of the Support Center and having the PSROs contracting for this computer work through the Support Center. Dr. Goran stated that a proposed common system for providing computer backup services to local PSROs is being developed. The type of system will depend primarily on the evolution of the profile system and how much of the profile can be obtained through Medicare and Medicaid payment mechanisms.

Another question raised in connection with Support Centers was concerned with the timing. In the cases of local PSROs being too far ahead in development to require the services of a Support Center, would this preclude the development of a State Support Center? Dr. Goran indicated as long as there are a number of areas in the State requiring services a Support Center could provide, the Centers would not be precluded.

Mention was also made of multi-state Support Centers being developed to provide assistance to States designated as single PSRO areas. Such contiguous States would pool their resources and have one Center supporting their efforts. Also, it might be possible to develop more than one Center in a very populous state to accommodate major metropolitan areas if this would serve a useful purpose.

The fact of the PSRO Program Manual, when issued, serving only as very flexible guidelines was discussed. Individual plans will be evaluated separately with the guidelines providing some limitation.

A legal opinion was requested from Mr. Edelman regarding the statement in the Manual pertaining to PSROs setting standards and criteria for admission certification and continued stay review instead of this being done in hospitals. The legislation states, with provisions, the hospitals can set standards and criteria for review. Mr. Edelman stated his initial reaction to this concept was the PSRO is charged with the responsibility of establishing norms, criteria, and standards which will be used to review medical care in its area. If there is a utilization review committee in a facility and the PSRO has assumed

responsibility for review of care in that facility, this committee must use these norms, standards, and criteria. The PSRO, however, is required to utilize the hospital review committee if, in the judgment of the PSRO, it meets the statutory conditions. The PSRO determines if the review committee is doing an effective, efficient and timely job in accordance with the established criteria, standards and norms. The statute provides immunity for a physician who uses norms and standards developed or approved by a PSRO. However, the physician would not be protected if he uses institutional norms and standards if they have not been adopted by the PSRO.

During this discussion, explanation was given that, in developing the Manual, attempt was made to indicate the PSRO was responsible for the total review system.

1. The PSRO is an organization of hospital and non-hospital physicians in the PSRO area; therefore, the norms, criteria, and standards developed by the PSRO would be developed by all physicians in that area. However, the PSRO could ask the various medical staffs to put together sets of criteria but would retain the responsibility.

2. Review can be performed in hospitals by the medical staff of the hospital if the PSRO so desires. However, the PSRO would have to agree to the measurement parameters used in the in-house review.

3. The evaluation of in-house review can be performed by the PSRO and hospitals working together to develop a review system that is most rational for each individual institution.

4. Medical care evaluation studies can be performed by the hospital medical staff or in a coordinated way by the PSRO with one or several hospitals.

The basic concept is to have the review responsibility resting solely upon the physicians within the PSRO area and organizing the review system that would best serve the needs of their individual area. PSRO has the prerogative of establishing norms, standards, and criteria for all institutions within the area taking into account the known necessary variations.

By-Laws and Articles of Incorporation

The changes recommended in this portion of the draft Manual were to include language stating the PSRO may contract with insurance companies willing to do medical care review for other than Titles XVIII, XIX, and V. Also, the recommendation was made to include a statement indicating this is a suggestion and not a requirement and that each organization should consult its State law as to the elements permissible under that law.

Dr. Scrivner raised the following questions: (1) what is the projected cost for the first year of operation of PSRO? (2) will the physicians doing the work have a voice in the amount of their compensation? (3) what is the final or acceptable role of foundations for medical care in PSRO?

Dr. Simmons provided the following answers: (1) The projected cost for fiscal year 1974 is $33 million and $55 million for next fiscal year. (2) The compensation fee could vary but will be fair and in line with the prevailing acceptable wage in that area for professional services. (3) Foundations could serve in roles such as Support Centers or sponsoring a PSRO.

Dr. Nelson emphasized the fact that a PSRO is not expected to "spring up" and begin review in all institutions in its area with the same degree of capability.

Dr. Saloom asked if hospitals would be reimbursed for development of quality assurance programs. Dr. Goran explained the guidelines on reimbursement have not been developed. The Department is in the process of determining how such activities can be financed.

Public Discussion

The meeting was opened to general public discussion at the end of each day's proceedings.

Monday, March 4, 1974

Dr. Thomas Ainsworth, consultant to the American Hospital Association, expressed his opinion that the AMA Committee on Rules and Regulations should be given the opportunity to have input into the guidelines. Also, he expressed his personal interest that quality be emphasized over utilization review. He stated further that PSRO legislation has the greatest potential for being the best thing to happen to organized medicine in this country or creating the most harm to organized medicine and the free enterprise system. The local level should be allowed maximum innovation in designing the review system and application of methodology and then evaluating systems and types of review.

Dr. Simmons commented that meetings have been held with the AMA Committee. He also indicated that there are more chapters being prepared to the Manual. However, he felt the program has been started in a reasonable way. An integral part of the program is the quality aspect of the medical care evaluation study, the profile analysis, and retrospective special studies. The Manual is only the first piece of guidance being provided to those who are ready to start the program.

Mr. Allan DeKaye, New York City Health and Hospitals Corporation, raised questions as to the feasibility of the time-table for the issuance of requests for proposals and announcement of the area designations. He stated there could be time pressure leading to a lack of creativity for actual systems design and adequate organizational protocols. Dr. Goran explained the time-table was for this fiscal year only and is for organizations that are ready to apply. There will be subsequent contract cycles soon.

Dr. Norman Fuller, West Side Research Group, expressed his concern of PSROs being geared to setting minimal standards of care which would be applicable to every State.

Mr. H. G. Pearce, Blue Cross Association, requested opportunity to review the Manual material pertaining to fiscal agents for Medicare and Medicaid relations as it is being developed. He was assured of DHEW's intent to review all of the chapters of the Manual with appropriate organizations in order to receive their advice.

Dr. Charles Summers, Utilization Coordinator of Jefferson Hospital in Philadelphia, indicated his feeling was the program as proposed was too rigid. There needs to be an educational program to make it work.

Tuesday, March 5, 1974

Mr. Allan DeKaye, New York City Health and Hospitals Corporation, asked if an organization comprised primarily of physicians could be considered for both a State Support Center and a local PSRO. Mr. Edelman stated that a dual entity with interlocking boards and members would present problems, such as conflict of interest, for the PSRO.

Dr. Arthur Ellenberger, Essex County Medical Society, New Jersey, inquired as to the maximum number of members on the board of directors of a PSRO. (The draft Manual stated a maximum of 21.) He was informed there would not be a limit set in the revised Manual on the maximum number. The corporate laws in each State would apply. Dr. Ellenberger then asked if chairmen of hospital utilization review committees would be precluded from serving on the board of trustees of a PSRO. He was told there would be no problem if they are nominated and duly elected.

Mrs. Patricia Ostrow, American Occupational Therapy Association, expressed concern over State Council and PSRO board meetings not being open to the public. Mr. Edelman explained that these organizations will not be subject to the Freedom of Information Act. This matter would be left to the discretion of the PSRO. Many of the Council members expressed an opinion of this decision being a prerogative of the PSRO; however, they suggested as much consumer representation as possible with open meetings whenever possible.

Dr. William Sale, American Hospital Association, asked for further clarification in connection with the development of criteria by in-house utilization review committees. Mr. Edelman reitereated the requirement of hospitals utilizing norms, criteria, and standards which are developed by the PSRO for admission certification and continued stay review. In those instances of a hospital feeling there is a valid reason for exceptions to these parameters, that hospital must receive apprcval from the PSRO prior to making such modifications. The norms, standards, and criteria applicable throughout the area will be those established by the PSRO. There can be variations depending on the special situations in the area.

It was further stated that in areas where a good quality assurance program is already in place and there is no PSRO, that program would continue. However, when a PSRO is established, those criteria will be reviewed by that PSRO. If the criteria are accepted, there is no problem. If the criteria are not acceptable, the institution must change them or get approval of the variance.

The meeting adjourned at 11:30 a.m.

ATTENDEES

NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL
March 4-5, 1974

T. H. Ainsworth, Jr., M.D.	AHA
Ralph Alterowitz	IBM
Charles S. Amorosino, Jr.	Commonwealth Institute of Medicine, Boston, Massachusetts
Al Ankrum	Maryland Medical Society
Richard J. Astello	OPEL/HSA
John T. Athunier	The Dikewood Corporation
Nedra Jean Bartholow	Hospital Utilization Project
Theodore C. Bedwell, Jr., M.D.	SSA-BHI
Mike Bernstein	American Hospital Association
J.M. Booth	Capital Systems Group
W.W. Boyles	Blue Shield of Michigan
Angela Bradby	Assistant to Dr. Greene
Harry Brenner	"COMPOS" San Antonio, Texas
James E. Bryan	American Association of Foundations for Medical Care
Norman D. Burch	College of American Pathology
John Butil	AHA
Jack Carow	ACS
Robert M. Carroll	Washington Hospital Center
Morton Chaliff	Medical Society of State of New York
Robert Chandler	DHEW Region VIII
Kee T. Chang	SRA/AAIS
Charles F. Coker	DHEW Region IV
F.L. Clare	DHEW Region II
Robert W. Coburn	American Health Systems
Gene Cohen, M.D.	DHEW-NIMH
G. Contis, M.D.	DHEW
Margaret Conwell	ADAMHA
Casey Crawford	National Health Insurance Reports
Allan DeKaye	New York City Health and Hospitals Corp.
Linda Demlo	ASPE, DHEW
E. A. Diephaus	H-OPO
Paul Donelan	AMA
Thomas Edwards	"The Blue Sheet"
Arthur R. Ellenberger	Essex County Medical Society
T. Elwood	NRTA-AARP
Chris Fenyvest	Federation of American Hospital
Larry R. Fosselmen	Pennsylvania Medical Care Foundation
S. Frazier	Arthur Young and Company
L. M. French	OPDP/OASH
J. M. Friedman	OPDP/OASH
Norman A. Fuller	Director of Planning, Westside Research Group

Mary Jo Gibson	SRS
Stanley Glaser	H-OPDP
Roger Graham	National Association of Blue Shield Plans
Verne Hamlin	BHI/SSA
John A. Harris	Blue Shield
Charles W. Hemisch, 3rd.	Thomas Jefferson Memorial Hospital
Winona Hocutt	BHI/SSA
Al B. Honick	BHI
Fred Hure, M.D.	Connecticut Hospital Association
Donald Jacobs	Massachusetts Hospital Association
Anne Jamieson	DHEW, Region III
E. V. Jobe	AMA
Jan Johnson	American Osteopathic Association
John L. Johnston, D.O.	Bashline Hospital, Grove City Pennsylvania
Calvin F. Kay	American College of Physicians
Alan Kaplan	PSRO Letter
Ann S. Kelly	VA
Harvey Kenek	
G. Kerdan	BCA
Kay Kimbrough	DHEW, Region VI
David Klein	BCA
Deanne Knapp, Ph.D.	FDA
A. A. Kramer	Association of American Physicians and Surgeons
Dean Krueger	NCHS/HRA
Charles R. Lewis	West Virginia Medical Institute, Inc.
Paul M. Lewis, M.D.	H.U.P.
Wm. Fred Lucas, M.D.	Indiana BC/BS
Sam Marcus	OPDP-H
Patricia McGuire	National Blue Shield
Eugene F. McMahon	DHEW, Region VI
Sue Meads	NCHS/HRA
Al Miller, M.D.	DHEW, Region IX
P. R. Moyer, M.D.	GWU Hospital
Patricia C. Ostrow	American Occupational Therapy Association
C. T. Packer	Consultant
H. G. Pearce	Blue Cross Association
Jack Perlman, M.D.	Commission on Professional and Hospital Activities
Arthur A. Peyan	MSA
John Pompelli	American College of Surgeons
Steven Portnoy	American Hospital Association
Thomas S. Powell	Hospital Association of Pennsylvania
Marsha A. Preble	Control Data Corporation
H. A. Press	VA
Suzanne Raufferbaut	National League for Nursing
Tim Redmon	American Optometric Association
Michele Robinson	Health Manpower Reports
Ruth S. Rolston	SRS/MSA

Leonard Rubin	Kaiser-Permanente
Melvin H. Rudov	OPEL, HSA
G. Ryan	American Medical Association
William Sale	AHA
P. J. Sanazaro, M.D.	Consultant
Carl D. Siegel, M.D.	DHEW, Region VII
Robert L. St. John	Illinois Regional Medical Program
John E. Sumter	Space Age Corp. Sys.
William Tash	HSA
John A. Teero	Space Age Corp. Sys.
Robert van Hoek, M.D.	HSA
Eugene W. Veverka, M.D.	ORO/PHS
Madeline Weiss	Electronic Data Systems Corp.
R. Wiley	Honeywell
Walter D. Wood	The Dikewood Corp.
Gooloo S. Wunderlich	OPDP/ASH
Allan Wyman	SSA/BHI
S. Yegger	VA
Don Young	Office of the General Counsel
D. Zwick	HRA

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

MEETING REPORT

January 21, 1974
9:00 a.m. - 4:45 p.m.

Conference Room 5051
HEW North Building
Washington, D.C.

January 22, 1974
9:00 a.m. - 11:00 a.m.

ATTENDANCE

MEMBERS PRESENT

Clement R. Brown, M.D.
Ruth M. Covell, M.D.
Thomas J. Greene, M.D.
Robert J. Haggerty, M.D.
Donald C. Harrington, M.D.
Robert B. Hunter, M.D.
Alan R. Nelson, M.D.
Raymond J. Saloom, D.O.
Ernest W. Saward, M.D.
Willard Scrivner, M.D.

STAFF & PROGRAM PARTICIPANTS

Rhoda Abrams
Sidney Edelman
John R. Farrell, M.D.
Jonathan Fielding, M.D.
Alvin Goodman, M.D.
Michael J. Goran, M.D.
Erwin Hytner
Howard Newman
James Roberts, M.D.
Dale Schumacher, M.D.
Henry Simmons, M.D., M.P.H.
Keith Weikel, Ph.D.
David Weinman

MEMBERS ABSENT

Merlin K. DuVal, M.D.

CALL TO ORDER

Dr. Ernest Saward, Chairman, opened the fifth meeting of the National Professional Standards Review Council at 9:00 a.m., January 21, 1974.

The Council approved the minutes of the November 26, 1973 meeting and the agenda for the present meeting of the Council.

REPORT OF THE DIRECTOR

Dr. Henry Simmons, Deputy Assistant Secretary for Health and Director of the Office of Professional Standards Review, presented the Director's report. He announced the program remains on schedule, and he is extremely optimistic about the progress being made in a wide variety of program areas. A two-week extension of the commenting period on the proposed regulations of PSRO Area Designation was granted.

Recruiting of personnel in the program is continuing with approximately 100 people working at the present time. There will be additional new positions for personnel and adequate financing in the FY 1975 Administration's budget The program has moved to the Parklawn Building to provide adequate space.

Among the additions to the staff are a nurse and an expert on drugs. Competence in other sections of the Department are being called upon for PSRO support. A preliminary meeting was held with the National Heart and Lung Institute and a meeting will be held with all the National Institutes of Health to examine the areas of technical support they can offer to the program. The National Heart and Lung Institute will probably be contributing in the area of hypertension treatment as well as in cardiac rehabilitation, standards for coronary revascularization, in the sickle cell program and in the blood program.

Since the last meeting of the Council, the Board of the American Society of Internal Medicine formally reaffirmed its support for the PSRO program and has submitted a thorough document on how PSROs can be set up and made operational. Other organizations such as the American College of Physicians, American Radiological Association, American College of Surgeons, American Academy of Pediatrics, and the American Nursing Association are lending support to the program.

The Kellogg Foundation recently granted a million dollars for a study to be handled by a consortium of the American College of Physicians, American Society of Internal Medicine, American Hospital Association, American Association of Foundations for Medical Care, and the American Medical Association. This is a very important study in which six conditional PSROs throughout the United States will be studied for a variety of ways to organize and manage the PSRO effort. The consortium has sent letters to all the areas designated asking for nominees to become eligible for the Kellogg Foundation study.

There is a tremendous amount of interest throughout the country in the program as evidenced by the request for speakers from the Department. There does, however, remain confusion and misinformation leading to groundless fear which must be dispelled. Recent polls show that physician

knowledge of PSRO is meager. The Director pointed out that most physicians' concerns about PSRO are based on misconception and that opposition is usually to a program which was never intended to exist and which will not exist.

To relieve legitimate concern of the medical profession, an effort will be made to protect the confidentiality of medical care information in the program. The question of how the PSRO program can be useful in bringing the malpractice problem under control is also being explored. This program could become a significant part of the long-term solution to the growing problem of malpractice litigation.

HEW is exploring ways in which the medical institutions under the jurisdiction of the Federal Government (such as PHS hospitals) would become part of the PSRO programs in the areas in which they are located and be subject to the same quality standards as the private sector.

The National Professional Standards Review Council and the Health part of HEW can be the quality control mechanism for the HMO effort recently signed into Law by the President. There is $40 million allocated in the quality area of the HMO program in which the PSRO program will be concerned with monitoring and guiding. The PSRO program will also be involved in the quality assurance provision of the Administration's health insurance proposal which is anticipated in the near future.

The Director announced that the PSRO Manual, which will be discussed by the Council at the present session, will be one of the important pieces of information to be distributed throughout the country as support to the implementation of PSROs.

REPORT OF THE SUBCOMMITTEE ON DATA AND NORMS

Dr. Harrington, reporting for the Subcommittee on Data and Norms, said the Subcommittee had met first with Dr. Welch, Chairman of the AMA Task Force of Guidelines and later with the entire Task Force. In view of the early PSRO need for critical criteria which could be utilized in screening on a "yes or no" basis, the AMA Task Force is working with all major national physician specialty organizations. The subcommittee feels there is a tendency toward setting up optimal criteria which are too extensive for purely screening purposes. It is hoped that the Department can arrange with the Task Force to print and distribute sets of model screening criteria to all organizations which will be doing PSRO review.

Dr. Nelson added that screening criteria are designed to be used by nonphysician personnel in the identification of services requiring peer review and should not include everything which might be done under any possible circumstance. He feels the concept of screening

is not sufficiently understood throughout the country and a major educational effort will have to be continued. Dr. Simmons noted that a "shopping list" type of all-inclusive criteria could potentially be more harmful than beneficial. Dr. Nelson also noted the value of screening is that 90% of patients would pass through the system for automatic payment and that only the remaining cases would require second-level review by peers.

Dr. Harrington referred the Council to the sets of coding criteria for diagnostic coding systems and for procedural coding systems which had been approved by the Subcommittee. He proposed these sets of coding criteria be used by any group in analyzing existing or new coding systems. Other parallel sets of coding criteria may be necessary for systems used for other purposes such as payment, health planning or purely statistical surveys. However, such coding criteria would be deeply intertwined with the proposed sets. The committee recommended adoption by the National Council of both sets of coding criteria. The relationship between the resolution and the Department's international collaborative effort in coding was noted. Dr. Harrington insisted the need for uniformity for PSROs is very important at this time. The motion that the Council recommend the coding criteria sets for both procedural and diagnostic coding systems to the Secretary was passed unanimously.

A second motion on coding, recommended by the Subcommittee on Data and Norms to the National Council, was as follows:

"It is recommended that the National Professional Standards Review Council urge the Secretary of the Department of Health, Education, and Welfare to provide leadership in the formation of a group having the representation of interested parties, with the necessary supporting staff resources, to study and evaluate existing terminology, nomenclature, classification and coding systems and to recommend a uniform coding system or, failing that, a set of compatible systems for the recording and retrieval of clinical and health-care related data." The motion was unanimously passed by the Council.

Dr. Harrington referred to a staff draft paper recommending initial PSRO review be focused on acute-care inpatient general hospitals, and, in succeeding steps, review encompass extended-care facilities and mental hospitals. He noted the concept of phasing-in as comtemplated was agreed upon. However, he foresaw that some organizations applying to become PSROs have had considerable experience in all of the above-mentioned types of review in the various settings. He suggested therefore that such organizations, to avoid discontinuity, be permitted to do review in those settings in which they are capable and/or experienced beginning with the initial agreement. The Chairman ruled that a formal resolution by the Council was not needed inasmuch as there was general agreement on the principle of priority for review of acute inpatient care on the capability of certain organizations to do other review.

The committee then considered a definition of the term "screening" and Dr. Harrington reported an error in the original definition as approved by the Council. The term "sample" had been used when in fact screening is not a sampling but rather a selection process. Consequently, the following definition of screening was proposed and unanimously adopted by the National Council. "Screening is a process in which norms, criteria or standards are used to analyze large numbers of cases in order to select for study in greater depth those cases not meeting the norms, criteria or standards."

Dr. Roberts announced the next item the Subcommittee wished to discuss was the paper on the National Council's role in norms, criteria, and standards which had been distributed at the November Council meeting. The paper stated the Council should consider it as part of their duty to look at the various available model sets, see how useful they would be to the PSROs and, if useful, provide them to the PSROs as models for their education and use.

Dr. Brown said that he was concerned about the Subcommittee's report (minutes of January meeting) regarding the role of the Council in norms, criteria, and standards in connection with hospitals using PSRO norms, criteria, and standards unless "variation(s) from them are approved by the PSRO." His first concern was that externally-developed criteria might not be internalized and operationalized to achieve change to improve care. It would be an assessment program and not an assurance program to assure quality care.

His second concern was that PSROs and people at local sites need to learn the process of criteria development because criteria are always going to change. Therefore, local development of criteria should be encouraged.

Dr. Hunter said the AMA Task Force had created guidelines broad enough so they could be subjected to local refinement. He added that these are strictly guidelines for technical assistance to founding organizations and not mandates. Dr. Harrington stated the Council needs to give guidelines to local areas but with emphasis made they are technical assistance guidelines and not a mandate of the National Council. Dr. Saloom stated he felt the Council was obligated to present some sort of starting guideline for local PSROs or they would need 3 or 4 years to develop a set. This would be providing them with technical assistance and hoping there would be local input so that we will have local criteria -- not national criteria. Dr. Covell agreed that model sets would be useful; however, local initiative could be destroyed. There could be local deviations in certain areas from what appear to be regional norms.

Dr. Simmons summarized the feeling that new organizations should be provided with assistance that could short-cut the long process necessary for them to come up with criteria. He asked the Council for suggestions

along this line. After discussion, Dr. Harrington read his suggested modifications for endorsement by Council: "That the National Council take an active initial role in PSRO development by providing, through the Department, leadership in the local development of norms, standards, and medical-care criteria to beginning PSROs." The Council endorsed the recommendation by consensus.

REPORT OF SUBCOMMITTEE ON EVALUATION

Dr. Haggerty, Chairman of the Subcommittee on Evaluation, briefly summarized the activities of the November and December meetings of the Subcommittee. During the January 20 meeting of the Subcommittee on Evaluation, the major goals of the National PSRO Program were revised. Dr. Haggerty presented the rewritten goals to the Council for acceptance. Dr. Nelson moved acceptance of the Subcommittee's report, and Dr. Saloom seconded the motion. After brief discussion, the report was approved.

Dr. Haggerty then introduced discussion on the proposed workplan of the Subcommittee. The workplan included establishing more precise objectives for each of the goals. He informed the Council of the Subcommittee's discussion of the need to have some pilot testing of phases before going into the field for full-blown testing. He sees the whole evaluation plan as being one that evolves and develops as the program goes along inasmuch as it is highly complicated.

Dr. Saward asked if a draft of uniform accounting systems output was underway since there is a projected completion date of April for this item. Dr. Schumacher said that there were staff members and a consultant working on it. However, if there are organizations which have accounting systems able to produce those "outputs," there will be no need for the model accounting system which is to be developed subsequently. He also said that there are meetings being held on that item.

REPORT OF SUBCOMMITTEE ON POLICY

Dr. Saloom reported the Subcommittee on Policy's discussion of the Management Resource Centers. He noted the Subcommittee preferred the term "PSRO Technical and Professional Resource Center." He also noted the Subcommittee did not wish to give the impression that resource centers would be located in each State, but rather they would be limited in number and that resource centers could cover several States. Conversely, in very large States such as New York, there may be a possible need for more than one such center. The Subcommittee had considered methods of contracting, i.e., contracting with such a Center directly by the Department verses subcontracting through PSROs, but came up with no solution. The Subcommittee felt a contract should run for a period of more than one year. It is anticipated there will come a time when the Resource Centers are no longer needed and would

be phased out. It was felt, however, that a specific time limit should not be given. The Subcommittee felt the relationship between such Resource Centers and third party payers should be further defined.

Dr. Simmons noted the importance of conserving Federal expenditures by assuring the Department does not give 180 contracts to answer the same contract need. A preferable alternative is the purchase of a generic product which could be distributed to PSROs as needed. It was agreed, however, that in addition there might be specific and unique needs of a particular PSRO. Dr. Saward and Dr. Saloom both stated that organizations were already soliciting prospective PSROs with promises of service and expressed concern about this. Dr. Hunter pointed out the contract should not be so designed to stifle initiative of PSRO's. Dr. Saloom emphasized the competitive basis for contracting between various qualified organizations. Dr. Nelson expressed the opinion that as time passes, he saw less need for a management resource center because of the questions answered in the PSRO Manual and the possibility of individual consultants acting to fulfill the needs of a PSRO.

AREA DESIGNATION

Mr. David Weinman reported that proposed geographic areas for PSROs were announced in the Federal Register on December 20. The period for comment upon those proposed area designations has been extended 15 days to February 5. Internally, all comments are being collected and collated so that beginning February 5, meetings will be held within the Department, including Regional Office personnel, and other interested parties to resolve any problems. In addition to written comments some delegations have visited the Director and other members of the staff. Mr. Weinman reported that all problems which have been identified so far were possible of resolution. It is hoped to publish final PSRO area designations in the Federal Register by March 15. As of the time of the Council meeting 389 comments had been received from various States and jurisdictions with only a few areas generating a considerable number of comments. In response to questioning Mr. Weinman stated the Department has met with all individuals who requested meetings so far but it was not planned to start a whole new round of consultation throughout the country.

Dr. Covell stated the Department would probably only be hearing from those who were not in agreement with area designations and not from others who agreed with the areas as designated.

LONG-TERM CARE ISSUES

Mr. Howard Newman congratulated the Council on its efforts to date, but pointed out many difficult issues lie ahead in the relationship of PSRO to the major financial programs. He reported the Medical

Services Administration of the Social and Rehabilitation Service has identified a range of problems in the relationship of PSROs to the 53 Medicaid programs and will be bringing those issues to the attention of the Council. The long-term care issue is one of those. Others are the potential problems of PSRO relationship with State agencies and the problems of data requirements for both PSROs and Medicaid.

Skilled nursing home services and intermediate care facilities services represent a major portion of the Department's total health expenditure. Consequently, even though it is logical that PSRO efforts have an initial focus on inpatient acute-care hospital services, the law is clear in addressing itself to long-term care, including mental hospital expenditures. Mr. Newman cautioned against prolonged deferment of action in the long-term care area because it would be a deterrent to the development of PSROs. He suggested an applicant PSRO be committed to a plan by which they intend to handle their long-term care review responsibilities.

Mr. Newman hopes PSRO's will help rationalize the whole long-term care system inasmuch as long-term care services have, to a great extent, been outside the jurisdiction of those groups reviewing the appropriateness of care. He hopes PSRO's will respond to the opportunity.

Dr. Nelson expressed concern that the situation be avoided where PSRO's are simply providing physicians for review of care for other parties. He suggested close cooperation between fiscal agents, Medicaid agents, and PSROs will be required.

UTILIZATION REVIEW PROPOSED REGULATIONS

Dr. Roberts announced that the commenting period deadline on the UR Regulations was February 8. They are currently "proposed" and not final. If adopted, they would have status as Medicare and Medicaid UR Regulations. As the PSRO effectively performs review, the Secretary could waive these requirements in favor of the PSRO mechanism. He then briefly summarized the requirements of the proposed regulations.

The Council entered into much discussion regarding the proposed regulations, particularly the sections on pre-admission certification.

Mr. Hytner reminded the Council the proposed regulations were published with the intention of getting comments and to achieve uniformity prior to publishing final regulations on the subject.

Dr. Nelson then proposed two motions:

1. "That the National Professional Standards Review Council inform the Secretary of HEW of strong opposition to implementation of a program of mandatory pre-admission certification for hospital services delivered under Title XVIII and Title XIX."

2. "That National Professional Standards Review Council request the PSRO program to develop a system of hospital review based upon concurrent review with retrospective studies as indicated." This motion was seconded by Dr. Greene.

In discussion, Dr. Greene expressed concern that pre-certification works against the interest of the patient to prevent his entry into the health care system. Dr. Saward, reenforcing this view, pointed out the disadvantaged would have to go through a special procedure to have an elective admission to a hospital that handles everyone else differently. Dr. Covell clarified that the Council was very much in favor of the objective of getting uniformity between the Title XVIII and XIX programs, but that the issue of disagreement was in required pre-certification. Mr. Hytner pointed out that several States were already doing pre-admission certification. Dr. Nelson responded that he wanted it on record there were effective alternate ways that some PSROs might select. Dr. Harrington noted that most physicians did not need overview through pre-admission certification but there will be some physicians and institutions who will have to have it. However, this can be accomplished without putting restrictions on the whole population.

Dr. Goran questioned whether the motions referred to just hospital review or were inclusive of SNFs and ICFs. Dr. Harrington suggested that many physicians might prefer prior authorization consulting services before admission to SNFs and ICFs and that such consultation would even be of help in dealing with families of patients. He proposed the motion be amended to apply to hospital services only. This was done and the motions as amended were unanimously passed. Dr. Harrington stated it was his opinion that the threat of mandatory pre-admission certification would act as leverage for rapid implementation of Professional Standards Review Organizations throughout the country. Dr. Saloom expressed concern the Medicaid pre-admission certification programs would continue in effect even after PSROs were capable of such review.

THE MEDICARE END-STAGE RENAL DISEASE PROGRAM

Dr. Goodman outlined the history of hemodialysis and kidney transplantation in order to acquaint the Council with the End-Stage Renal Disease Program (ESRD).

Prior to July 1, 1973, there was no Federal program responsible for financing care for persons with a particular diagnosis or providing nearly all costs of expensive transplantation and dialysis therapies. Public Law 92-603, Section 299I, provided for this type of program with reimbursement being made under Medicare. This law authorized the Secretary of HEW to limit facility participation, establish minimal utilization rates for participating facilities, and to create medical review boards. Plans are being developed to carry out the intent of this legislation.

These plans include: early identification and registration of patients; certification of patients who require this therapy; rapid referral of such patients from primary level of care to a more expert level of care; and availability of the full range of dialysis in various settings.

There will be an interim program in which the current providers of care will be accepted to continue as providers before the full gamut of regulations are developed in order to maintain continuity. An "exceptions package" was also developed so that new institutions and facilities could be certified to provide this care until permanent regulations are developed.

Under consideration for the long-range policy is a network of ESRD facilities which will include: Kidney Disease Transplant and Dialysis Center; Renal Disease Center; Maintenance Dialysis Facilities; and Home Dialysis. The proposed review boards would be at the local, regional, and National levels. The systems of review and data gathering are attuned to and parallel with that of the PSRO efforts. Dr. Goodman estimated 12,000 people as currently eligible patients with an anticipated additional 10,000-15,000 added every year and a possible total of 50,000 in several years. Parallel or duplicative review organizations and review procedures will be avoided.

Dr. Goran stated the reason the background of the end-stage renal disease program was being presented to the National Professional Standards Review Council was to begin a communication process. Policies are not yet worked out but are in development. Many aspects of the program will be coming before this Council. One indication the Department believes the two do mesh together is the fact they are being administered by the same unit, the Bureau of Quality Assurance.

PSRO MANUAL - INTRODUCTION AND CHAPTER I

Dr. Goran, in discussing the Manual, announced that it will represent what is considered the second phase of the program. With final area designations, organizations will wish to apply to become conditional PSROs. Such an organization will necessarily have to meet membership and organizational requirements as spelled out in the legislation and detailed in the Manual as guidelines. Included will be membership policies, organizational structure and the development of a "formal plan." The formal plan outlines how the PSRO review system will be phased in and how norms and data will be used to accomplish the review. In addition it will indicate how a PSRO will integrate with existing review activities for Titles XVIII and XIX. A notification and polling process is also being developed.

Presented at this meeting of the Council were Chapters I, III, V and VII and they were individually reviewed. The Manual, when issued, will not have the effect of regulations, but when the regulations are published they will be accurately and adequately reflected in the Manual contents. Continual review and expansion of the Manual will be undertaken as additional policies are developed. Dr. Goran identified the possible Chapter headings as follows:

I. Introduction
II. Designation of PSRO Service Areas
III. Organizational Requirements for PSROs
IV. Duties and Function of a PSRO
V. PSRO Selection and Agreement Process
VI. Reimbursement of Administrative Costs
VII. State Professional Standards Review Councils
VIII. Hearings, Review and Sanctions
IX. National Professional Standards Review Council
X. Data Collection and Evaluation

It is anticipated the Manual will come out in two sections. The first, covering the PSRO planning stage, will be ready in 4 to 6 weeks. It will be followed at a later date by a second section covering the remaining requirements.

The Secretary is authorized to provide assistance to developing PSROs. One form of assistance is the Manual itself. In addition, the HEW Regional Offices and the Central Office staff will be providing assistance to potential organizations. Also, those organizations requiring financial assistance during the planning stage, i.e., the development of formal plan, will be considered for initial funding. It is planned to fund a number of organizations by June of 1974 for planning or as conditional PSRO's, depending on the status of the organization.

Mr. Edelman in response to a question, said the Manual is not the same as regulations but is an administrative instruction. Regulations have to be written in suitable form, appropriate for publication in the Federal Register, go through a process of Notice of Proposed Rule Making and then be adopted.

Dr. Goran noted that the first chapter would have to be re-written once the other chapters were developed. The present contents of Chapter I are only preliminary.

PSRO MANUAL CHAPTER III - ORGANIZATIONAL REQUIREMENTS OF PSROS

Dr. Fielding, in reviewing Chapter III, noted it spells out in greater detail that which is outlined in the legislation. It is designed to provide clarification for potential applicants where it seems appropriate. The present chapter is in early draft form for discussion only. Dr. Fielding went through the Chapter selecting areas of probable interest to the Council.

Discussion centered around:

1. Obtaining certificate of exemption from the Internal Revenue Service;
2. Eligibility for membership in a PSRO;
3. Role of physicians working in Federal facilities;

4. The effect of dues imposed by an organization;
5. Level of membership ("consisting of a minimum of 25% of the eligible physicians in the PSRO area.");
6. Number of directors and composition of the governing body of a PSRO;
7. Committees; and
8. Review activities.

PUBLIC DISCUSSION

During a session of public observer questions and answers, Mr. William Sale of the American Hospital Association in Chicago discussed the exclusion of certain physicians from participating in review activities. Members of hospital staff who have a financial interest in that hospital may not participate in the utilization review of that hospital. Mr. Edelman from the HEW Office of the General Counsel stated the PSRO legislation has a provision which does preclude such a physician from reviewing care provided by that institution. Such a physician, however, could take part in the review of care provided by other institutions.

CHAPTER V - APPLICATION PROCESS

Dr. Fielding described the purpose of Chapter V as providing clarification for organizations regarding application for designation as a PSRO. In order to be qualified organizations, they must meet the membership and organizational requirements set forth in the Act, and the Secretary of HEW must be satisfied the organization is willing and capable of fulfilling the duties and functions.

During the developmental phase, an applicant PSRO will work to meet the requirement to qualify as a conditional PSRO. During this time it may request and receive technical and financial assistance.

During the planning phase, organizations will make application for conditional designation, and the Secretary will decide whether to enter into a conditional PSRO agreement with the applicant. When the Secretary determines the applicant is qualified, and tentatively plans to designate the applicant as a conditional PSRO, he must notify the physicians in the designated area of his intent. Those physicians will have 30 days in which to notify the Secretary whether the organization is or is not representative of the area. Responses will be tabulated by Regional Offices.

CHAPTER VII-STATEWIDE PROFESSIONAL STANDARDS REVIEW COUNCILS

Miss Abrams led the discussion of Chapter VII of the Manual. She noted that the material had previously been reviewed by the Subcommittee on Policy. Some of the items included in the discussion were:

1. Need for incorporation of these Councils;
2. Procedures for establishing Councils (sequence and time frame of events and method of nominating members);
3. Coordination of activities among PSROs within the State;
4. Norms and criteria;
5. Assuring compliance with PSRO requirements;
6. Facilitating and coordinating compliance activities of PSROs; and
7. Enlisting support of other organizations.

The Council discussed the number of nominations to be submitted for membership on the Statewide Professional Standards Review Councils. The law defines the number of members to be appointed by the Secretary of HEW and the Council discussed the possibility of allowing one nomination per "slot" versus two nominations per "slot." Dr. Scrivner made the motion that Council adhere to the language of the law which was unanimously approved by the Council.

DEVELOPMENT AND USE OF NORMS, CRITERIA, AND STANDARDS

Dr. Roberts discussed a paper which had previously been presented to the Council and since reviewed by the Subcommittee on Data and Norms. He noted that the paper focuses on the development and use of norms, criteria, and standards but does not attempt to pull it together in a review system. It is only a portion of the review activity. The Council accepted the paper with minor variations which will be included in the final version.

RESPONSIBILITY FOR IN-HOUSE REVIEW ACTIVITIES

Dr. Harrington introduced the topic by stating that some in-house review programs currently being encouraged are not a replacement for PSRO review of medical care being delivered to patients under Titles XVIII, XIX and V. He noted there are two antipodal points of view. One in which the PSRO would employ the necessary people to do the review work within an institution. The other where institutional review is done completely by the hospital medical staff with the PSRO only doing retrospective review of profiles to identify those institutions not carrying out their necessary obligation. Dr. Simmons stated there is throughout the country, a wasteful amount of activity with many overlapping review systems attempting to satisfy various interests. He suggested a PSRO established approach be decided upon so that all interests can be fitted into a single system.

Dr. Harrington stated one faction feels the nurse-coordinator, or other non-physician screening person, should be in the employment of the PSRO rather than the individual hospital. Speaking for himself, however, he feels sufficient data can be produced retrospectively to identify problem hospitals for further consideration. Dr. Saloom stated his feeling is the utilization function should remain in the hands of the physicians of the individual hospitals.

Dr. Hunter suggested there were a variety of methods that might be employed with all shades of responsibility in various locations. He said some hospitals may not have the competence and the PSRO will

have to provide it for them, but in general such competence did exist. There was general agreement that looking into the future and considering ambulatory care review a completely hospital utilization review oriented program would give some difficulty.

A discussion followed as to variations in criteria and standards between hospitals within a PSRO. Dr. Brown expressed the opinion that the development of criteria by physicians within a hospital was important if they were to understand the use of the criteria and to profit educationally from the whole review cycle. Though agreeing, Dr. Harrington noted that it was the responsibility of the PSROs to develop community-wide screening criteria and standards. Dr. Roberts pointed out the difference between the types of criteria needed for admission certification and length-of-stay review as opposed to the in-depth special quality assurance studies which would be done by PSROs. The Chairman thanked the Council for its valuable contribution in presenting its viewpoints on the subject and noted the topic would require further discussion.

PUBLIC COMMENT

No comments or questions were voiced by the observers in attendance.

ADJOURNMENT

The meeting was adjourned at 11 a.m.

ATTENDEES

NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

January 21 & 22, 1974

B. D. Atelseh	Health Resources Administration, BHSR
Nedra Jean Bartholow	Hospital Utilization Project
Jon Bates, M.D.	ASH/DHEW
William J. Beck	Region I - DHEW
T. C. Bedwell, Jr., M.D.	BHI, SSA Baltimore
Berkeley V. Bennett	National Council of Health Care Services
Jim M. Booth	Capital Systems Group, Inc.
William Boyles	Blue Shield of Michigan
Angela Bradby	Assistant to Dr. Greene (Council)
Joseph E. Brantley, Jr.	PHS, Region III Philadelphia
J. E. Bryan	American Association of Foundation for Medical Care
David Buchanan	Utah Professional Review Organization
Norman Burch	College of American Pathologists
Ed ~~Carels~~	National Association of Blue Shield
J. Carow	American College of Surgeons
Cleveland R. Chambliss	HRA/Regional Medical Programs
Kee T. Chang	DMS/SRS
Larry Clare	Region II
Robert W. Coburn	American Health Systems, San Francisco
Bill Cohan	American Medical Association
Gene Cohen, M.D.	National Institute of Mental Health
G. Contis	DHEW
Margaret Conwell	National Institute of Mental Health
Casey Crawford	National Health Insurance Reports
Joseph C. Danfra, D.O.	Administration on Aging
Allan DeKaye	New York Health and Hospital Corp.
E. A. Diephaus	OPO
Edward Dixon	National Medical Association
Paul R. Donelan	American Medical Association
Herman Efron, Ph.D.	Veterans Administration
Arthur R. Ellenberger	Essex County Medical Society, New Jersey
Thomas Elwood	NRTA-AARP
Lily O. Engstrom	Association of American Medical Colleges
J. S. Fleming	Blue Cross, Philadelphia
Arlene L. Ford	BHI/SSA

Sam Gibson	Food and Drug Administration
Bob Goodnow	PHS Region V Chicago
J. Grady	MSA/SRS
Roger Graham	National Association of Blue Shield Plans
Richard Greene	Health Resources Administration
R. J. Harvey, D.O.	Administration on Aging
Leonard H. Hellman, M.D.	Region VIII, HEW
Lance Hoxie	B.S./NABSP
Thomas E. Hoyer	BHI/SSA
Donald Jacobs	Massachusettts Hospital Association
Anne Jamieson	Region III
Alan Kaplan	PSRO Letter - McGraw Hill
G. Kendar, Jr.	Blue Cross Association
C. Dexter Kimsey	PSRO Region IV, Atlanta
M. P. Klitzner	OPSR, Consultant
Deanne Knapp, M.D.	Food and Drug Administration
Debora Kramer	American Association of Psych. Services for Children
M. A. Kramer, M.D.	Association of American Physicians and Surgeons
Dean Kruzer	National Center for Health Statistics
Lawrence E. Kucken	Blue Cross Association, Chicago
Paul M. Lewis	Hospital Utilization Project
Carol Mabry	Health Insurance Associations of America
Dick Marquardt	Region X DHEW, Seattle
Ken Mayfield	PHS, Kansas City
Al Miller, M.D.	PHS, San Francisco
Paul R. Moyer, M.D.	George Washington University Medical Center
Robert McGarrah	Health Research Group
Patricia McGuire	National Association Blue Shield Plans
Patricia Ostrow	American Occupational Therapy Association
H. B. Pearce	Blue Cross Association
Jack Perlman, M.D.	Committee on Professional and Hospital Activities
Molly Pierce	Blue Cross Association
M. Plaska	APHA
John Pompelli	American College of Surgeons
Steven Portnoy	American Hospital Association
Thomas S. Powell	Hospital Association of Pennsylvania
J. E. Queen, M.D.	Maryland Blue Cross
Timothy J. Redmon	American Optometric Association
Janyce Rohde	AMRA
Dr. Melvin H. Rudov	CPEL
William B. Sale	American Hospital Association

Paul J. Sanazaro, M.D.	Consultant
Rose Scalise	Student - Pittsburgh
Ken Schneider, M.D.	PHS- Dallas
Charles W. Sernescl	Thomas Jefferson University
Carl D. Siegel, M.D.	Region VII
Russell D. Squires	George Washington University
E. H. Stark, D.O.	Administration on Aging
Michael H. Stolar, Ph.D.	USHP
Fred E. Tosh, M.D.	PHS Region VIII Denver
Eugene Ververka, M.D.	ORO/H
Susan J. Vierow	PHS Region V Chicago
Joanne L. Walker	BHI Program Policy
Paul E. Wilson, D.O.	Administration on Aging
Cole T. Yache	BHI Region V, Chicago
Dr. Zwick	Health Resources Administration

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

MEETING REPORT

August 27, 1973
9:00 a.m. - 3:45 p.m.

Parklawn Building
Conference Room G/H
Rockville, Maryland

ATTENDANCE

MEMBERS PRESENT

Clement R. Brown, M.D.
Ruth M. Covell, M.D.
Merlin K. DuVal, M.D.
Thomas J. Greene, M.D.
Robert J. Haggerty, M.D.
Donald C. Harrington, M.D.
Robert B. Hunter, M.D.
Alan R. Nelson, M.D.
Raymond J. Saloom, D.O.
Ernest W. Saward, M.D.
Willard Scrivner, M.D.

STAFF AND PROGRAM PARTICIPANTS

Rhoda Abrams
William I. Bauer, M.D.
Sidney Edelman
John Farrell, M.D.
Catherine Forrester
Michael Goran, M.D.
Katherine Gresham
Merle Griffin
David Hodgson, Ph.D.
Erwin Hytner
Alexander E. Kuehl, M.D.
James Morant
Robert Ouloosian
Paul Pryor
James Roberts, M.D.
Patricia Schoeni
Dale Schumacher, M.D.
Joyce Somsak

Dr. Ernest Saward, Chairman, opened the meeting at 9:00 a.m.

The minutes of the July 9-10 meeting were approved without dissent.

UNFINISHED BUSINESS

Mr. Sidney Edelman, Assistant General Counsel, DHEW, summarized his legal opinions which were furnished to the Council in full prior to the meeting. His position was as follows:

1) With respect to the establishment of PSROs with overlapping

boundaries so that two areas may include territory that is common to both, Mr. Edelman explained that the statute clearly contemplated that each PSRO would have exclusive jurisdiction with respect to the area for which it was designated

2) As to the question of whether any state regardless of size can have the option to become a statewide PSRO, Mr. Edelman stated that the statute does not address itself directly to this specific point. However, the statute does direct the Secretary to establish areas appropriate for the functioning of PSROs. In the opinion of Mr. Edelman the criteria for establishing PSRO areas which were developed by OPSR are legally supportable in terms of both the statute and its legislative history.

   In responding to questions about the designation of PSRO areas based on the population of physicians within the area, Mr. Edelman said that reasonably read, the statute contemplates an upper limit and a lower limit. Where the upper limit rests, however, would be an administrative judgment. Mr. Edelman felt the upper limit of 2,500 physicians in an area selected by OPSR in drafting their guidelines, is defensible.

   Discussion of substantive issues relevant to the administrative judgments regarding designation of PSRO areas was deferred until after the report of the Policy Development Subcommittee.

3) Concerning the matter of whether Council members can convene meetings of the National Professional Standards Review Council, Mr. Edelman said under the Federal Committee Management Act and the PSRO statute (P.L.92-603), the meetings of the National Council can be convened only by a federal official.

Report of the Evaluation Subcommittee

Dr. Robert Haggerty, Chairman of the Evaluation Subcommittee, reported that the Subcommittee met once to discuss the development of a draft Evaluation Plan. A final draft of this plan will be available for the Council in the late Fall. In discussing the draft plan, Dr. Haggerty explained that the authority for evaluation stems from two sources:

1) Overall departmental strategy for evaluation administered by the Assistant Secretary for Planning and Evaluation.

2) Public Law 92-603 which says that the Council has responsibility for evaluating performance of PSROs and conducting research in the area of peer review.

Dr. Haggerty said that the Subcommittee report will stress the long-term nature of any evaluation effort. Since it will be necessary to have "before" data in order to carry out effective evaluation, the Subcommittee has begun to identify some guidelines for fulfilling the data needs of the evaluation program. These guidelines include having a limited amount of data and a uniform data base. In addition, data on consumer attitudes should be obtained prior to implementing peer review.

Dr. Haggerty strongly emphasized the desirability of using EMCROs, the Federal-State-local multiple data systems, EHSDS and independent surveys for obtaining this data, rather than mounting a new national survey.

Another important function of an evaluation program is to detect unforeseeable events and have a capability to measure unanticipated occurrences.

The role of the Evaluation Subcommittee will not concern itself with the detailed methods but will provide overall guidance to the staff.

Report of the Policy Development Subcommittee

Dr. Raymond Saloom, Chairman, reported that the Policy Development Subcommittee made the following recommendations:

1) With respect to Area Designation Guideline #5:

Insert the word "generally" so that the Guideline will read: "A PSRO area should generally include a minimum of approximately 300 licensed, practicing physicians. While the maximum can be expected to vary with local circumstances, it generally should not exceed 2,500 licensed, practicing physicians."

2) Legal opinions should be provided to the Council on the following questions:

a) Once an area is officially designated within the particular geographic area (without overlapping) could

there be more than one PSRO within the designated area serving discreet areas of its own?

b) Can PSRO areas, once designated, be changed?

c) Can two or more designated areas have the same PSRO organization?

d) With reference to the membership of the Statewide Councils, there is a designation of two physician representatives of the State Medical Society. Which Medical Society or medical societies would be eligible for membership?

3) A position statement on statewide PSROs.

Dr. Saloom then identified some of the issues which the Subcommittee will be considering in the future:

1) Criteria to determine the capability and appropriateness of groups petitioning to become a PSRO for a designated area.

2) Criteria for determining whether in-house hospital review activities are acceptable and substantially meet the requirements of PSROs.

3) The fiscal aspects of the PSRO program, specifically with respect to (a) cost of PSRO program administration and (b) total medical care costs of Medicare and Medicaid.

4) Priorities of OPSR.

Discussion of the position statement on statewide PSROs was deferred until the afternoon and the other issues raised by the Subcommittee are to be listed as agenda items for a future meeting of the Council.

Report of the Data and Norms Subcommittee

Dr. Alan Nelson explained that this Subcommittee will address itself to the following matters:

1) Data

2) Norms, Standards & Criteria

3) Methods of review to be employed, including the anticipated integration of currently extant data system capability.

Dr. Nelson said the Subcommittee recognizes the importance of working with the Evaluation Subcommittee in defining a minimum data set, and expressed the hope that the data needs for evaluation, screening and, fiscal purposes could be integrated. Pursuant to this goal of identifying a uniform data base, the Subcommittee will examine the claims forms used by Medicare & Medicaid fiscal agents and make a recommedation as to those areas in which the claims forms could be augmented.

The Subcommittee felt with respect to norms, standards and criteria that while regional development of criteria and norms is the intent of the law, it would be appropriate to identify prototype criteria and norms, which the regions could modify. It was noted that the AMA Task Force on Guidelines could be a potential source of such prototype criteria and norms.

Report of the Executive Director

1. Dr. William I. Bauer, Director of the Office of Professional Standards Review, briefed the Council on the evolution of OPSR/BQA. He noted that the Director of OPSR will have direct line authority over the PSRO activities in BQA. He noted that funds are presently being transferred from the Social Security and Medicaid trust funds and a supplemental request for additional OPSR staff positions has been developed.

2. Mr. Robert Oulousian reported that area designation consultations taking place in the ten federal regions have been moving along on schedule with 35 state meetings already completed and the balance to take place by the end of the second week of September. The meetings have been well attended by a broad spectrum of health related organizations and have produced helpful information.

Where necessary a second round of meetings will be held the end of September and through October. We hope to have all the area designation announcements made by the middle of December.

During the discussion following Mr. Oulousian's remarks, it was suggested that Council members would have an opportunity to review area designation recommendations prior to final action by the Secretary.

3. Dr. David Hodgson presented a history of a National Center for Health Services Research and Development grant to the Health Services Foundation for the development of a Uniform Hospital Discharge Data Set. The objective of developing a uniform data set was to be able to identify information from hospital records that would be useful for a multiplicity of purposes, such as health care research, utilization review, management purposes, health planning and determining the feasibility of combining abstract information with basic billing information to simplify the claims review process. Dr. Hodgson said that the project results indicate that a uniform data set can be adapted to many software systems, but indicated some of the areas where problems connected with the adaptation could be expected. The utility of the selected data set was also tested. Then the individual components of the data set and issues relating to certain components were discussed.

Dr. Hodgson concluded with remarks about the implications of UHDDS for federal programs.

Substantive Issues

The afternoon session was devoted to discussion of specific substantive issues about which the Council had expressed interest.

1. Area Designation

Dr. Raymond Saloom reviewed the recommendations of the Policy Development Subcommittee on area designation.

a. Regarding area designation guideline #5, the word "generally" should be inserted between "it" and "should" to read:

"A PSRO area should generally include a minimum of approximately 300 licensed, practicing physicians. While the maximum can be expected to vary with local circumstances, it generally should not exceed 2,500 licensed, practicing physicians."

MOTION: Dr. Robert Hunter moved and the Council unanimously agreed to accept the Subcommittee's recommendation.

b. The Subcommittee's recommendation on Statewide PSROs was presented in the form of a position statement. During the discussion the Subcommittee said that local preference and emphasis on regional designation should be the overriding determinant of area designation within a state, however, questions were raised as to how

preference could actually be measured. The intent of the statement as restated was that this should provide our exception to the guidelines so that the Secretary of HEW would not be bound by the physician population limits when designating PSRO areas.

Mr. Edelman, Assistant General Counsel, pointed out that the statute and the legislative history clearly contemplate that organizations of physicians are to be provided an opportunity to generate enough capability to qualify to become the PSRO for a designated area until January 1, 1976. The statute directs the Secretary to provide technical assistance to them and to aid them in forming. Where the Secretary finds that such organizations are not willing or cannot reasonably be expected to develop capabilities to carry out Professional Standards Review Organization functions in an effective, economical timely and objective manner, he would enter into agreements with such other agencies or organizations with professional medical competence as he finds are willing and capable of carrying out such functions.

Mr. Edelman said that for this reason the effect of the position statement would be to deprive localities that have not achieved a high degree of organization by the time areas are designated of the opportunity to mature into viable PSROs.

It was the Council's feeling that their position statement allowed counties to opt out of the "Statewide" PSRO (as defined in the statement) as their organizations did mature and qualify as PSROs.

MOTION: Dr. Hunter moved to accept the position statement as revised and read. The motion was passed by a vote of 9-1. (A copy of the statement is attached at Tab 1.)

2. Earlier in the meeting the Policy Development Subcommittee had asked for a staff report on specific subjects of interest to them. Dr. Michael Goran, Director of the Bureau of Quality Assurance, said that the staff is working on staff papers to address these subjects, however, they are in varying stages of development. Once the papers

have gone through enough revision and OPSR/BQA is satisfied that they reflect an adequate approach, these will be made available to the Council for their advice and input.

3. The Council requested the General Counsel's office to report to them on the following:

a. If Statewide Councils are permitted in states with less than 3 PSROs, would there be an advisory group to this Council in addition to the advisory groups required by each PSRO in states with less than 3 (Ref.: Section 1162(e)) or are advisory groups to the PSROs still required?

b. If Statewide Councils are permitted in states with Statewide PSROs, could the Board of Directors of the group becoming a Statewide PSRO serve as the Statewide Council?

c. Is the membership of the "advisory group" restricted to physicians, or might it also include consumers?

d. Prototype articles of incorporation for organizations wanting to apply to become PSROs.

4. Other areas of interest to the Council were mentioned and the staff was asked to report at some point on:

a. A definition and detailing of what constitutes a profile of individual providers and individual patients.

b. "Confidentiality" issue. This question was raised in connection with reports that intermediaries are being required to submit names of those they are reviewing. The Policy Development Subcommittee was asked to review the issue.

Administrative Issues

1. The Council voted to continue holding their meetings on Mondays and Tuesdays.

2. The Council expressed a desire to meet someplace outside of Washington area once or twice a year.

Adjournment

The meeting adjourned at 3:45 p.m.

ATTENDEES
NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL
August 27, 1973

Name	Affiliation
Sandy Crank	Regional Rep. BHS - Boston
Al B. Honick	BHI Regional Office - Boston
D. F. Schramm	PHS - Kansas City
L. F. Kucken	Blue Cross Assoc. - Chicago
Joseph N. Gitlin	BRH-FDA
Len Janchar	BQA
Jack M. Perlman, M. D.	Comm. on Professional & Hospital Activities - Ann Arbor
Helen L. Rhetta, M.D.	DHEW Region V
John Farrell, M.D.	OPSR
S. Weinstein	BQA
Henry Miller	Arthur Young & Co.
Pat Schoeni	OPSR
William Bauer, M.D.	OPSR
Bill Cohan	AMA
A. Kuehl, M.D.	OPSR
John Pompelli	ACS - Chicago
Kurt Darr	GWU, Washington
Geza Kadar	Blue Cross Assoc.
Michael Lespane	American Hospital Assoc.
Sandra J. Leiman	American Occupational Therapy Assoc.
Alan Kaplan	PSRO Letter
William J. Skinner	American Assoc. Colleges of Pharmacy
James E. Bryan	Am. Assoc. of Fd. for Medical Care
James T. Cummin	Jewis Men's Hospital - Boston
Norman D. Beucher	College of American Pathologists
Paul R. M. Danley	American Med. Assoc.
Sam T. Gibson	FDA - BOB
Dr. Ralph Engel	National Pharmacy Insurance Council
Paul Woodard	NIMH
R. A. Dilweg	Honewell
Stephen J. Ackerman	American Assoc. of Medical Colleges
Jim Marriman	SRS/ MSA
Robert McGarrah	Health Research Group
Theodis Thompson	National Medical Assoc. Foundation
Barbara J. Harrelson	American Dental Assoc.
Patrick McCarthy	SRS/MSA
J. Richardson	EPA
Robert McAlpine	NRTA/AARP
J. Reynolds	
Rhoda Abrams	BQA

Name	Affiliation
Thomas Elwood	NRTA-AARP
Anne J. Amieson	SSA-BHI
Jane Burton	Health Insurance Assoc. of America
Tim Redman	American Optometric Assoc.
Dennis Yamanato, O.D.	AOA
William J. Beck,	OPSR - Boston
Patricia A. McGuire	NABSP - Washington, D.C.
Kathleen R. Ratichek	HSA - Denver RO
Michael M. Schoor	U.S. Chamber of Commerce
Joyce Somsak	OPSR
Fred Stone	HSA
Roger Myer, M.D.	SRS - HEW V
Nancy Hicks	N.Y. Times
Casey Crawford	NHI Reports
Peter Frishauf	
Bob Harper	DHEW - SFRO
Al Miller	" "
C. Robert Dean, M.D.	PHS - Reg. II NYC
F. Laurence Clare, M.D.	" " "
Carol J. Bohannon	Dept. of Human Resources - DC Gov't.
Edward A. Rowenow, Jr.	American College of Physicians
M. Zukert	The Blue Sheet
B. Bennett	Nat. Council Health Care Services
Elizabeth J. Cornwell	" " " " "
Clyde Couchman	HEW Region III
S. Frazier	Arthur Young & C o.
Winona Hocutt	BHI

TAB 1

POSITION STATEMENT ON AREA DESIGNATION

Adopted by the National Professional
Standards Review Council 8/27/73

It is clear that area designation considerations within a state recognize that appropriate geographic sublimits within the state with the capability to develop a PSRO meeting law and regulatory requirements can seek, and can be expected to obtain, area designation.

It is recognized that there are approximately 29 states with less than 3,000 physicians and it is acknowledged that the Secretary could, if desirable, designate the entire state in such case as a single PSRO area.

At the same time, in any of the approximately 21 other states where the professional association(s) concerned demonstrate a desire and capability of successfully sponsoring a state level PSRO, the option of a "statewide" area designation or an area designation encompassing the remainder of the state could be considered even though the 2,500 physician general limit (Guideline #5) is exceeded. Under either option the state level PSRO would contract directly with DHEW to coordinate and administer all professional review functions within its purview, with the actual review performed locally throughout the designated area.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

MEETING REPORT

October 15, 1973
9:00 a.m. - 3:30 p.m.

Conference Room 5051
HEW North Building
Washington, D.C.

ATTENDANCE

MEMBERS PRESENT

Clement R. Brown, M.D.
Ruth M. Covell, M.D.
Thomas J. Greene, M.D.
Robert J. Haggerty, M.D.
Robert B. Hunter, M.D.
Alan R. Nelson, M.D.
Raymond J. Saloom, M.D.
Ernest W. Saward, M.D.
Willard Scrivner, M.D.

MEMBERS ABSENT

Merlin K. DuVal, M.D.
Donald C. Harrington, M.D.

STAFF AND PROGRAM PARTICIPANTS

Rhoda Abrams
Helaine Cohen
Sidney Edelman
Charles Edwards, M.D.
Assistant Secretary for Health
John Farrell, M.D.
Catherine Forrester
Elmer A. Gardner, M.D.
Michael Goran, M.D.
Katherine Gresham
Merle Griffin
Arthur Hess, Acting Commissioner,
Social Security Administration
David Hodgson, Ph.D.
Erwin Hytner
Alexander E. Kuehl, M.D.
Patrick McCarthy, PSRO Staff,
Medical Services Administration,
SRS
James Morant
William Munier, M.D.
Paul Pryor
James Roberts, M.D.
Patricia Schoeni
Dale Schumacher, M.D.
Dennis Siebert
Henry Simmons, M.D., M.P.H.
Joyce Somsak

CALL TO ORDER

Dr. Ernest Saward, Chairman, opened the third meeting of the National Council at 9:00 a.m.

The Council approved the minutes of the August 27, 1973 meeting and the agenda for the third meeting of the Council.

Dr. Charles Edwards, Assistant Secretary for Health, told the Council that the Professional Standards Review program remains his number one priority. The program is complex, entailing a major coordinating job. Dr. Henry Simmons, Deputy Assistant Secretary of Health, in taking on the additional responsibility of Acting Director of OPSR will be able to assure that this important coordination will be done successfully. He brings to the position an outstanding professional background as a practicing physician and several years of management experience.

The single most important task facing the Department at the present time, Dr. Edwards said, is the development of an area designation system that will provide local autonomy in the judgment of professional standards while allowing a broad umbrealla approach in the provision of management and administrative support functions.

In response to a question on the role of the National Council, Dr. Edwards stated that the Department must take the ultimate responsibility for the management of the program, but all major decisions should be discussed by the Council and their advice and guidance obtained.

One of the Council members asked what the Department's positon was with respect to the Council's recommendation that government hospitals adopt a system of peer review. Dr. Edwards explained that because the PSRO authorizing legislation does not cover government hospitals the Department has no jurisdiction in the matter. If peer review proves to be a meaningful approach, however, he said it would be as applicable to government hospitals as it is to non-government hospitals.

Dr. Edwards then introduced Dr. Henry E. Simmons.

Report from the Acting Director

Dr. Simmons expressed his pleasure at having responsibility for one of the most interesting medical programs ever to be developed. He said he feels that the PSRO legislation will have a greater impact on the practice of medicine than any other health legislation that has ever been enacted. It also represents Medicine's last hope to monitor itself and remain an independent profession. The potential for good and the opportunity it provides our profession to bring some order in areas where serious problems now exist and to improve the quality of medical care on the public's behalf, are virtually unlimited.

He also said that HEW is unequivically committed to the PSRO program and although there have been administrative problems in the past, the program has not lost its vital momentum.

Between now and January 1 fifty new positions will be added bringing the total personnel to 80. Even though the program involves several agencies, it will be directed out of Dr. Edwards' office. Dr. Edwards' office has the ability to get all appropriate elements throughout government together to work on this program.

Dr. Simmons then introduced the Department's PSRO workplan.

At the next meeting, the Council will have an opportunity to review detailed program goals and long-term and short-term objectives, but very generally speaking the following six goals are guiding us at the present time:

1. To assure that the quality of care rendered at any point within the health care system is of uniformly acceptable quality.

2. To identify health care problems and work towards their improvement.

3. To improve health care through medical education.

4. To assure that the costs are appropriate to the level, type and location of services.

5. To effect improvements in physician practices through use of the financing systems and sanctions.

6. To assure uniform and effective utilization review policy and practices.

The legislative authority and implementation plans for the PSRO program were then presented in detail through visual aids. Copies of the charts used are attached at Tab. 11.

Dr. Simmons noted the following short-term milestones:

By January 1: Area Designation proposals for comment will be published in the Federal Register. Appropriate modifications on the basis of the comments will then be made.

By February 1: Policy Guidelines for the selection of PSROs.

By July 1, 1974: Review, approval and award of funds to the first 50 PSROs and 25 State Councils.

Dr. Michael Goran then reviewed the detailed PSRO workplan noting that there are really two separate planning schedules. There is the Implementation Plan which attempts to lay out the program direction for the next two years and predict the major milestones for that period. Then we have another process which is designed to take us through the next three months. Dr. Goran highlighted each component of the plans and copies of the charts he used are included at Tab 1.

At the close of the presentation on the Implementation Plan, the Council commended Dr. Simmons and the staff for such an organized, lucid and informative presentation.

Before proceeding into a discussion on Area Designation, Dr. Simmons introduced Dr. Elmer A. Gardner, recently head of the Division of Neuropharmacological Drugs and the Methadone Program in FDA, will serve as his Assistant in directing the PSRO program.

Area Designation

Dr. Simmons reviewed the six area designation guidelines. With regard to Guideline Six:

> "A PSRO area should generally include a minimum of approximately 300 licensed practicing physicians. While the maximum can be expected to vary with local circumstances, it will generally not exceed approximately 2500 licensed practicing physicians,"

a policy statement was read which emphasized that review of care must be controlled and performed at the local level in agreed upon sub-units of the state. In some instances, a statewide organization could be recognized to take responsibility for general administration, coordination and support of the local review process. Through this arrangement, local review and control would be retained, but a structure would also be allowed to facilitate program management and make the best use of available resources.

Dr. Raymond Saloom, Chairman of the Policy Development Subcommittee, said that Dr. Simmons' statement was consistent with the position on area designation taken by the Council at their August meeting.

Legal Opinions

Mr. Sidney Edelman gave a report on the legal issues raised by the Council. Complete written opinions will be sent to the Council prior to their next meeting.

1. Representation of consumers on advisory groups to Statewide Councils and in the absence of Statewide Councils, the individual PSROs.

In Mr. Edelman's opinion, consumers cannot sit on a Council in their capacity as consumers. There is nothing to prohibit practitioners from designating a person who is a consumer to represent them, however, the statute limits membership to "representatives of health care practitioners."

A consumer advisory group could be formed by a PSRO, but it would not be part of the official statutory advisory group structure.

2. Is the Secretary authorized to appoint Statewide Councils in states with less than three PSROs?

Mr. Edelman says he has concluded that in the context of the statute, the Secretary cannot appoint a Statewide Council in a state with less than three PSROs.

At the next meeting, Mr. Edelman will respond to a question as to whether consumers can be represented on PSRO Boards of Directors.

Report of the Evaluation Subcommittee

Dr. Robert Haggerty, Chairman of the Evaluation Subcommittee, reported that they had reviewed the evaluation of the EMCRO experience as a guide to the evaluation of PSROs. Noting that while EMCROs are not PSROs, there are some lessons from the EMCRO evaluation that would be useful for the PSRO Council to examine.

1. An Evaluation Plan should be built into the PSRO program as early in its development as possible.

2. There is a host of methodological problems accompanying diagnostic and procedural categories.

3. An evaluation plan cannot be set up until program goals have been clearly outlined.

4. There must be adequate program operating time before an evaluation can be useful and show results.

The Subcommittee suggested that in the beginning a measured approach would be desired in identifying data items and trends.

It was the feeling of the Subcommittee that specifications as to program goals and objectives must be made before a detailed evaluation plan can be developed.

Dr. Simmons proposed that at the next meeting the Council focus on the detailed goals and objectives of the program. The staff will distribute a paper on this subject prior to November 26.

Report of the Data and Norms Subcommittee

Dr. Alan Nelson reported that the Subcommittee considered the following matters at their last meeting:

1. Data Elements in the Uniform Hospital Discharge Data Set.

2. Definitions of the terms "norms," "standards," "criteria" and "screening."

3. Diagnostic and procedural coding systems.

The Subcommittee recommendations to the Council in these areas were

1. Review recommended hospital discharge minimal data set for use in the PSRO program.

2. Adopt revised definitions of the terms "norms," "standards," "criteria," and "screening."

3. Review coding system criteria to be developed by staff. The Subcommittee directed staff to begin development of criteria specifying the characteristics a given coding system should possess to be useful in the PSRO program.

At their next meeting, the Subcommittee is planning to examine approaches to data collection using the Medicare and Medicaid billing forms and the Modified Uniform Hospital Discharge Data Set.

Consideration of the Subcommittee's revised definition of "norms," "standards," "criteria" and "screening" was tabled until the next Council meeting.

During the discussion of the Subcommittee's recommendations on a minimal data set, questions were raised as to the appropriateness of including in a "minimal" set the items "total charges" and a breakdown of the totals into line items such as x-ray, pharmacy, etc. It was noted that a number of hospitals are not compiling bills on patients that are getting reimbursed, but instead are using some other kind of methodology.

Dr. Nelson said that the charges and breakdown items had been suggested because there can be such a variance between hospitals in average pharmaceutical costs and this can serve a screening value.

In response to a question as to the deadline for the development of a minimal data set, Dr. Goran said the Department is already exploring the implementation of the minimum basic data set in Medicare and Medicaid, and hopefully for other third party programs. Decisions on implementation will be made before April, and there are two issues for the program which must be resolved before then. The first is the adequacy of the basic data set as recommended by the National Committee on Vital and Health Statistics. The second is the identification of the additional data items that are desirable for specific purposes of the program.

Mr. Patrick McCarthy, Chairman of the PSRO Task Force in the Medical Services Administration addressed the Council on the implications of the PSRO program for Medicaid (Title XIX).

Medicaid is a State program that receives federal matching if certain minimal services are provided. Great prerogatives are given to states in designing their programs and the administrative organization of them. Therefore, we have 53 different Medicaid program.

Growth of the program expenditure since 1966 has been from $1.25 million to $8.7 billion in 1973 covering 23.5 million. In 1974 it is anticipated to be $10.1 billion covering 27.5 million people.

Originally, there was nothing in legislation on utilization review. Now there are two program provisions in sections 1902 (a) 46 and 30 which require states to conduct utilization review.

The last Congress added Section 237 to P.L. 92-603 which requires additional efforts to increase states' activities in U.R. and 207 which covers sanctions, setting forth certain disincentives to the states if they don't carry out these things. Section 235, is a matching program for the development and installation of management information systems.

The states have enthusiasm for the objectives of the PSRO program and see the advantages in having a professional organization review utilization. The states are pressing forward with utilization review as required by the law; however, at the same time MSA is holding discussions about relinquishing those responsibilities to another organization.

1. The principal problem for the states with respect to PSRO appears to be accountability, that is, some entity other than the state government making a decision about the expenditure of state funds. Mr. McCarthy said he expects the accountability problem to be resolved by individual states and PSROs with the federal government providing general guidelines.

2. Another complication for Medicaid programs in converting to PSRO will be the Medicaid Management Information system (MMIS). This program includes three major subsystems: claims processing, surveillance, utilization review and MARS, which is the Management Administrative Report System. MMIS could be the principal mechanism for providing information to the PSRO; however, at the present time the majority of proposals from the states have not built in the requirements of local PSROs. It is important, therefore, that PSROs get involved as soon as possible in determining what their needs are and what the system should be.

3. The states have also expressed concern about the fact that states have utilization review requirements for every service included in their benefits. When PSROS come in they want to be able to relinquish all responsibilities in this regard, not just review of in-patient hospitalization.

MSA has initiated some incentives to states to become involved in PSRO-type organizations.

4. States have raised a question as to their role during the transition into the PSRO system.

5. After PSROs are operational, what role will the states have in monitoring the effectiveness of the PSRO with respect to the handling of the state's funds.

In responding to a question, Mr. McCarthy said that among the Medicaid programs, uniformily of data is limited.

A Council member pointed out that while the requirement for two kinds of utilization review will present a problem for the profession as well as the states.

With respect to integrating PSRO and the existing data system capability, one Council member said he felt the PSRO organization must manage the data system, rather than be just a recipient of data produced by someone else's system.

Noting that Medicaid recipients require pre-certification for hospital admission, Dr. Simmons clarified the Department's definition of pre-admission certification is the identification of criteria and screening standards set by the profession which must be met before a specific diagnosis warrants hospitalization. The mechanism for this has not been worked out. A problem arises in implementation because of the dichotomy between medical necessity and elements in a benefit package.

Remarks of Mr. Arthur Hess

Dr. Saward introduced Mr. Arthur Hess, Acting Commissioner of Social Security who addressed the Council on the implications of PSRO for the Medicare Program.

Mr. Hess said he sees a gap between where we are today in the way in which medicine is practiced and health care services are consumed, delivered and financed. This gap will have to be surmounted in the next few years to make the concept of peer review a working reality.

Medicare originally was patterned as a financing mechanism which operated on existing coverages and on the premise that there would be not interference with the practice of medicine or the management of a medical institution. Eventually it became necessary for carriers and intermediaries to step up their relationships with medical societies in order to get a higher degree of peer review involvement in the claims process.

Mr. Hess said he feels one of the realities of life in the PSRO program is to find a way to accomodate and rationalize the process with the claimsprocess and vice versa. This presents a huge logistical question.

There were also conditions of participation for institutions wanting to participate in the Medicare program. One of these conditions was utilization review for inpatient care, and this has not worked in all places.

H.R. 1 last year, in an effort to attack the problem of retroactive denials cases that had not had proper utilization review attention created an incentive for hospitals and patients to get off the hook as far as liability goes for questioned cases, if they have an effective inhouse utilization review plan which promises that improper coverage or questionable use of services will be kept at a minimum, and is demonstrated to be kept at a minimum by the records of the hospital.

The Social Security Administration felt irrespective of PSROs that they had to lean more heavily on hospitals in order to control the federal budget. Most hospital utilization review committees are in a position to do what needs to be done without waiting for PSROs. Mr. Hess said this will have a positive impact on the implementation of the PSRO program.

In noting the inevitable problems that will occur between a new national program's conception and implementation, Mr. Hess advised that PSROs be approached in small, manageable steps dealing to the fullest extent with existing data and systems, noting that in the beginning PSROs will have more impact on the community if they look at patterns of care in a community rather than individual transactions.

Ms. Patricia Schoeni presented to the Council the Communications Plan for the PSRO program. Three audiences were identified in the plan, namely, the medical care community, potential and actual PSROs and the general public. The objective and approach for each audience were delineated and milestones and schedules were discussed. Among the first issuances will be an OPSR Memo to be sent approximately once a month to professional medical organizations to keep them informed about developments in the PSRO program and a leaflet to all physicians in the country containing questions and answers about PSRO.

Dr. Saward asked that the Policy Development Subcommittee undertake a study of the Communications Plan and report to the Council on it.

Future Meetings

Dr. Saward announced that meetings of the Council have been scheduled for November 26 and January 21.

Adjournment

The meeting adjourned at 3:30 p.m.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

MEETING REPORT

August 27, 1973
9:00 a.m. - 3:45 p.m.

Parklawn Building
Conference Room G/H
Rockville, Maryland

ATTENDANCE

MEMBERS PRESENT

Clement R. Brown, M.D.
Ruth M. Covell, M.D.
Merlin K. DuVal, M.D.
Thomas J. Greene, M.D.
Robert J. Haggerty, M.D.
Donald C. Harrington, M.D.
Robert B. Hunter, M.D.
Alan R. Nelson, M.D.
Raymond J. Saloom, D.O.
Ernest W. Saward, M.D.
Willard Scrivner, M.D.

STAFF AND PROGRAM PARTICIPANTS

Rhoda Abrams
William I. Bauer, M.D.
Sidney Edelman
John Farrell, M.D.
Catherine Forrester
Michael Goran, M.D.
Katherine Gresham
Merle Griffin
David Hodgson, Ph.D.
Erwin Hytner
Alexander E. Kuehl, M.D.
James Morant
Robert Ouloosian
Paul Pryor
James Roberts, M.D.
Patricia Schoeni
Dale Schumacher, M.D.
Joyce Somsak

Dr. Ernest Saward, Chairman, opened the meeting at 9:00 a.m.

The minutes of the July 9-10 meeting were approved without dissent.

UNFINISHED BUSINESS

Mr. Sidney Edelman, Assistant General Counsel, DHEW, summarized his legal opinions which were furnished to the Council in full prior to the meeting. His position was as follows:

1) With respect to the establishment of PSROs with overlapping

boundaries so that two areas may include territory that is common to both, Mr. Edelman explained that the statute clearly contemplated that each PSRO would have exclusive jurisdiction with respect to the area for which it was designated

2) As to the question of whether any state regardless of size can have the option to become a statewide PSRO, Mr. Edelman stated that the statute does not address itself directly to this specific point. However, the statute does direct the Secretary to establish areas appropriate for the functioning of PSROs. In the opinion of Mr. Edelman the criteria for establishing PSRO areas which were developed by OPSR are legally supportable in terms of both the statute and its legislative history.

   In responding to questions about the designation of PSRO areas based on the population of physicians within the area, Mr. Edelman said that reasonably read, the statute contemplates an upper limit and a lower limit. Where the upper limit rests, however, would be an administrative judgment. Mr. Edelman felt the upper limit of 2,500 physicians in an area selected by OPSR in drafting their guidelines, is defensible.

   Discussion of substantive issues relevant to the administrative judgments regarding designation of PSRO areas was deferred until after the report of the Policy Development Subcommittee.

3) Concerning the matter of whether Council members can convene meetings of the National Professional Standards Review Council, Mr. Edelman said under the Federal Committee Management Act and the PSRO statute (P.L.92-603), the meetings of the National Council can be convened only by a federal official.

Report of the Evaluation Subcommittee

Dr. Robert Haggerty, Chairman of the Evaluation Subcommittee, reported that the Subcommittee met once to discuss the development of a draft Evaluation Plan. A final draft of this plan will be available for the Council in the late Fall. In discussing the draft plan, Dr. Haggerty explained that the authority for evaluation stems from two sources:

1) Overall departmental strategy for evaluation administered by the Assistant Secretary for Planning and Evaluation.

2) Public Law 92-603 which says that the Council has responsibility for evaluating performance of PSROs and conducting research in the area of peer review.

Dr. Haggerty said that the Subcommittee report will stress the long-term nature of any evaluation effort. Since it will be necessary to have "before" data in order to carry out effective evaluation, the Subcommittee has begun to identify some guidelines for fulfilling the data needs of the evaluation program. These guidelines include having a limited amount of data and a uniform data base. In addition, data on consumer attitudes should be obtained prior to implementing peer review.

Dr. Haggerty strongly emphasized the desirability of using EMCROs, the Federal-State-local multiple data systems, EHSDS and independent surveys for obtaining this data, rather than mounting a new national survey.

Another important function of an evaluation program is to detect unforeseeable events and have a capability to measure unanticipated occurrences.

The role of the Evaluation Subcommittee will not concern itself with the detailed methods but will provide overall guidance to the staff.

Report of the Policy Development Subcommittee

Dr. Raymond Saloom, Chairman, reported that the Policy Development Subcommittee made the following recommendations:

1) With respect to Area Designation Guideline #5:

Insert the word "generally" so that the Guideline will read: "A PSRO area should generally include a minimum of approximately 300 licensed, practicing physicians. While the maximum can be expected to vary with local circumstances, it generally should not exceed 2,500 licensed, practicing physicians."

2) Legal opinions should be provided to the Council on the following questions:

a) Once an area is officially designated within the particular geographic area (without overlapping) could

there be more than one PSRO within the designated area serving discreet areas of its own?

b) Can PSRO areas, once designated, be changed?

c) Can two or more designated areas have the same PSRO organization?

d) With reference to the membership of the Statewide Councils, there is a designation of two physician representatives of the State Medical Society. Which Medical Society or medical societies would be eligible for membership?

3) A position statement on statewide PSROs.

Dr. Saloom then identified some of the issues which the Subcommittee will be considering in the future:

1) Criteria to determine the capability and appropriateness of groups petitioning to become a PSRO for a designated area.

2) Criteria for determining whether in-house hospital review activities are acceptable and substantially meet the requirements of PSROs.

3) The fiscal aspects of the PSRO program, specifically with respect to (a) cost of PSRO program administration and (b) total medical care costs of Medicare and Medicaid.

4) Priorities of OPSR.

Discussion of the position statement on statewide PSROs was deferred until the afternoon and the other issues raised by the Subcommittee are to be listed as agenda items for a future meeting of the Council.

Report of the Data and Norms Subcommittee

Dr. Alan Nelson explained that this Subcommittee will address itself to the following matters:

1) Data

2) Norms, Standards & Criteria

3) Methods of review to be employed, including the anticipated integration of currently extant data system capability.

Dr. Nelson said the Subcommittee recognizes the importance of working with the Evaluation Subcommittee in defining a minimum data set, and expressed the hope that the data needs for evaluation, screening and, fiscal purposes could be integrated. Pursuant to this goal of identifying a uniform data base, the Subcommittee will examine the claims forms used by Medicare & Medicaid fiscal agents and make a recommedation as to those areas in which the claims forms could be augmented.

The Subcommittee felt with respect to norms, standards and criteria that while regional development of criteria and norms is the intent of the law, it would be appropriate to identify prototype criteria and norms, which the regions could modify. It was noted that the AMA Task Force on Guidelines could be a potential source of such prototype criteria and norms.

Report of the Executive Director

1. Dr. William I. Bauer, Director of the Office of Professional Standards Review, briefed the Council on the evolution of OPSR/BQA. He noted that the Director of OPSR will have direct line authority over the PSRO activities in BQA. He noted that funds are presently being transferred from the Social Security and Medicaid trust funds and a supplemental request for additional OPSR staff positions has been developed.

2. Mr. Robert Oulousian reported that area designation consultations taking place in the ten federal regions have been moving along on schedule with 35 state meetings already completed and the balance to take place by the end of the second week of September. The meetings have been well attended by a broad spectrum of health related organizations and have produced helpful information.

Where necessary a second round of meetings will be held the end of September and through October. We hope to have all the area designation announcements made by the middle of December.

During the discussion following Mr. Oulousian's remarks, it was suggested that Council members would have an opportunity to review area designation recommendations prior to final action by the Secretary.

3. Dr. David Hodgson presented a history of a National Center for Health Services Research and Development grant to the Health Services Foundation for the development of a Uniform Hospital Discharge Data Set. The objective of developing a uniform data set was to be able to identify information from hospital records that would be useful for a multiplicity of purposes, such as health care research, utilization review, management purposes, health planning and determining the feasibility of combining abstract information with basic billing information to simplify the claims review process. Dr. Hodgson said that the project results indicate that a uniform data set can be adapted to many software systems, but indicated some of the areas where problems connected with the adaptation could be expected. The utility of the selected data set was also tested. Then the individual components of the data set and issues relating to certain components were discussed.

Dr. Hodgson concluded with remarks about the implications of UHDDS for federal programs.

Substantive Issues

The afternoon session was devoted to discussion of specific substantive issues about which the Council had expressed interest.

1. Area Designation

Dr. Raymond Saloom reviewed the recommendations of the Policy Development Subcommittee on area designation.

a. Regarding area designation guideline #5, the word "generally" should be inserted between "it" and "should" to read:

"A PSRO area should generally include a minimum of approximately 300 licensed, practicing physicians. While the maximum can be expected to vary with local circumstances, it generally should not exceed 2,500 licensed, practicing physicians."

MOTION: Dr. Robert Hunter moved and the Council unanimously agreed to accept the Subcommittee's recommendation.

b. The Subcommittee's recommendation on Statewide PSROs was presented in the form of a position statement. During the discussion the Subcommittee said that local preference and emphasis on regional designation should be the overriding determinant of area designation within a state, however, questions were raised as to how

preference could actually be measured. The intent of the statement as restated was that this should provide our exception to the guidelines so that the Secretary of HEW would not be bound by the physician population limits when designating PSRO areas.

Mr. Edelman, Assistant General Counsel, pointed out that the statute and the legislative history clearly contemplate that organizations of physicians are to be provided an opportunity to generate enough capability to qualify to become the PSRO for a designated area until January 1, 1976. The statute directs the Secretary to provide technical assistance to them and to aid them in forming. Where the Secretary finds that such organizations are not willing or cannot reasonably be expected to develop capabilities to carry out Professional Standards Review Organization functions in an effective, economical timely and objective manner, he would enter into agreements with such other agencies or organizations with professional medical competence as he finds are willing and capable of carrying out such functions.

Mr. Edelman said that for this reason the effect of the position statement would be to deprive localities that have not achieved a high degree of organization by the time areas are designated of the opportunity to mature into viable PSROs.

It was the Council's feeling that their position statement allowed counties to opt out of the "Statewide" PSRO (as defined in the statement) as their organizations did mature and qualify as PSROs.

MOTION: Dr. Hunter moved to accept the position statement as revised and read. The motion was passed by a vote of 9-1. (A copy of the statement is attached at Tab 1.)

2. Earlier in the meeting the Policy Development Subcommittee had asked for a staff report on specific subjects of interest to them. Dr. Michael Goran, Director of the Bureau of Quality Assurance, said that the staff is working on staff papers to address these subjects, however, they are in varying stages of development. Once the papers

have gone through enough revision and OPSR/BQA is satisfied that they reflect an adequate approach, these will be made available to the Council for their advice and input.

3. The Council requested the General Counsel's office to report to them on the following:

a. If Statewide Councils are permitted in states with less than 3 PSROs, would there be an advisory group to this Council in addition to the advisory groups required by each PSRO in states with less than 3 (Ref.: Section 1162(e)) or are advisory groups to the PSROs still required?

b. If Statewide Councils are permitted in states with Statewide PSROs, could the Board of Directors of the group becoming a Statewide PSRO serve as the Statewide Council?

c. Is the membership of the "advisory group" restricted to physicians, or might it also include consumers?

d. Prototype articles of incorporation for organizations wanting to apply to become PSROs.

4. Other areas of interest to the Council were mentioned and the staff was asked to report at some point on:

a. A definition and detailing of what constitutes a profile of individual providers and individual patients.

b. "Confidentiality" issue. This question was raised in connection with reports that intermediaries are being required to submit names of those they are reviewing. The Policy Development Subcommittee was asked to review the issue.

Administrative Issues

1. The Council voted to continue holding their meetings on Mondays and Tuesdays.

2. The Council expressed a desire to meet someplace outside of Washington area once or twice a year.

Adjournment

The meeting adjourned at 3:45 p.m.

ATTENDEES
NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL
August 27, 1973

Name	Affiliation
Sandy Crank	Regional Rep. BHS - Boston
Al B. Honick	BHI Regional Office - Boston
D. F. Schramm	PHS - Kansas City
L. F. Kucken	Blue Cross Assoc. - Chicago
Joseph N. Gitlin	BRH-FDA
Len Janchar	BQA
Jack M. Perlman, M. D.	Comm. on Professional & Hospital Activities - Ann Arbor
Helen L. Rhetta, M.D.	DHEW Region V
John Farrell, M.D.	OPSR
S. Weinstein	BQA
Henry Miller	Arthur Young & Co.
Pat Schoeni	OPSR
William Bauer, M.D.	OPSR
Bill Cohan	AMA
A. Kuehl, M.D.	OPSR
John Pompelli	ACS - Chicago
Kurt Darr	GWU, Washington
Geza Kadar	Blue Cross Assoc.
Michael Lespane	American Hospital Assoc.
Sandra J. Leiman	American Occupational Therapy Assoc.
Alan Kaplan	PSRO Letter
William J. Skinner	American Aseoc. Colleges of Pharmacy
James E. Bryan	Am. Assoc. of Fd. for Medical Care
James T. Cummin	Jewis Men's Hospital - Boston
Norman D. Beucher	College of American Pathologists
Paul R. M. Danley	American Med. Assoc.
Sam T. Gibson	FDA - BOB
Dr. Ralph Engel	National Pharmacy Insurance Council
Paul Woodard	NIMH
R. A. Dilweg	Honewell
Stephen J. Ackerman	American Assoc. of Medical Colleges
Jim Harriman	SRS/ NSA
Robert McGarrah	Health Research Group
Theodis Thompson	National Medical Assoc. Foundation
Barbara J. Harrelson	American Dental Assoc.
Patrick McCarthy	SRS/NSA
J. Richardson	EPA
Robert McAlpine	NRTA/AARP
J. Reynolds	
Rhoda Abrams	BQA

Name	Affiliation
Thomas Elwood	NRTA-AARP
Anne J. Amieson	GSA-BHI
Jane Burton	Health Insurance Assoc. of America
Tim Redman	American Optometric Assoc.
Dennis Yamanato, O.D.	AOA
William J. Beck,	OPSR - Boston
Patricia A. McGuire	NABSP - Washington, D.C.
Kathleen R. Ratichek	HSA - Denver RO
Michael M. Schoor	U.S. Chamber of Commerce
Joyce Somsak	OPSR
Fred Stone	HSA
Roger Myer, M.D.	SRS - HEW V
Nancy Hicks	N.Y. Times
Casey Crawford	NHI Reports
Peter Rifshauf	
Bob Harper	DHEW - SFRO
Al Miller	" "
C. Robert Dean, M.D.	PHS - Reg. II NYC
F. Laurence Clare, M.D.	" " "
Carol J. Bohannon	Dept. of Human Resources - DC Gov't.
Edward A. Rowenow, Jr.	American College of Physicians
M. Zukert	The Blue Sheet
B. Bennett	Nat. Council Health Care Services
Elizabeth J. Cornwell	" " " " "
Clyde Couchman	HEW Region III
S. Frazier	Arthur Young & C o.
Winona Hocutt	BHI

TAB 1

POSITION STATEMENT ON AREA DESIGNATION

Adopted by the National Professional
Standards Review Council 8/27/73

It is clear that area designation considerations within a state recognize that appropriate geographic sublimits within the state with the capability to develop a PSRO meeting law and regulatory requirements can seek, and can be expected to obtain, area designation.

It is recognized that there are approximately 29 states with less than 3,000 physicians and it is acknowledged that the Secretary could, if desirable, designate the entire state in such case as a single PSRO area.

At the same time, in any of the approximately 21 other states where the professional association(s) concerned demonstrate a desire and capability of successfully sponsoring a state level PSRO, the option of a "statewide" area designation or an area designation encompassing the remainder of the state could be considered even though the 2,500 physician general limit (Guideline #5) is exceeded. Under either option the state level PSRO would contract directly with DHEW to coordinate and administer all professional review functions within its purview, with the actual review performed locally throughout the designated area.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

MEETING REPORT

July 9, 1973
8:45 a.m. - 4:15 p.m.

July 10, 1973
8:45 a.m. - 11:35 a.m.

National Institutes
of Health
Conference Room 31C10
Bethesda, Maryland

The meeting was opened at 8:45 a.m. on July 9, 1973 by Dr. William I. Bauer, Director, Office of Professional Standards Review. Dr. Bauer introduced Dr. Ernest W. Saward who will serve as Chairman of the Council for a period of one year. Dr. Saward presided throughout the remainder of the meeting.

ATTENDANCE

MEMBERS PRESENT

Ernest W. Saward, M.D.
Ruth M. Covell, M.D.
Merlin K. DuVal, M.D.
Thomas J. Greene, M.D.
Robert J. Haggerty, M.D.
Donald C. Harrington, M.D.
Robert B. Hunter, M.D.
Alan R. Nelson, M.D.
Raymond J. Saloom, D.O.
Willard C. Scrivner, M.D.

PROGRAM PARTICIPANTS

Honorable Caspar W. Weinberger
Honorable Charles Edwards, M.D.
William I. Bauer, M.D.
Catherine Forrester
Dale Schumacher, M.D.
James Roberts, M.D.
John Farrell, M.D.
Joyce Somsak
Sheila Ryan

ANNOUNCEMENTS

Ms. Forrester, Staff Assistant to the National Professional Standards Review Council, advised the Council of the provisions of the Freedom of Information Act as they relate to the closing of Council meetings to the public.

An Overview of Professional Standards Review

Dr. William I. Bauer explained how the professional standards review legislation developed. He then described the professional standards review implementation program. (A complete transcript of Dr. Bauer's remarks can be found at Tab 1.)

Dr. John Farrell highlighted some of the problems surrounding the development of norms, standards and criteria for use by individual PSROs. (Remarks at Tab 2.)

Ms. Sheila Ryan briefed the Council on the portions of Public Law 92-603 which overlap or conflict with the provisions of the law pertaining to professional standards review. In this regard, Ms. Ryan stressed the need for coordination in these areas. (Remarks at Tab 3.)

In discussing the data needs for PSROs, Dr. James Roberts addressed the problem of identifying the data necessary to support PSRO activities and the development of an efficient system for supplying this data to the PSROs.

One of the concerns is how to integrate data needs of PSROs with the information being developed by Medicare, Medicaid and other programs examining data collection and processing. Dr. Roberts also discussed the usefulness of minimal data set models in the PSRO program. (Dr. Roberts' remarks at Tab 4.)

The Honorable Caspar Weinberger, Secretary of the Department of Health, Education and Welfare, expressed appreciation to the Council on behalf of the Department for their contribution of personal time and experience in the PSRO effort, and emphasized the interest he personally has in the success of the program. Secretary Weinberger also discussed the importance of the program both as a coordination effort within the Department and for the future of health care in the country. (The Secretary's remarks are attached at Tab 5.)

Dr. Dale Schumacher, in reviewing the evaluation mandate in the legislation, noted that the evaluation functions to be performed must include setting goals by which to measure the whole PSRO program effectiveness, means for evaluating the implementation strategy and the quantifiable parameters for judging the performance of individual PSROs. (See Tab 6.)

Joyce Somsak explained that the funds for PSRO implementation will be available on a 50-50 basis from the PSRO funds appropriated to the Bureau of Health Insurance in the Social Security Administration and the Medical Services Administration in the Social and Rehabilitation Service. The FY 73 budget for the PSRO program included $8.7 million

in program funds and $.7 million in salary expenditures. However, the appropriation was not signed into law until FY 74, making these funds unavailable for obligation. FY 74 expenses will run $32.1 million program and $1.8 million in salaries. Ms. Somsak also reported that OPSR requested proposals for contracts on four scopes of work: training institutes for PSRO personnel, an information clearinghouse to gather, store and disseminate technical information useful to PSROs, design for evaluation of conditional PSROs and development of a model utilization review and medical care assessment plan for public mental hospitals. (See Tab 7.)

Dr. James Roberts discussed area designation and said that the regional office personnel will perform a major role in this process. The Regional Health Director's Office will take the lead in cooperation with the regional offices of the Social Security Administration and the Medical Services Administration. The regional offices will hold meetings in the States throughout the months of July and August with groups interested in area designation. After this period of consultation, the regional offices will work with OPSR in putting together final recommendations to the Secretary on area designation. The Secretary must announce area designations by January 1, 1974.

Dr. Roberts then reviewed the six guidelines that have been developed with respect to the designation of areas. He also gave the rationale underlying each of the guidelines. (See Tab 8.)

As the Council's discussion of area designation guidelines developed, they requested the General Counsel's Office to give them legal opinion on two specific points:

1. Does the law permit two PSRO areas to overlap?

2. Does the law prohibit any State, regardless of size and/or number of physicians, from forming a single Statewide PSRO?

Dr. Saward announced that the Council will meet approximately every six weeks. Meeting dates for the balance of 1973 are:

August 27-28
October 15-16
November 26-27.

Pursuant to a request from Dr. Saward, the representatives of the regional offices reported briefly on how the area designation activities were developing within their regions.

Questions and comments were received from the floor.

Dr. Robert Hunter introduced two exhibits on the state surveys the American Medical Association has made on PSROs. Exhibit 1 is the February, 1973 survey and Exhibit 2 is the June, 1973 survey.

The meeting adjourned at 4:15 p.m.

Dr. Ernest Saward reconvened the meeting at 8:45 a.m. Tuesday, July 10, 1973. Dr. Saward related the agenda items for the day which had been requested by Council members:

1. Dr. Harrington - Data.

2. Dr. Scrivner - Area Designation.

3. Dr. Covell - Development of regulations and guidelines in the next 6 months and the Council's role in this process.

4. Dr. Haggerty -

   a. Staff resources, autonomy of OPSR, relationship to SSA and SRS.

   b. Ways to influence provider behavior incentives and sanctions. What principles should underlie the approach?

   c. Data development.

Before commencing the discussion, Dr. Saward announced the appointment of three Council Subcommittees to run for the Council's first six month period. The Subcommittees and their memberships are:

Evaluation: Dr. Haggerty (Chairman)
Dr. Hunter
Dr. Greene

Data and Norms: Dr. Harrington (Chairman)
Dr. Nelson
Dr. DuVal

Policy Development: Dr. Saloom (Chairman)
Dr. Covell
Dr. Scrivner

Dr. Harrington led a discussion on data and the issue surrounding the choice of the computer system to be used by a PSRO. He specifically emphasized the importance of identifying the kind of data PSROs will need and then determining how to get the data. Dr. Harrington felt that statistics should be compiled on the procedures undertaken in the hospital and that the data needs of PSROs will cover two main areas: diagnostic and ancillary services.

Dr. Nelson and Dr. Harrington both discussed the importance of coordinating PSRO data needs with the data capabilities already existing or being developed by the States or fiscal agents.

Dr. Scrivner suggested, with respect to area designation, that a State which has demonstrated a capacity and acquired experience in a program like PSRO should have the option of being a Statewide PSRO. The discussion on Statewide PSROs led the Council to request Mr. Sidney Edelman to develop a third legal opinion, specifically on the matter of whether all States can have State Councils, regardless of the number of PSROs in the State.

Dr. Hunter made a motion, seconded by Dr. Scrivner, as follows:

Motion: In any State, regardless of size or number of resident physicians, there shall be the option of forming a Statewide PSRO or administrative unit.

This shall not prohibit any adequately sized unit therein from choosing to administer and function in their behalf.

By the same token, any Statewide unit must be charged to oversee conduction of review functions at the local level and at the same time shall serve as a source of communication from below to higher echelons and from higher echelons to the review level.

This should be an option available for those States where the professional associations express the desire and evidence the capability of successfully performing such a Statewide coordinating system function.

Dr. Nelson moved to table the motion until the next meeting. Dr. Covell seconded. By a vote of 7-2 the motion was tabled.

Dr. Hunter moved that the First Annual Report of the National Professional Standards Review Council be accepted. Dr. DuVal seconded the motion which was unanimously approved.

Dr. Bauer, in response to a request to comment upon the role of the Council, outlined the Council's responsibilities as set forth in the legislation. These responsibilities include advising the Secretary on the implementation of the PSRO legislation, approving regional norms of care, reviewing the operations of Statewide Professional Standards Review Councils and PSROs to determine the effectiveness and comparative performance of such Councils and Organizations, and submitting an annual report to the Secretary and to Congress on its activities, findings and recommendations. Dr. Bauer said that OPSR would provide as much support to the Council as possible to assist them in carrying out their responsibilities.

Following Dr. Bauer's remarks, a request was made for the General Counsel's Office to develop a legal opinion on the authority to convene meetings of the Council.

Dr. Saward instructed the Policy Development Subcommittee to study the unresolved area designation issues raised by the Council at this meeting and bring in several optional guidelines that will constitute items for discussion at the next meeting.

The following motion was made by Dr. DuVal and seconded by Dr. Hunter:

Motion: If peer review is an instrument devised by the government to assure quality care while containing health care costs, then the government has a co-equal obligation to be sure that it conducts peer review in all Federally-operated establishments; i.e., military hospitals, Veterans Administration hospitals, Public Health Service institutions, etc. Federal institutions should be models of peer review.

The motion was unanimously approved and the Council directed that their First Annual Report be amended to reflect this action.

Dr. Harrington moved that the six Area Designation Guidelines developed by the OPSR staff be accepted with the understanding that they can be deviated from when necessary. Dr. Saloom seconded the motion. Dr. Hunter moved to amend the motion by excluding guideline #5. Dr. Harrington and Dr. Saloom agreed to the amendment and the amended motion was unanimously accepted.

The meeting adjourned at 11:35 a.m.

ATTENDEES
NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL
July 9-10, 1973

NAME	AFFILIATION
D. Knapp	FDA
H.L. Rhetta, M.D. for Dr. Hope Snider	Region V
K.D. Mayfield	Region VII
C.R. Dean, M.D.	Region II
P. McMenamin	OS/OPSR
A. Eicolano	College of Am. Pathologists
P. Schoeni	OPSR
C. Spicer	AAMC
L. Janchar	CHS
L.H. Hellman	Region VIII
K.C. Schneider	Region VI
L. Ozakin	NIMH
W.I. Bauer, M.D.	OPSR
T.M. Antone	CHS
H. Rosenfeld	Visitor
D. Hodgson	HEW
Ann Ewing	Int'l. Med. News
J.E. Bryan	AAFMC - Washington
J. Roberts, M.D.	OPSR
S. Edelman	OS/GC
S. Weinstein	CHS
D.J. Fink	Visitor (BHRD-PEB)
P.J. Sanazaro	HRA
E.W. Veverka	ORO
E.V. Jobe	AMA
J.N. Gitlin	FDA
Judy Kim	ANA
Patricia McGuire	Nat'l. Blue Shield
Bill Cohan	AMA
H.G. Pearce	Blue Cross Assn.
A.K. Richards	Blue Cross Assn.
B. Ouloosian	OPSR
Bill Gaylord	Electronic Data Systems
M. H. Stolar, Ph.D.	Am. Society of Hospital Pharmacists
Sam T. Gibson, M.D.	FDA
Dale Schumacher, M.D.	OPSR
Joyce Somsak	OPSR
E. Bullis	OPSR
Neill Casto	OPSR
Iona Elam	OPSR
Paul Pryor	OPSR
Harry Hetherington	BHI- PP
Merle Griffin	OPSR
F. Ainsworth	AHA

NAME	AFFILIATION
B. Schumacher	OPSR
F.L. Barham, M.D.	Medical Center at Princeton
A.J. McNevin	Amer. Pod. Assoc.
Andrew Johnston	Region I
F. Kalibat	NIMH
E. Worford	NIH
John Farrell, M.D.	OPSR
L.P. Wheat	ADA
T. Elwood	NRTA - AARP
John F. Burton	NIMH
D.R. McNutt	Md. State Health
Voris H. Fabik	Travelers Ins. Co. - HIAA
M. Conwell	NIMH
Mike Bernstein	AHA
Jeanne Kruhm	Am. Dietetic Assn.
Paul Bennett	Medicom
Patti Kenney	Health Research Group
Robert Chase	Ohio State Univ.
Joan Mancuso	Federation of Amer. Hospitals
Tim Redman	Amer. Optometric Assoc.
Robert Vidaver	NIMH
John Levant	Movement for EION Justice
J.W. Pompelli	AGS
CA. Alexander	Nat'l. Assoc. of Social Workers
Robert McAlpine	NRIA-AARP
Lawrence Kreeken	Blue Cross Assoc.
O.W. Linden	ACR
Cleo Tavoni	AA
Alan Kaplan	McGraw Hill
Barbara Nagel	CHS
J.S. Reibel	NY County Medical Society
Sheila Ryan	SSA/BHI
Robert van Hoek, M.D.	NCHSRD
W.J. McNeary, Jr.	Region III
G. Simon	APHA
Angela Bradby	
Michele Robinson	Health Manpower Report
Linda Thomas	Amer. Society of Clinical Pathologists
Carl Siegel, M.D.	Region VII
Michael Goran	HSA
A.E. Kuehl, M.D.	OPSR
T. Turney	BHI
Jeffrey Merrill	APHA
David A. Knapp, Ph.D.	Univ. of Maryland
A. Wertheimer	PSRO

NAME	AFFILIATION
J.J. Mariman	SRS
Casey Crawford	NHI Reports
Robert Cohen	NASS
J.A. Reynolds	
James J. Walker	SSA - BHI
E. Leon Cooper	NMAF
Robert Roddy	CHS
E. Walford	HRA - DDH
William B. Munier	OASH
Garrett M. Swain	AANS - CNS
Berkeley V. Bennett	Nat. Council of Health Care Service

Appendix D

Department of Health, Education, and Welfare
PSRO Program Manual

P.S.R.O. PROGRAM MANUAL

U.S. Department of Health,
Education and Welfare
Office of Professional Standards Review
5600 - Fishers Lane
Rockville, Maryland 20852

P.S.R.O. Program Manual

FOREWORD

This manual contains statutory requirements and interim guidelines for organizations desiring to participate in the implementation of the provisions of Public Law 92-603 relating to professional standards review. It contains informational and procedural material which organizations will need in order to apply for funding, to initiate their responsibilities under the law and to answer inquiries from the public and the professional community.

The manual is not yet complete. Several chapters are still under development and will be issued subsequently. The chapters which are included are those pertinent to organizations desiring to initiate PSRO activities. A careful effort has been made to insure that the provisions of the law are accurately reflected in the contents of the manual. The manual is subject to revision based upon the experience of organizations participating in the PSRO program and the comments of concerned organizations and individuals. As experience is gained portions of the material contained in the manual will be issued as proposed regulations.

The statutory requirements and interim guidelines in the manual are designed to assist organizations in establishing an effective and efficient peer review program. The policies and procedures set forth in the manual describe organizational, membership and review requirements for the PSRO program. Alternatives to the review system described in the manual will be considered by the Department provided they have the potential for resulting in an approach to review that is equally or more effective than that contained in the manual.

The interim policies and procedures described in this manual have been devised to satisfy the administrative need of the program with a minimum of inconvenience for all participants, including physicians, hospitals, other provider institutions and patients. The law, however, does impose upon the Federal Government an obligation to assure administrative effectiveness and efficiency and this, in turn, requires the application, wherever feasible, of uniform administrative procedures.

Organizations and individuals desiring to be included on a mailing list for distribution of additional chapters or for revisions of the manual should write to:

Office of Professional Standards Review
5600 Fishers Lane
Room 16A-17
Rockville, Md. 20852

PSRO PROGRAM MANUAL

TABLE OF CONTENTS

* To be issued subsequently

CHAPTER I:
GENERAL INFORMATION ABOUT THE PROGRAM

Chapter I

INTRODUCTION

INTRODUCTION

100 GENERAL

This Manual contains descriptive information and guidelines related to the initial phases of the PSRO program. It includes guidelines to qualify for participation in the PSRO program and instructions for organizations wishing to apply for a contract for planning purposes (Chapter IV); a contract for designation as a conditional PSRO (Chapter V); or a contract as a Statewide PSRO support center (Chapter III). These instructions specify the qualifications and requirements for organizations who are considering applying for a specific type of contract. Chapter VI outlines the application procedures which should be followed.

Chapter II contains a list of the PSRO areas which have been designated by the Secretary of Health, Education, and Welfare, and applicants who wish to apply for either a planning or conditional contract should utilize Chapter II to identify the PSRO area they wish to serve.

Organizations interested in obtaining additional information and in applying for any of these contracts are urged to contact the appropriate DHEW Regional Office. A list of these are included at the end of Chapter VI.

102 INFORMATION ON THE PSRO PROGRAM

The 1972 Amendments to the Social Security Act provide for the creation of Professional Standards Review Organizations (PSROs) designed to involve local practicing physicians in the ongoing review and evaluation of health care services covered under the Medicare, Medicaid and the Maternal and Child Health programs. The legislation is based on the concepts that health professionals are the most appropriate individuals to evaluate the quality of medical services and that effective peer review at the local level is the soundest method for assuring the appropriate use of health care resources and facilities. The PSRO is the means by which the legislation attempts to translate these concepts into practice.

Under Title XI of the Social Security Act, as amended by the 1972 Amendments, the Secretary of Health, Education, and Welfare is required to designate PSRO geographic areas throughout the United States no later than January 1, 1974. These initial area designations may be altered at any time changes in the boundaries appear warranted or necessary. Subsequent to the designation of areas, the Secretary is to enter into agreements with qualified organizations in each area. Until January 1, 1976, only a non-profit professional association representing a substantial proportion of the practicing physicians in an area can qualify as a PSRO. If such an organization does not apply to be a PSRO by that date, the Secretary can designate any other organization that he determines has the professional competence and is otherwise suitable to be a PSRO.

The PSRO is responsible for assuring that health care paid for under Medicare, Medicaid, and Maternal and Child Health Programs is medically necessary and consistent with professionally recognized standards of care. It must also seek to encourage the use of less costly sites and modes of treatment where medically appropriate.

The PSRO is required to review services furnished in and by hospitals and other health care institutions, such as skilled nursing facilities. The review of other types of health care, such as ambulatory care, can be undertaken at the option of the individual PSRO and with the Secretary's approval. The internal review activities of hospitals and other health care institutions are to be utilized by the PSRO in carrying out its functions to the extent these activities are determined to be effective by the PSRO. The PSRO is also required to review institution, physician, and patient profiles, and to utilize regional norms of care in its review. Fiscal agents are required to abide by the PSRO's determination as to the medical necessity and appropriateness of services in paying Medicare and Medicaid claims.

104 DESIGNATION OF PSRO AREAS

In accordance with the requirements of Title XI, the Secretary, after consultation with national, State and local, public and private medical care organizations, designated PSRO geographic areas throughout the country. A listing of these areas appears in Chapter II of this Manual. Each PSRO must be recognized in and serve a designated area. These area designations may be modified if, as the system is placed into operation, changes seem desirable.

105 ORGANIZATIONS QUALIFIED TO SERVE AS PSROs

105.10 The essential requirements an organization must meet in order to qualify as a PSRO are set forth in Section 1150 of the Social Security Act. Chapter V of this Manual provides DHEW policies on the implementation of these requirements. In general, prior to January 1, 1976, a qualified organization is one which:

105.11 is a non-profit professional association (or a component of such an association);

105.12 is composed of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in the established PSRO area;

105.13 includes as members a substantial proportion of all licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in the area;

105.14 provides for voluntary membership and is open to all doctors of medicine or osteopathy in the area without any requirement of membership in or payment of dues to any organized medical society or association;

105.15 does not restrict the eligibility of any member for service as an officer of the PSRO or eligibility for assignment to duties of the PSRO;

105.16 is organized in a manner which makes available professional competence to review health care services of the types and kinds with respect to which PSROs have review responsibilities; and

105.17 the Secretary finds, on the basis of his examination of a formal plan submitted to him by the organization (as well as other relevant data and information), is willing and capable of performing in an effective, timely, and objective manner and at reasonable cost, the duties, functions, and activities of a PSRO required by or pursuant to Title XI of the Act.

105.20 On or after January 1, 1976, where there is no qualified physician association in the area, the Secretary may enter into an agreement with such other public, non-profit private, or other agency or organization (e.g., State or local health department, medical school, etc.) which he determines has the professional medical competence to perform the functions of a PSRO.

106 SUMMARY OF PSRO REVIEW RESPONSIBILITIES

Professional Standards Review Organizations will review the health care provided under the Medicare, Medicaid and Maternal and Child Health programs and make judgments on the medical necessity and quality of the care. In addition, PSROs will determine whether care is proposed to be provided or has been provided at a level of care which is most economical, consistent with the patient's medical care needs.

PSROs are required over time, to perform review of the care provided in institutions (i.e., short-stay general hospitals, tuberculosis hospitals, mental health hospitals, skilled nursing facilities and intermediate care facilities). A PSRO may review non-institutional care if it requests to do so and if the Secretary approves such a request.

Initially, PSROs should, at a minimum, establish a system for review of care provided to inpatients in short-stay general hospitals and develop a phased plan for the performance of review in long-term care facilities. If it demonstrates capability in these areas, the PSRO may develop review systems for care provided in other institutions and for non-institutional care.

For review in short-stay general hospitals, the PSRO will at a minimum perform (a) admission certification concurrent with the patient's admission, (b) continued stay review, and (c) medical care evaluation studies. As the capability progresses in its area to develop profiles, the PSRO will be required to review these. The PSRO will develop criteria and standards and select norms for each type of review which it performs. A description of these review mechanisms and of norms, criteria, and standards is contained in Chapter VII of this Manual.

PSROs are required to utilize the services and accept the findings of review committee(s) of hospitals which, in the judgment of the PSRO, are capable of performing review effectively. The process by which a PSRO assesses the capability of a hospital, works with it to initiate review, and evaluates its performance is contained in Chapter VII of this Manual.

The PSRO will work closely with Medicare, Medicaid, and Maternal and Child Health administrative and fiscal agents in the development, implementation and operation of its review program. These relationships will be described in Sections of this Manual which are currently under development.

107 DATA COLLECTION, PROCESSING AND REPORTING

The data collection and processing system is structured in accordance with guidelines developed by the Secretary in consultation with the National PSR Council, with a view toward assuring maximum efficiency, economy, and coordination in all data-gathering efforts and the compatibility of data across different geographic areas. Data flowing from the Medicare and Medicaid claims process is to be utilized to the maximum extent possible. The mechanics of the data processing system, e.g. coding of diagnostic and procedural data, integration of Medicare, Medicaid, and other data bases, must be consistent with the policy and procedural guidelines issues by the Secretary. This Manual will include Federal requirements on baseline data; data requirements for the conduct of medical care services; and federal reporting requirements.

108 DISCLOSURE OF INFORMATION

Under Section 1166 of Title XI, any data or information acquired by any PSRO in the exercise of its functions must be held in confidence and may not be disclosed to any person except (a) to the extent that it may be necessary to carry out the PSRO's responsibilities, or (b) in such cases and under such circumstances as the Secretary may, by regulations, provide to assure adequate protection of the rights and interests of patients, health care practitioners, and providers of health care services. Violations of the disclosure, prohibitions, are subject to a penalty, upon conviction, of a fine of not more than $1,000, and imprisonment for not more than 6 months, or both.

110 HEARINGS, REVIEW, AND SANCTIONS

110.10 A Medicare beneficiary, Medicaid recipient, provider of services, or health care practitioner who is dissatisfied with a determination by a PSRO is entitled to reconsideration of that determination by the PSRO; where the matter in controversy is $100 or more the reconsideration would be subject to review, on appeal, by a State PSR Council or by the Secretary. Where the amount in question exceeds $1,000, the Secretary's final decision is subject to judicial review.

110.20 On the basis of its investigations of situations of possible abuse identified in its reviews, the PSRO may (after reasonable notice and opportunity

for discussion with the provider or practitioner) recommend to the Secretary appropriate action against persons responsible for gross or continued overuse of services or for inadequate quality of services.

Where a PSRO finds that voluntary and educational efforts fail to remedy an improper situation, it would transmit its recommendations concerning sanctions through the State Council to the Secretary. Protective appeals procedures are provided for those against whom sanctions have been recommended. Where an individual receives such a recommendation, the Secretary may terminate or suspend Medicare and Medicaid payment for the services of the practitioner or provider involved, or assess an amount reasonably related to the costs to the program deriving from acts involved--but not to exceed $5,000 against persons or institutions found to be at fault. In such cases, the practitioner or provider would be granted a hearing by the Secretary on request and could seek judicial review of the final determination of the Secretary.

110.30 Procedures regarding hearings and appeals are now under development.

111 STATEWIDE PROFESSIONAL STANDARDS REVIEW COUNCILS

111.10 Statewide PSR Councils (and an advisory group to each Council) must be established in States which have three or more PSROs. Membership to a Statewide PSR Council shall be appointed by the Secretary. A council consists of one representative from each PSRO, four physicians, two of whom may be designated by the State Medical Society and two of whom may be designated by the State Hospital Association, and four persons, knowledgeable in health care, selected by the Secretary as public representatives, at least two of whom are recommended by the Governor.

A Statewide Council participates in several administrative activities, including the coordination of the activities of PSROs within the State, the dissemination of information and other data to them, and the review of PSRO performance.

More detail on the function of Statewide Councils and the process for nominating and appointing members will appear in Chapter XIV of this Manual.

112 ADVISORY GROUPS

Each Statewide PSR Council, and in States with no Council, each PSRO, shall be advised and assisted in its activities by an advisory group consisting of representatives of hospitals, health care practitioners (other than physicians) and other health care institutions. Chapter XV of this Manual will provide further details on their membership and functions.

114 NATIONAL PSR COUNCIL

The National PSR Council consists of 11 physicians of recognized standing in the review of medical practice who are appointed by the Secretary.

The National Council arranges for the collection and distribution of data and other information useful to PSROs, particularly information relating to the development and application of norms, standards, and criteria for care. The National Council reports regularly to the Secretary and to the Congress on the overall effectiveness of the PSRO program and offers such recommendations as it might have for improvement of the program, including specific pertinent data with respect to each PSRO.

116 DEVELOPMENT AND SELECTION OF PSROs

Under the provisions of Title XI a qualified organization is one which, among other things, the Secretary finds on the basis of his examination and evaluation of a formal plan submitted to him and other relevant information including possible informal site visits, that the organization is capable of performing effectively as a PSRO. Thus, the law requires that the formal plan be the primary means of selecting a PSRO. A formal plan consists of a complete description of the organizational structure and management of the PSRO, as well as a detailed statement of the review activities it plans to undertake.

116.10 Statewide PSRO Support Centers

Contracts will be available to existing organizations capable of providing assistance to developing and conditional PSROs on a variety of organizational, professional and administrative matters. Requirements necessary to qualify as a support center are spelled out in Chapter III, along with the activities which may be carried out by these centers.

116.20 Planning Contracts

Short-term financial assistance, in the form of planning contracts, is available to qualified organizations which require financial assistance to help develop the necessary PSRO organizational and membership requirements and to develop a formal plan for the gradual assumption of PSRO duties and responsibilities. The procedures which should be followed in applying for such a contract are specified in Chapter IV of this Manual.

116.30 Conditional Designation Contracts/Agreements

When an applicant's formal plan has been found to be satisfactory, the Secretary is required to announce his intention to designate that organization to serve as the area's conditional PSRO. Following the announcement there is a period during which dissenting opinions may be registered, and if, during this notification process, more than 10 percent of the area physicians object to the proposed conditional designation, a poll is to be taken of all the area physicians. Where more than 50 percent of the physicians voting in the poll then indicate that the organization does not represent them, the Secretary is precluded from entering into an agreement with the applicant organization. (Contractual arrangements will be entered into during FY74. Subsequently, the agreement mechanism will be used.)

A qualified PSRO applicant can be approved on a conditional basis for a period not to exceed 2 years during which it is to develop and expand its review activities and capacity. Agreements may be terminated upon 90 days notice by either the PSRO or the Secretary. At the end of the conditional period, where the PSRO has satisfactorily demonstrated its effectiveness, the PSRO would be regarded as a fully qualified PSRO and would renew its agreement with the Secretary on that basis. Chapter V provides more specifics on qualifying as a conditional PSRO.

117 REIMBURSEMENT

Execution of an agreement or contract with the Secretary by a PSRO or a State PSR Council obligates the Secretary to reimburse all reasonable and necessary costs incurred by the PSRO or Council in carrying out or preparing to carry out the functions required by the agreement. The reimbursement process involves a comprehensive financial management system. The allowability of costs for reimbursement purposes are determined in accordance with reimbursement principles promulgated by the Secretary. A chapter of the manual on reimbursement is under development.

CHAPTER II: DESIGNATION OF PSRO SERVICE AREAS

Chapter II

DESIGNATION OF PSRO SERVICE AREAS

CHAPTER II

DESIGNATION OF PSRO SERVICE AREAS

200 LEGISLATIVE HISTORY

The Secretary's initial statutory responsibility under Section 1152(a) of the Social Security Act was to designate tentative PSRO service areas throughout the United States by January 1, 1974. These tentative designations may subsequently be modified if, as the system is placed into operation, circumstances warrant a change.

Although Title XI does not address itself specifically to the question of the appropriate size or characteristics of a PSRO area, the statutory language and the Report of the Senate Committee on Finance, taken together, permit clear inferences as to Congressional intent. The Department's policy in defining PSRO areas, therefore, was based on the following fundamental premises:

A. The law contemplates the establishment of a fairly substantial number of PSRO areas and, in many instances, the designation of three or more areas within a single State. This is evidenced by fact that the Committee Report states that "...in smaller or more sparsely populated States, the designation would probably be on a Statewide basis," and the law calls for the establishment of Statewide Professional Standards Review Councils in States in which three or more PSROs are established.

B. Priority in designation as a PSRO is to be given to organizations established at local levels representing the practicing physicians in the local areas.

C. There is a very strong emphasis both in the legislation and the Senate Committee Report on local responsibility and autonomy in the conduct of peer review activities.

D. The Committee Report addresses itself to the premise that the areas should be of sufficient size to assure broad, diverse, and objective representation of physicians.

E. The area designations should also take into consideration the need to assure a reasonably coordinated administrative arrangement among PSROs and the various Medicare and Medicaid administrative mechanisms in a State or area.

202 PSRO AREA DESIGNATION GUIDELINES

With the legislation and legislative history as guides, the Department developed and disseminated guidelines for the designation of PSRO areas and initiated a widespread process of consultation with State and local public and private physician and other medical care organizations.

The guidelines are as follows:

A. In general, a PSRO should not cross State lines. The basis for this guideline is the provision of Title XI relating to the creation of Statewide PSR Councils and the several references in the Senate Finance Committee Report to areas established on a multi-county or State basis. In addition, the Medicaid program is organized on a State-by-State basis.

B. In general, a PSRO area should not divide a county. Considerations of administrative practicability serve as the basis for this guideline. However, in instances of large geographic areas or large county populations, it may be necessary and appropriate to divide a county.

C. Existing boundaries of local medical review organizations and health planning areas should be considered. Since the Senate Finance Committee Report recognizes the existence of local professional medical review organizations, the current boundaries of these organizations should be considered. In addition, established health planning areas need to be considered as possible precedents.

D. A PSRO area should generally include a minimum of approximately 300 licensed, practicing physicians. While the maximum can be expected to vary with local circumstances, generally, it should not exceed 2,500 licensed, practicing physicians. The purpose of an approximate limitation on the maximum size of an area's physician population is to emphasize the statutory concepts of local peer review responsibility and the active participation of local practicing physicians in the activities of the PSRO.

E. A PSRO area should, to the extent possible, coincide with a medical service area and assure broad, diverse representation of all medical specialties. The PSRO area should be drawn to include, to the extent possible, the existing medical service or medical trade areas. Consideration should be given to existing medical centers and to natural geographic barriers. In addition, effective peer review is attainable only if the review body has available to it the necessary range of professional expertise.

F. The designation of a PSRO area should take into account the need to allow effective coordination with Medicare/Medicaid fiscal agents. This principle is stated in the statute and the Senate Finance Committee Report. Since the PSRO is involved in the Medicare and Medicaid programs, it will have a significant effect on the claims process.

203 PROCEDURE FOR REQUESTING CHANGES IN AREA DESIGNATIONS

The Senate Finance Committee Report states that "tentative area designations could be modified if, as the system was placed into operation, changes seemed desirable." Therefore, as operating experience is gained consideration will be given to possible modifications of the areas.

Organizations desiring changes in the PSRO areas as designated by the Secretary should submit their request to the Department's Regional Health Administrator for their State (see list of Regional Health Administrators in Appendix A). The request should contain the following information:

A. Identification by State and, if applicable, area numbers of the areas that would be affected.

B. A listing of counties or the political subdivisions describing the proposed realignment. Where political subdivisions are to be divided, use postal zones, streets, highways, etc.

C. The reason(s) for requesting the change. Examples of valid reasons that could form the basis for a change are:

1. Changes have occurred in medical service area configurations.

2. The workload of an operating PSRO(s) is either too low or high to operate effectively.

3. A peer review organization is already in operation and its service area does not coincide with a designated PSRO area.

4. Changes have taken place in political subdivisions.

5. The physician population in an area(s) has changed substantially.

The Regional Health Administrator will submit his recommendation to the Assistant Secretary for Health who will transmit it to the Secretary with a statement of his concurrence or rejection. If the Secretary approves the change

it will be published in the Federal Register as a Notice of Proposed Rulemaking with an invitation for public comment.

It should be noted that all changes must be consistent with the PSRO Area Designation Guidelines as spelled out in Section 202 of this chapter.

204 AREA DESIGNATIONS--STATE-BY-STATE LISTING AND STATISTICAL SUMMARIES

204.1 The Individual Area Designations, As Published in the Federal Register Are As Follows:

ALABAMA : The State of Alabama is designated as a single Professional Standards Review Organization area.

ALASKA : The State of Alaska is designated as a single Professional Standards Review Organization area.

ARIZONA : Two Professional Standards Review Organization areas are designated in Arizona, composed of the following counties:

AREA I :	Mohave	Yavapai
	Coconino	Maricopa
	Navajo	Gila
	Apache	
AREA II :	Yuma	Pima
	Pinal	Santa Cruz
	Graham	Cochise
	Greenlee	

ARKANSAS : The State of Arkansas is designated as a single Professional Standards Review Organization area.

CALIFORNIA : Twenty-eight Professional Standards Review Organization areas are designated in California, composed of the following counties, with the exception of Areas XVIII through XXV which are composed of cities and parts of Los Angeles denoted by postal zone:

AREA I :	Del Norte	Lake	Humboldt
	Mendocino	Sonoma	
AREA II :	Siskiyou	Tehama	Colusa
	Modoc	Plumas	Sutter
	Trinity	Glenn	Yuba
	Shasta	Butte	Sierra
	Lassen		

AREA III	:	Napa	Solano	Marin
AREA IV	:	Nevada Placer	Yolo Sacramento	El Dorado
AREA V	:	San Francisco		
AREA VI	:	San Mateo		
AREA VII	:	Contra Costa	Alameda	
AREA VIII	:	San Joaquin Amador	Alpine Calaveras	Tuolumne
AREA IX	:	Santa Clara		
AREA X	:	Stanislaus	Merced	Mariposa
AREA XI	:	Fresno	Madera	
AREA XII	:	Santa Cruz	San Benito	Monterey
AREA XIII	:	Kings	Tulare	
AREA XIV	:	Kern		
AREA XV	:	Mono	San Bernardino	Inyo
AREA XVI	:	San Luis Obispo	Santa Barbara	
AREA XVII	:	Ventura		
AREA XVIII	:	Altadena Alhambra San Marino Tujunga Glendale San Gabriel Temple City Sunland	Verdugo City Pasadena Garvey Eagle Rock Rosemead La Crescenta Montrose	La Vina El Monte South Pasadena Monterey Park La Canada South San Gabriel Wilmar
AREA XIX	:	Avalon Wilmington Palos Verdes Estates Long Beach	Terminal Island Hawaiian Gardens Lakewood San Pedro	Dominguez Harbor City Palos Verdes Peninsula Los Alamitos

AREA XX :	Agoura	Littlerock	Calabasas
	Palmdale	Canoga Park	Pearblossom
	Chatsworth	Quartz Hill	Encino
	Burbank	Granada Hills	Mission Hills
	Hidden Hills	North Hollywood	Newhall
	Olive View	Northridge	Pacoima
	Raseda	Panorama City	Saugus
	San Fernando	Sherman Oaks	Sepulveda
	Tarzana	Studio City	Van Nuys
	Sun Valley	Woodland Hills	Sylmar
	Lancaster	Toluca Lake	
AREA XXI :	Commerce	Durate	Hacienda Heights
	Glendora	La Mirada	La Puente
	East Los Angeles	Monrovia	Los Nietos
	Rowland Heights	Montebello	Sierra Madre
	Norwalk	Temple City	Pico Rivera
	Valinda	Santa Fe Springs	West Covina
	Whittier	Claremont	Arcadia
	La Verne	Azusa	Pomona
	Baldwin Park	San Dimas	Covina
	Walnut		
AREA XXII :	Culver City	Santa Monica	Malibu
	Sawtelle	Marina del Rey	Venice
	Mar Vista	Westwood	Ocean Park
	Pacific Palsades	Palms	Playa del Rey
	Los Angeles Postal Zones:		
	90034	90049	90064
	90066	90073	
AREA XXIII :	Gardena	Rolling Hills	Hermosa Beach
	Torrance	Lomita	Artesia
	Manhattan Beach	Bell	Palos Verdes
	Bellflower	Redondo Beach	Bell Gardens
	Compton	Willowbrook	Downey
	El Segundo	Home Gardens	Hawthorne
	Huntington Park	Inglewood	Lynwood
	Lawndale	Maywood	Lennox
	Paramount	South Gate	
	Los Angeles Postal Zones:		
	90009	90045	
AREA XXIV :	Los Angeles Postal Zones:		
	90006	90013	90033
	90008	90056	90007
	90012	90023	90053
	90043	90062	90018

AREA XXIV (Continued) :	90058	90005	90014
	90035	90042	90059
	90002	90016	90031
	90003	90055	90004
	90057	90020	90039
	90037	90001	90010
	90017	90065	90054
	90047	90026	90019
	90021	90011	90063
	90061	90015	90051
	90032	90044	

AREA XXV : Beverly Hills
Los Angeles Postal Zones:

90027	90028	90029
90036	90038	90046
90048	90068	90069

AREA XXVI : Orange

AREA XXVII : Riverside

AREA XXVIII: San Diego Imperial

COLORADO : The State of Colorado is designated as a single Professional Standards Review Organization area.

CONNECTICUT : Four Professional Standards Review Organization areas are designated in Connecticut, composed of the following counties:

AREA I : Fairfield

AREA II : Litchfield New Haven

AREA III : Hartford

AREA IV : Tolland Middlesex New London
Windham

DELAWARE : The State of Delaware is designated as a single Professional Standards Review Organization area.

DISTRICT OF COLUMBIA : The District of Columbia is designated as a single Professional Standards Review Organization area.

FLORIDA : Twelve Professional Standards Review Organization areas are designated in Florida, composed of the following counties:

AREA I	:	Santa Rosa	Gadsden	Okaloosa
		Liberty	Walton	Franklin
		Holmes	Leon	Washington
		Jefferson	Jackson	Madison
		Wakulla	Bay	Calhoun
		Taylor	Escambia	Gulf
AREA II	:	Hamilton	Levy	Suwannee
		Marion	Columbia	Lafayette
		Union	Dixie	Bradford
		Gilchrist	Alachua	Putnam
		Citrus	Hernando	Sumter
AREA III	:	Nassau	Clay	Baker
		St. Johns	Duval	Flagler
AREA IV	:	Pinellas		
AREA V	:	Pasco	Hillsborough	
AREA VI	:	Polk	Highlands	Hardee
AREA VII	:	Lake	Orange	Seminole
		Osceola		
AREA VIII	:	Volusia	Brevard	
AREA IX	:	Manatee	Charlotte	Sarasota
		Glades	De Sotto	Lee
AREA X	:	Indian River	Okeechobee	St. Lucie
		Martin	Palm Beach	Hendry
AREA XI	:	Collier	Broward	
AREA XII	:	Monroe	Dade	

GEORGIA : The State of Georgia is designated as a single Professional Standards Review Organization area.

HAWAII, GUAM, THE TRUST TERRITORY OF THE PACIFIC ISLANDS AND AMERICAN SAMOA : Hawaii, Guam, the Trust Territory of the Pacific Islands and American Samoa are designated as a single Professional Standards Review Organization area.

IDAHO : The State of Idaho is designated as a single Professional Standards Review Organization area.

ILLINOIS : Eight Professional Standards Review Organization areas are designated in Illinois, composed of the following counties:

AREA I :	Jo Daviess	Ogle	Stephenson
	De Kalb	Winnebago	Whiteside
	Boone	Carroll	Lee
AREA II :	McHenry	Kane	Lake
	DuPage		
AREA III :	Cook		
AREA IV :	Kendall	Will	Grundy
	Kankakee		
AREA V :	Rock Island	Stark	Mercer
	Marshall	Henry	Bureau
	McDonough	Putnam	Fulton
	La Salle	Peoria	Henderson
	Tazewell	Warren	Woodford
	Knox		
AREA VI :	Livingston	Macon	Ford
	Iroquois	Douglas	McLean
	Edgar	De Witt	Shelby
	Piatt	Coles	Champaign
	Cumberland	Vermillion	Clark
	Moultrie		
AREA VII :	Adams	Morgan	Hancock
	Schuyler	Sangamon	Brown
	Christian	Cass	Calhoun
	Mason	Greene	Menard
	Jersey	Logan	Macoupin
	Pike	Montgomery	Scott
AREA VIII :	Madison	Richland	Bond
	Williamson	Fayette	Saline
	Effingham	Gallatin	Jasper
	Union	Crawford	Johnson
	Randolph	Lawrence	Perry
	Washington	Franklin	Jefferson
	Hamilton	Wayne	White
	Edwards	Jackson	Wabash
	Monroe	Pope	St. Clair
	Hardin	Clinton	Alexander
	Marion	Pulaski	Clay
	Massac		

INDIANA	:	Seven Professional Standards Review Organization areas are designated in Indiana, composed of the following counties:		
AREA I	:	Lake	La Porte	Porter
AREA II	:	St. Joseph	Cass	Elkhart
		Miami	Newton	Wabash
		Jasper	Carroll	Starke
		Warren	Marshall	Tippecanoe
		Kosciusko	Clinton	Pulaski
		Howard	Fulton	Tipton
		Benton	Fountain	White
		Montgomery		
AREA III	:	Lagrange	Allen	Steuben
		Huntington	Noble	Wells
		De Kalb	Adams	Whitley
AREA IV	:	Grant	Fayette	Blackford
		Union	Jay	Madison
		Franklin	Delaware	Randolph
		Ripley	Dearborn	Henry
		Jefferson	Wayne	Ohio
		Switzerland	Rush	
AREA V	:	Boone	Morgan	Jackson
		Hamilton	Johnson	Jennings
		Putnam	Shelby	Washington
		Hendricks	Brown	Scott
		Marion	Bartholomew	Clark
		Hancock	Decatur	Floyd
		Orange	Crawford	Harrison
AREA VI	:	Vermillion	Sullivan	Parke
		Greene	Vigo	Monroe
		Lawrence	Clay	Owen
AREA VII	:	Knox	Gibson	Daviess
		Pike	Martin	Dubois
		Posey	Warrick	Vanderburgh
		Spencer	Perry	
IOWA	:	The State of Iowa is designated as a single Professional Standards Review Organization area.		
KANSAS	:	The State of Kansas is designated as a single Professional Standards Review Organization area.		

KENTUCKY	:	The State of Kentucky is designated as a single Professional Standards Review Organization area.		
LOUISIANA	:	Four Professional Standards Review Organization areas are designated in Louisiana, composed of the following parishes:		
AREA I	:	Caddo	Quachita	Grant
		Bossier	Richland	La Salle
		Webster	Madison	Catahoula
		Claiborne	De Soto	Concordia
		Lincoln	Red River	Vernon
		Union	Natchitoches	Rapides
		Morehouse	Winn	Avoyelles
		West Carroll	Caldwell	Sabine
		East Carroll	Franklin	Tensas
		Bienville	Jackson	
AREA II	:	Beauregard	Allen	Evangeline
		St. Landry	Calcasieu	Jefferson Davis
		Acadia	Lafayette	St. Martin
		Cameron	Vermilion	Iberia
		St. Mary		
AREA III	:	Point Coupe	West Feliciana	East Feliciana
		St. Helena	Tangipahoa	Washington
		Iberville	West Baton Rouge	East Baton Rouge
		Livingston	Ascension	
AREA IV	:	Assumption	St. James	St. John the Baptist
		St. Tammany	St. Charles	Jefferson
		Orleans	St. Bernard	Terrebonne
		Lafourche	Plaquemines	
MAINE	:	The State of Maine is designated as a single Professional Standards Review Organization area.		
MARYLAND	:	Seven Professional Standards Review Organization areas are designated in Maryland, composed of the following counties:		
AREA I	:	Garrett	Allegany	Washington
		Frederick		
AREA II	:	Baltimore City		
AREA III	:	Montgomery		
AREA IV	:	Prince Georges		

AREA V :	Baltimore	Carroll	Harford
	Howard		
AREA VI :	Anne Arundel	Calvert	Charles
	St. Marys		
AREA VII :	Cecil	Kent	Queen Annes
	Caroline	Talbot	Dorchester
	Wicomico	Somerset	Worchester

MASSACHUSETTS : Five Professional Standards Review Organization areas are designated in Massachusetts, composed of the following cities and townships:

AREA I :	Williamstown	Adams	Clarksburg
	Monroe	North Adams	Florida
	Rowe	Huntington	Heath
	Westhampton	Colrain	Northampton
	Leyden	Hadley	Bernardston
	Amherst	Northfield	West Stockbridge
	Warwick	Stockbridge	Orange
	Lee	Savoy	Becket
	Charlemont	Alford	Hawley
	Petersham	Great Barrington	Buckland
	Tryingham	Shelburne	Monterey
	Greenfield	Otis	Gill
	Blandford	Erving	Russell
	Hancock	Montgomery	New Asford
	Westfield	Cheshire	Southhampton
	Windsor	Easthampton	Plainfield
	Holyoke	Ashfield	South Hadley
	Conway	Granby	Deerfield
	Chicopee	Montague	Ludlow
	Windell	Belchertown	New Salem
	Ware	Lanesborough	Palmer
	Dalton	Egremont	Warren
	Mount Washington	Peru	Hinsdale
	Worthington	New Marlborough	Sheffield
	Sandisfield	Goshen	Cummington
	Chesterfield	Granville	Tolland
	Williamsburg	Whately	Southwick
	West Springfield	Hatfield	Agawam
	Sunderland	Pelham	Longmeadow
	Pittsfield	East Longmeadow	Richmond
	Wilbraham	Leverett	Hampden
	Shutesburg	Monson	Lenox
	Brimfield	Washington	Wales

	Middlefield	Holland	Chester
	Royalston	Athol	Phillipston
AREA II :	Winchedon	Ashby	New Braintree
	Oakham	Ashburnham	Paxton
	Townsend	Templeton	Gardiner
	Westminster	Fitchburg	Lunenburg
	Hubbardston	Princeton	Leominster
	Lancaster	Shirley	Harvard
	Ayer	Barre	Rutland
	Holden	Sterling	West Boylston
	Clinton	Bolton	Berlin
	Northborough	Hardwick	Worcester
	Shrewsbury	Westborough	West Brookfield
	North Brookfield	Leicester	Auburn
	Brookfield	Spencer	East Brookfield
	Millbury	Grafton	Upton
	Sturbridge	Southbridge	Charleton
	Oxford	Dudley	Webster
	Douglas	Sutton	Northbridge
	Uxbridge	Mendon	Millville
	Blackistone	Boylston	Dunstable
	Medway	Pepperell	Bellingham
	Gorton	Franklin	Westford
	Littleton		
AREA III :	Hudson	Sudbury	Newton
	Wayland	Weston	Waltham
	Needham	Wellesley	Natick
	Sherborn	Marlborough	Southborough
	Framingham	Ashland	Hopkinton
	Holliston	Milford	Hopedale
AREA IV :	Amesburg	Salisbury	Merrimac
	Haverhill	West Newbury	Newburyport
	Newbury	Groveland	Georgetown
	Methuen	Rowley	Dracut
	Tyngsborough	Chelmsford	Lowell
	Tewksbury	Andover	North Andover
	Lawrence	Boxford	Ipswich
	Middleton	Topsfield	Hamilton
	Essex	Gloucester	Rockport
	Wenham	Beverly	Manchester
	Danvers	Peabody	Salem
	Marblehead	Swampscott	Lynn
	Nahant	Saugus	Lynnfield
	North Reading	Reading	Wilmington
	Billerica	Carlisle	Bedford

		Burlington	Lexington	Woburn
		Winchester	Wakefield	Melrose
		Malden	Medford	Everett
		Chelsea	Revere	Winthrop
		Somerville	Cambridge	Arlington
		Belmont	Watertown	Brookline
		Lincoln	Concord	Acton
		Roxborough	Stow	Maynard
		Boston	Dedham	Milton
		Quincy	Randolph	Braintree
		Holbrook	Weymouth	Hingham
		Cohassett	Hull	Westwood
		Dover	Medfield	Millis
		Wrentham	Norfolk	Foxborough
		Plainville	North Attleborough	Norton
		Taunton	Raynham	Mansfield
		Attleboro	Berkley	Dighton
		Rehoboth	Seekonk	Freetown
		Norwell	Scituate	Stoneham
AREA	V :	Norwood	Walpole	Canton
		Sharon	Stoughton	Avon
		Easton	Brockton	Abington
		Rockland	Hanover	Whitman
		Hanson	Pembroke	Marshfield
		Duxbury	Kingston	Halifax
		East Bridgewater	West Bridgewater	Bridgewater
		Lakeville	Middleborough	Plympton
		Carver	Wareham	Rochester
		Marion	Plymouth	Bourne
		Sandwich	Falmouth	Mashpee
		Barnstable	Yarmouth	Dennis
		Brewster	Chatham	Orleans
		Wellfleet	Truro	Provincetown
		Gosnold	Gay Head	Chilmark
		West Tisbury	Edgartown	Oak Bluffs
		Tisbury	Mattapoisett	Acushnet
		Fairhaven	New Bedford	Dartmouth
		Westport	Fall River	Somerset
		Swansea	Eastham	Nantucket
		Harwick		

MICHIGAN : Ten Professional Standards Review Organization areas are designated in Michigan, composed of the following counties:

AREA	I :	Keweenaw	Gogebic	Ontonagon
		Houghton	Baraga	Marquette

		Alger	Schoolcraft	Luce
		Chippewa	Iron	Dickinson
		Menominee	Delta	Mackinac
AREA	II :	Emmet	Cheboygan	Presque Isle
		Charlevoix	Antrim	Otsego
		Montmorency	Alpena	Leelanau
		Benzie	Grand Traverse	Kalkaska
		Gladwin	Crawford	Oscoda
		Alcona	Wexford	Missaukee
		Roscommon	Ogemaw	Manistee
AREA	III :	Mason	Lake	Osceola
		Oceana	Newaygo	Mecosta
		Muckegon	Montcalm	Ottawa
		Kent	Ionia	Barry
AREA	IV :	Clare	Arenac	Isabella
		Midland	Bay	Iosco
		Saginaw	Huron	Tuscola
		Sanilac	St. Clair	
AREA	V :	Shiawassee	Genesee	Lapeer
AREA	VI :	Clinton	Eaton	Ingham
		Livingston	Gratiot	
AREA	VII :	Washtenaw	Lenawee	Monroe
		Jackson	Hillsdale	
AREA	VII :	Wayne		
AREA	IX :	Oakland	Macomb	
AREA	X :	Allegan	Van Buren	Kalamazoo
		Calhoun	Berrien	Cass
		St. Joseph	Branch	

MINNESOTA : Three Professional Standards Review Organization areas are designated in Minnesota, composed of the following counties:

AREA	I :	Kittson	Roseau	Lake of the Woods
		Koochiching	St. Louis	Lake
		Cook	Marshall	Beltrami
		Itasca	Polk	Pennington
		Red Lake	Norman	Mahnomen

	Clearwater	Hubbard	Cass
	Wadena	Crow Wing	Aitkin
	Calton	Todd	Morrison
	Mille Lacs	Kanabeo	Pine
	Pope	Stearns	Benton
	Cherbourne	Isanti	Chisago
	Wright	Clay	Becker
	Wilkin	Otter Tail	Traverse
	Grant	Douglas	Big Stone
	Stevens		
AREA II :	Anoka	Hennepin	Ramsey
	Washington	Carver	Scott
	Dakota		
AREA III :	Swift	Lac Qui Parle	Chippewa
	Kandiyohi	Meeker	Yellow Medicine
	Renville	McLeod	Lincoln
	Lyon	Redwood	Brown
	Sibley	Nicollet	LeSeur
	Rice	Goodhue	Wabasha
	Pipestone	Murray	Cottonwood
	Watowan	Blue Earth	Waseca
	Steele	Dodge	Olmstead
	Winona	Rock	Nobles
	Jackson	Martin	Faribault
	Freeborn	Mower	Fillmore
	Houston		

MISSISSIPPI : The State of Mississippi is designated as a single Professional Standards Review Organization area.

MISSOURI : Five Professional Standards Review Organization areas are designated in Missouri, composed of the following counties:

AREA I :	Atchison	Grundy	Lafayette
	Nodaway	Buchanan	Saline
	Worth	Clinton	Cass
	Harrison	Caldwell	Johnson
	Mercer	Livingstone	Pettis
	Holt	Platte	Bates
	Andrew	Clay	Henry
	Gentry	Ray	Benton
	De Kalb	Carroll	Vernon
	Daviess	Jackson	St. Clair

AREA II :	Putnam	Chariton	Moniteau
	Schuler	Randolph	Cole
	Scotland	Monroe	Osage
	Clark	Ralls	Gasconade
	Sullivan	Pike	Miller
	Adair	Howard	Maries
	Knox	Boone	Camden
	Lewis	Audrain	Pulaski
	Linn	Callaway	Phelps
	Macon	Montgomery	Crawford
	Shelby	Cooper	Dent
	Marion	Morgan	
AREA III :	Lincoln	St. Charles	St. Louis
	Warren	Franklin	St. Louis City
AREA IV :	Barton	Lawrence	Douglas
	Cedar	Greene	Howell
	Hickory	Webster	Oregon
	Dallas	Wright	McDonald
	Laclede	Texas	Barry
	Dade	Shannon	Stone
	Polk	Newton	Taney
	Jasper	Christian	Ozark
AREA V :	Jefferson	Cape Girardeau	Washington
	Carter	St. Francois	Ripley
	Ste. Genevieve	Butler	Iron
	Madison	Scott	Stoddard
	Perry	Mississippi	Reynolds
	New Madrid	Wayne	Dunklin
	Bollinger	Pemiscot	

MONTANA : The State of Montana is designated as a single Professional Standards Review Organization area.

NEBRASKA : The State of Nebraska is designated as one Professional Standards Review Organization area.

NEVADA : The State of Nevada is designated as a single Professional Standards Review Organization area.

NEW HAMPSHIRE: The State of New Hampshire is designated as a single Professional Standards Review Organization area.

NEW JERSEY : Eight Professional Standards Review Organization areas are designated in New Jersey, composed of the following counties:

AREA I :	Sussex Except Chilton Hospital	Warren	Morris	
AREA II :	Passaic	Chilton Hospital		
AREA III :	Bergen			
AREA IV :	Essex			
AREA V :	Hudson			
AREA VI :	Union			
AREA VII :	Hunterdon Somerset	Mercer Middlesex	Monmouth Ocean	
AREA VIII :	Burlington Camden Gloucester	Atlantic Salem	Cumberland Cape May	

NEW MEXICO : The State of New Mexico is designated as one Professional Standards Review Organization area.

NEW YORK : Seventeen Professional Standards Review Organization areas are designated in New York, composed of the following counties:

AREA I :	Niagara Genesee Cattaraugus	Orleans Wyoming Allegany	Erie Chautauqua
AREA II :	Monroe Ontario Steuben	Wayne Seneca	Livingston Yates
AREA III :	St. Lawrence Cayuga Cortland Chemung	Jefferson Onondaga Tioga Schuyler	Oswego Tompkins Broome
AREA IV :	Oneida Chenango	Herkimer Lewis	Madison
AREA V :	Franklin Essex Saratoga	Clinto Fulton Washington	Hamilton Warren
AREA VI :	Schenectady	Montgomery	Schoharie

AREA VII :	Otsego Delaware	Albany	Rensselaer
AREA VIII :	Greene Ulster	Columbia Dutchess	Sullivan Orange
AREA IX :	Putnam	Westchester	
AREA X :	Rockland		
AREA XI :	New York		
AREA XII :	Richmond		
AREA XIII :	Kings		
AREA XIV :	Queens		
AREA XV :	Nassau		
AREA XVI :	Suffolk		
AREA XVII :	Bronx		

NORTH CAROLINA : Eight Professional Standards Review Organization areas are designated in North Carolina, composed of the following counties:

AREA I :	Watauga Avery Caldwell Burke Mitchell Yancey Haywood	McDowell Rutherford Madison Buncombe Henderson Polk Clay	Transylvania Swain Jackson Macon Graham Cherokee
AREA II :	Ashe Alleghany Wilkes Alexander	Surry Yadkin Iredell Davie	Rowan Stokes Forsyth Davidson
AREA III :	Rockingham Caswell	Guilford Alamance	Randolph
AREA IV :	Person Orange	Durham	Chatham
AREA V :	Granville	Franklin	Harnett

	Vance	Wake	Johnston
	Warren	Lee	
AREA VI:	Halifax	Nash	Pitt
	Northampton	Edgecombe	Beaufort
	Hertford	Bertie	Hyde
	Gates	Martin	Lenoir
	Chowan	Washington	Craven
	Perquimans	Tyrrell	Pamlico
	Pasquotank	Dare	Jones
	Camden	Wilson	Carteret
	Currituck	Greene	
AREA VII:	Catawba	Mecklenberg	Montgomery
	Lincoln	Cabarrus	Anson
	Cleveland	Stanly	Moore
	Gaston	Union	Richmond
AREA VIII:	Scotland	Sampson	Wayne
	Hoke	Bladen	Duplin
	Cumberland	Brunswick	Onslow
	Robeson	New Hanover	Pender
	Columbus		

NORTH DAKOTA : The State of North Dakota is designated as a single Professional Standards Review Organization area.

OHIO : Twelve Professional Standards Review Organization areas are designated in Ohio, composed of the following counties:

AREA I :	Butler	Warren	Clinton
	Hamilton	Clermont	Brown
	Highland	Adams	
AREA II :	Darke	Shelby	Champaign
	Miami	Clark	Preble
	Montgomery	Greene	
AREA III :	Van Wert	Allen	Hancock
	Seneca	Mercer	Auglaize
	Hardin	Logan	Wyandot
	Crawford	Marion	
AREA IV :	Williams	Fulton	Lucas
	Ottawa	Defiance	Henry
	Wood	Sandusky	Paulding
	Putnam		

AREA V :	Lake	Geauga	Ashtabula
AREA VI :	Summit	Portage	Trumbull
	Stark	Mahoning	Columbiana
AREA VII :	Coshocton	Tuscarawas	Carroll
	Jefferson	Harrison	Belmont
	Monroe		
AREA VIII :	Licking	Muskingham	Guernsey
	Fairfield	Perry	Morgan
	Noble	Athens	Washington
AREA IX :	Hocking	Vinton	Meigs
	Pike	Jackson	Gallia
	Scioto	Lawrence	
AREA X :	Morrow	Knox	Union
	Delaware	Madison	Franklin
	Fayette	Pickaway	Ross
AREA XI :	Erie	Lorain	Huron
	Medina	Richland	Ashland
	Wayne	Holmes	
AREA XII :	Cuyahoga		

OKLAHOMA : The State of Oklahoma is designated as one Professional Standards Review Organization area.

OREGON : Two Professional Standards Review Organization areas are designated in Oregon, composed of the following counties:

AREA I :	Multnomah		
AREA II :	Clatsop	Union	Deschutes
	Columbia	Wallowa	Crook
	Tillamook	Lincoln	Coos
	Washington	Polk	Douglas
	Yamhill	Benton	Curry
	Clackamas	Marion	Josephine
	Hood River	Linn	Jackson
	Wasco	Jefferson	Klamath
	Sherman	Wheeler	Lake
	Gilliam	Grant	Harney
	Morrow	Baker	Malheur
	Umatilla	Lane	

PENNSYLVANIA : Twelve Professional Standards Review Organization areas are designated in Pennsylvania, composed of the following counties:

AREA I :	Erie	Potter	Elk
	Warren	Crawford	Cameron
	McKean	Forest	
AREA II :	Tioga	Centre	Columbia
	Bradford	Union	Snyder
	Clinton	Northumberland	Mufflin
	Lycoming	Montour	Juniata
	Sullivan		
AREA III :	Susquehanna	Lackawanna	Luzerne
	Wyoming		
AREA IV :	Wayne	Monroe	Northampton
	Pike	Carbon	Lehigh
AREA V :	Mercer	Jefferson	Butler
	Venango	Clearfield	Armstrong
	Clarion	Lawrence	Indiana
AREA VI :	Allegheny		
AREA VII :	Beaver	Westmoreland	Fayette
	Washington	Greene	
AREA VIII :	Cambria	Huntington	Bedford
	Blair	Somerset	
AREA IX :	Schuylkill	Berks	Franklin
	Perry	Cumberland	Adams
	Dauphin	Lancaster	York
	Lebanon	Fulton	
AREA X :	Chester	Delaware	
AREA XI :	Bucks	Montgomery	
AREA XII :	Philadelphia		

PUERTO RICO : Puerto Rico is designated as a single Professional Standards Review Organization area.

RHODE ISLAND : The State of Rhode Island is designated a single Professional Standards Review Organization area.

SOUTH CAROLINA: The State of South Carolina is designated as a single Professional Standards Review Organization area.

SOUTH DAKOTA : The State of South Dakota is designated as a single Professional Standards Review Organization area.

TENNESSEE : Two Professional Standards Review Organization areas are designated in Tennessee, composed of the following counties:

AREA I :	Lauderdale	Tipton	Haywood
	Madison	Henderson	Decatur
	Shelby	Fayette	Hardeman
	Chester	McNairy	Hardin
AREA II :	Lake	Obion	Weakley
	Henry	Dyer	Gibson
	Carroll	Benton	Crockett
	Stewart	Montgomery	Robertson
	Sumner	Trousdale	Macon
	Clay	Pickett	Houston
	Dickson	Cheatham	Davidson
	Wilson	Smith	Jackson
	Overton	Fentress	Humphreys
	Hickman	Williamson	Rutherford
	Cannon	Scot	Campbell
	Claiborne	Hancock	Hawkins
	Sullivan	Johnson	Morgan
	Anderson	Union	Grainger
	Sevier	Hamblen	Jefferson
	Cocke	Greene	Washington
	De Kalb	White	Putnam
	Cumberland	Perry	Lewis
	Maury	Marshall	Bedford
	Coffee	Warren	Van Buren
	Wayne	Lawrence	Giles
	Lincoln	Moore	Franklin
	Unicoi	Carter	Roane
	Loudon	Knox	Blount
	Bledsoe	Rhea	Meigs
	McMinn	Monroe	Grundy
	Sequatchie	Marion	Hamilton
	Bradley	Polk	

TEXAS : Nine Professional Standards Review Organization areas are designated in Texas, composed of the following counties:

AREA I :	Dallam	Hansford	Lipscomb
	Sherman	Ochiltree	Hartley

AREA I (Continued)	:	Moore	Lamb	Garza
		Hutchinson	Hale	Kent
		Roberts	Floyd	Stonewall
		Hemphill	Motley	Haskell
		Oldham	Cottle	Throckmorton
		Potter	Foard	Young
		Carson	Wilbarger	Jack
		Gray	Witchita	Surry
		Wheeler	Cochran	Fisher
		Deaf Smith	Hockley	Jones
		Randall	Lubbock	Shackelford
		Armstrong	Crosby	Stephens
		Donley	Dickens	Mitchell
		Collingsworth	King	Nolan
		Parmer	Knox	Taylor
		Castro	Baylor	Callahan
		Swisher	Archer	Eastland
		Briscoe	Clay	Coleman
		Hall	Montaque	Brown
		Childress	Yoakum	Comanche
		Hardeman	Terry	Runnels
		Bailey	Lynn	
AREA II	:	Wise	Parker	Hood
		Palo Pinto	Tarrant	Somervell
		Johnson	Erath	
AREA III	:	Grayson	Dallas	Navarro
		Fannin	Rockwall	Cooke
		Collin	Ellis	Denton
		Hunt	Kaufman	
AREA IV	:	Lamar	Marion	Shelby
		Red River	Van Zandt	Sabine
		Bowie	Smith	Trinity
		Delta	Gregg	San Jacinto
		Hopkins	Harrison	Polk
		Franklin	Henderson	Tyler
		Titus	Anderson	Jasper
		Camp	Cherokee	Newton
		Morris	Rusk	San Augustine
		Cass	Panola	Hardin
		Rains	Houston	Orange
		Wood	Angelina	Jefferson
		Upshur	Nacogdoches	

AREA V	:	Andrews	Coke	Crockett
		Martin	Ward	Schleicher
		Howard	Crane	Menard
		El Paso	Upton	Mason
		Hudspeth	Reagan	Sutton
		Culberson	Sterling	Kimble
		Reeves	Irion	Presido
		Loving	Tom Green	Brewster
		Winkler	Concho	Terrell
		Ector	McCulloch	Gaines
		Midland	Jeff Davis	Dawson
		Glasscock	Pecos	Borden
AREA VI	:	Mills	Robertson	Grimes
		Hamilton	Leon	Blanco
		Bosque	Madison	Travis
		Hill	Llano	Bastrop
		Limestone	Burnet	Lee
		Freestone	Bell	Burleson
		Lampasas	Williamson	Washington
		Coryell	Milam	Hays
		McLennan	Brazos	Caldwell
		Falls	San Saba	Fayette
AREA VII	:	Walker	Harris	Chambers
		Montgomery	Liberty	
AREA VIII	:	Austin	Brazoria	Waller
		Wharton	Galveston	Colorado
		Fort Bend	Matagorda	
AREA IX	:	Val Verde	Maverick	Calhoun
		Edwards	Zavala	San Patricio
		Real	Frio	Aransas
		Kerr	Atascosa	Webb
		Bandera	Karnes	Duval
		Gillespie	De Witt	Jim Wells
		Kendall	Victoria	Nueces
		Comal	Jackson	Kleberg
		Kinney	Dimmit	Zapata
		Medina	La Salle	Jim Hogg
		Bexar	McMullen	Brooks
		Guadalupe	Live Oak	Kenedy
		Gonzales	Bee	Starr
		Lavaca	Goliad	Hidalgo
		Wilson	Refugio	Willacy
			Uvalde	Cameron

UTAH : The State of Utah is designated as a single Professional Standards Review Organization area.

VERMONT : The State of Vermont is designated as a single Professional Standards Review Organization area.

VIRGIN ISLANDS : The Virgin Islands are designated as one Professional Standards Review Organization area.

VIRGINIA : Five Professional Standards Review Organization areas are designated in Virginia, composed of the following counties and independent cities:

	Counties		Independent Cities
AREA I :	Frederick	King George	Winchester
	Clarke	Highland	Harrisonburg
	Warren	Augusta	Fredericksburg
	Shenandoah	Albemarle	Staunton
	Page	Orange	Waynesboro
	Rappahannock	Louisa	Charlottesville
	Fauquier	Spotsylvania	Buena Vista
	Rockingham	Caroline	
	Greene	Bath	
	Madison	Rockbridge	
	Culpeper	Nelson	
	Stafford	Fluvanna	
AREA II :	Loudoun	Fairfax	Alexandria
	Prince William	Arlington	Fairfax
			Falls Church
AREA III :	Alleghany	Patrick	Clifton Forge
	Craig	Henry	Covington
	Botetourt	Bland	Lynchburg
	Bedford	Wythe	Roanoke
	Amherst	Grayson	Radford
	Appomattox	Tazewell	Norton
	Campbell	Smyth	Bristol
	Roanoke	Buchanan	Galax
	Giles	Russell	Martinsville
	Montgomery	Washington	Danville
	Floyd	Dickenson	
	Franklin	Wise	
	Pittsylvania	Scott	
	Pulaski	Lee	
	Carroll		

AREA IV	:	Buckingham	Prince George	Richmond
		Cumberland	Surry	Colonial Heights
		Goochland	Nottoway	Hopewell
		Powhatan	Dinwiddie	Petersburg
		Hanover	Sussex	South Boston
		Henrico	Charlotte	
		New Kent	Lunenburg	
		Charles City	Brunswick	
		Prince Edward	Greensville	
		Amelia	Halifax	
		Chesterfiled	Mecklenburg	
AREA V	:	Westmoreland	King and Queen	Williamsburg
		Northumberland	Gloucester	Newport News
		Accomack	King William	Hampton
		Richmond	James City	Franklin
		Lancaster	York	Suffolk
		Northampton	Southampton	Nansemond
		Essex	Isle of Wight	Portsmouth
		Middlesex		Norfolk
		Mathews		Chesapeake
				Virginia Beach

WASHINGTON : The State of Washington is designated as a single Professional Standards Review Organization area.

WEST VIRGINIA: The State of West Virginia is designated as a single Professional Standards Review Organization area.

WISCONSIN : Two Professional Standards Review Organization areas are designated in Wisconsin, composed of the following counties:

AREA I	:	Douglas	Green Lake	Adams
		Chippewa	Brown	Langlade
		Iron	Richland	Marinette
		Pierce	Jefferson	Winnebago
		Washburn	Dodge	Shawano
		Buffalo	Rock	Marquette
		Oneida	Dunn	Outagamie
		Wood	Ashland	Sheboygan
		Polk	Marathon	Dane
		Monroe	Burnett	Columbia
		Taylor	Eau Clair	Green
		Vernon	Price	Iowa
		St. Croix	Jackson	Bayfield
		Oconto	Florence	Clark
		Calumet	La Crosse	Vilas
		Menominee	Rusk	Pepin

AREA I (Continued)	:	Sawyer	Lincoln	Fond Du Lac
		Trempealeau	Crawford	Kewaunee
		Forest	Waushara	Sauk
		Portage	Door	Lafayette
		Barron	Manitowoc	Grant
		Juneau	Waupaca	
AREA II	:	Washington	Walworth	Ozaukee
		Racine	Waukesha	Kenosha
		Milwaukee		

WYOMING : The State of Wyoming is designated as a single Professional Standards Review Organization area.

204.3 Number of Proposed and Final Areas for Each State

	Proposed Areas	Final Areas		Proposed Areas	Final Areas
ALABAMA	1	1	ILLINOIS	7	8
ALASKA	1	1	INDIANA	5	7
ARIZONA	2	2	IOWA	1	1
ARKANSAS	1	1	KANSAS	1	1
CALIFORNIA	21	28	KENTUCKY	1	1
COLORADO	1	1	LOUISIANA	4	4
CONNECTICUT	4	4	MAINE	1	1
DELAWARE	1	1	MARYLAND	5	7
DISTRICT OF COLUMBIA	1	1	MASSACHUSETTS	5	5
FLORIDA	8	12	MICHIGAN	8	10
GEORGIA	3	1	MINNESOTA	3	3
HAWAII, AMERICAN SAMOA, GUAM, TRUST TERRITORIES OF THE PACIFIC ISLANDS	2	1	MISSISSIPPI	1	1
IDAHO	1	1	MISSOURI	5	5
			MONTANA	1	1
			NEBRASKA	1	1

NEVADA	1	1	SOUTH CAROLINA	1	1
NEW HAMPSHIRE	1	1	SOUTH DAKOTA	1	1
NEW JERSEY	8	8	TENNESSEE	3	2
NEW MEXICO	1	1	TEXAS	8	9
NEW YORK	14	17	UTAH	1	1
NORTH CAROLINA	4	8	VERMONT	1	1
NORTH DAKOTA	1	1	VIRGIN ISLANDS	1	1
OHIO	9	12	VIRGINIA	5	5
OKLAHOMA	1	1	WASHINGTON	3	1
OREGON	2	2	WEST VIRGINIA	1	1
PENNSYLVANIA	12	12	WISCONSIN	4	2
PUERTO RICO	1	1	WYOMING	1	1
RHODE ISLAND	1	1			
			TOTAL.....	182	203

204.4 National Summary of PSRO Areas

Total Number of Proposed PSRO Areas - 203

States Designated as Single PSRO Areas - (31):

Alabama
Alaska
Arkansas
Colorado
Delaware
District of Columbia
Georgia
Hawaii, American Samoa, Guam
Trust Territories of the
Pacific Islands
Idaho
Iowa
Kansas
Kentucky
Maine
Mississippi
Montana
Nebraska
Nevada
New Hampshire
New Mexico
North Dakota
Oklahoma
Puerto Rico
Rhode Island
South Carolina
South Dakota
Utah
Vermont
Virgin Islands
Washington
West Virginia
Wyoming

States Designated as Multiple PSRO Areas - (22):

Arizona
California
Connecticut
Florida
Illinois
Indiana
Louisiana
Maryland
Massachusetts
Michigan
Minnesota
Missouri
New Jersey
New York
North Carolina
Ohio
Oregon
Pennsylvania
Tennessee
Texas
Virginia
Wisconsin

APPENDIX A

REGIONAL HEALTH ADMINISTRATORS

Region I — Maine, Vermont, New Hampshire, Massachusetts, Connecticut, and Rhode Island

Gertrude Hunter, M.D.
John F. Kennedy Federal Building
Government Center - Room 1400
Boston, Massachusetts 02203

Region II — New York, New Jersey, Puerto Rico, and Virgin Islands

Jaime-Rivera-Dueno, M.D.
Federal Building
26 Federal Plaza
New York, New York 10007

Region III — Pennsylvania, Maryland, Delaware, Virginia, West Virginia, and District of Columbia

George C. Gardiner, M.D.
Post Office Box 13716
Philadelphia, Pennsylvania 19101

Region IV — Alabama, Georgia, Mississippi, South Carolina, North Carolina, Tennessee, Kentucky, and Florida

George Reich, M.D.
Peachtree-Seventh Building
50 Seventh Street, N.E.
Atlanta, Georgia 30323

Region V — Illinois, Indiana, Ohio, Michigan, Wisconsin, and Minnesota

Frank Ellis, M.D.
300 South Wacker Drive
Chicago, Illinois 60607

REGIONAL HEALTH ADMINISTRATORS

Region VI Louisiana, Arkansas, Oklahoma, Texas, and New Mexico

Floyd A. Norman, M.D.
1114 Commerce Street
Dallas, Texas 75202

Region VII Missouri, Iowa, Kansas, and Nebraska

Holman Wherritt, M.D.
Federal Office Building
601 East 12th Street
Kansas City, Missouri 64106

Region VIII Colorado, Utah, Wyoming, South Dakota, North Dakota, and Montana

Hilary H. Connor, M.D.
Federal Office Building
19th and Stout Streets
Denver, Colorado 80202

Region IX California, Nevada, Arizona, Guam, Hawaii, and Samoa

Donald P. McDonald, M.D.
Federal Office Building
50 Fulton Street
San Francisco, California 94102

REgion X Washington, Oregon, Idaho, and Alaska

David W. Johnson, M.D.
Arcade Building
1321 Second Avenue
Seattle, Washington 98101

CHAPTER III: STATEWIDE PSRO SUPPORT CENTERS

Chapter III

STATEWIDE PSRO SUPPORT CENTERS

STATEWIDE PSRO SUPPORT CENTERS

300 PURPOSE AND GENERAL RESPONSIBILITIES OF SUPPORT CENTERS

300.1 Introduction

It has been recognized that in many cases newly emerging PSROs will not have the resources or experience to organize initially and undertake without assistance the many activities required during both organizational and operational phases. Thus, in accordance with the legislative directives to the Secretary to provide all necessary assistance in the establishment of local PSROs under Sections 1156(a), 1163(c), and 1169 of P.L. 92-603 Statewide PSRO Support Centers will be established to assist in the creation and operation of local PSROs.

300.2 General Purpose of Support Centers

The general purpose of Support Centers shall be to stimulate and support the development and operation of the PSRO program and the growth of local PSROs by furnishing a variety of educational, organizational, administrative, and professional assistance to applicant or designated planning, conditional or operational PSROs. The specific kinds of assistance will depend in part upon the particular experience and expertise of the Support Center and in part upon the particular needs of the applicant and designated PSROs desiring assistance from the Support Center.

300.3 Initial Focus of Support Center Activity

Initial DHEW funding of Support Centers will be predicated on the basis that applicants for Support Center contracts are qualified to perform special services in terms of educating physicians about the PSRO program and assisting organizing groups seeking planning or conditional contracts in their developmental and operational activities. Support Center assistance is expected to expedite organization of local PSROs through the introduction of common and proven techniques of recruiting and organizing as well as through the benefit of basic administrative experience and professional and technical expertise. Support Center assistance must, however, be extended to the individual organization in a way that maintains local autonomy and responsibility.

302 TECHNICAL AND PROFESSIONAL ASSISTANCE TO POTENTIAL PSRO APPLICANTS

302.1 Initial Task Under DHEW Contract

The initial task of a Support Center will be to provide, under a direct contract with DHEW, encouragement as necessary to physicians in the officially designated local PSRO geographic areas in organizing for the purpose of qualifying as a planning or conditional PSRO. The DHEW contract will call for the Support Center to:

302.11 Educate all physicians in the areas served by the Support Center about the PSRO program, peer review, and quality assurance.

302.12 Identify physician groups in the areas served by the Support Center which need assistance in meeting the requirements of a PSRO.

302.13 Assist physician groups in PSRO areas served by the Support Center where there are no organizations that have received a conditional PSRO contract in developing an organizational format and structure as a non-profit corporation consistent with DHEW rules, regulations, and guidelines.

302.14 Arrange initial consultations with individual organizations to ascertain the nature and magnitude of specific needs of each to qualify for conditional designation as a PSRO. Such consultation shall involve a determination of the individual organization's levels of technical organization and professional competence in peer review activities. From this information an assistance and advisory plan for the respective organization shall be formulated by the Support Center and submitted to the PSRO Focal Point in the DHEW Regional Office along with a request for such assistance from the involved physician group where it will be evaluated as described in Section 302.2.

302.2 Procedure for Approval of Additional Assistance

A physician group desiring additional assistance as described under Sections 302.1, 302.3 and 302.4 from the Support Center shall request such assistance in writing to the PSRO Focal Point in the DHEW Regional Office. (See Appendix A, Chapter VI.)

The request should include the name of the organization (or physician group), the current number of members, indications of organization support (see Chapter IV of the PSRO Manual), and the specific nature of assistance desired. The Regional Office Focal Point will review the request in conjunction with other appropriate Department Staff. If this request is approved, the Support Center will receive a written authorization from the Project Officer to proceed with the provision of specific forms of technical assistance to the requesting organization. Such assistance is reimbursable under the contract between the Support Center and DHEW.

302.3 Support Center Assistance to Organizations to Meet Requirements for Conditional Designation

Support Center assistance to organizations that are working to become eligible for conditional designation may include any of the following activities:

302.31 Assistance to the physician group in meeting the organizational and membership requirements of a PSRO, including but not limited to:

(a) Developing an organizational format and structure as a nonprofit corporation consistent with DHEW regulations, and guidelines.

(b) Developing by-laws that conform to guidelines set forth in Chapter V of this manual.

(c) Organizing programs to recruit broad physician membership on a continuing basis.

302.32 Assistance in formulating the application required for planning contract assistance for those organizations that are unable to apply for conditional designation without preliminary direct DHEW financial assistance.

302.33 Assistance to organizations in the development of a formal plan (See Chapter V, Section 505.7), such as:

(a) Assistance in the development of review procedures, including methods for selection and rotation of reviewing health care professionals.

(b) Assistance in familiarizing the organization with the options for peer review techniques based on PSRO Manual guidelines.

(c) Assistance in planning for the application of medical criteria and standards to the review of institutional care in short-stay hospitals and/or in long-term care institutions.

(d) Assistance in the identification of specialists for recruitment as reviewers.

(e) Assistance in formulating a plan for the evaluation of in-house review mechanisms.

(f) Assistance in formulating a plan for the inclusion of non-physician health care professionals in review activities.

(g) Assistance in developing a plan for coordinating with Medicare intermediaries and Medicaid agencies in the integration of review activities and the payment mechanism.

304 ASSISTANCE TO CONDITIONAL AND OPERATIONAL PSROs

Needed forms of technical and professional assistance to conditional and operational PSROs may be provided by Support Centers through a subcontracting arrangement initiated by an individual PSRO in the conditional or operational phase of development. Such subcontracting arrangements require the approval of the Secretary. (See Chapter V).

The following types of assistance will serve as examples of possible useful services to a conditional or operational PSRO which a Support Center might be requested to provide:

(a) Assistance in the further development and elaboration of review procedures.

(b) Assistance in the continuing recruitment of all types of physicians to ensure a broad base of physician reviewers.

(c) Assistance in developing procedures for development of special criteria necessary for the conduct of medical care evaluation studies.

(d) Assistance with the interpretation and use of data to support PSRO review activities.

(e) Assistance in planning programs to train physicians to perform review activities, to conduct medical care evaluation studies, and to interpret aggregate data related to review.

(f) Assistance in developing data output formats to measure objectively the effectiveness of review efforts of individual institutions and of the PSRO.

(g) Assistance in planning the involvement of non-physician health care practitioners in peer review and in the setting of criteria and standards for care delivered by their profession.

(h) Provision of common professional and technical services to PSROs as appropriate.

(i) Assistance in developing mechanisms for integrating PSRO review determinations with reimbursement under Titles V, XVIII and XIX programs.

306 ASSISTANCE TO STATE PSR COUNCILS

A Support Center may also, under subcontract at the request of a State PSR Council and with the approval of the Secretary, furnish technical and

professional assistance to the Council in the performance of its duties and functions.

The following examples are types of assistance which may be sought by a State PSR Council from a Support Center.

(1) Assistance in the dissemination of information among PSROs.

(2) Assistance in ensuring sufficient expertise for specialty review in all PSROs within the State.

(3) Assistance in coordinating the data requirements of PSROs in line with the responsibilities of the State Council.

(4) Assistance in fostering cooperation between PSROs and appropriate health planning bodies.

(5) Assistance in developing relationships between individual PSROs and Statewide health and health-related agencies.

(6) Assistance to the Secretary and State PSR Councils in coordination and evaluation of PSROs.

308 QUALIFICATIONS FOR SUPPORT CENTERS

The following requirements comprise the basic qualifications for an organization to receive funding as a Support Center. Emphasis will be placed on a demonstration of experience and expertise in peer review and related activities. It should be noted that no group will be eligible for contract awards both as a Support Center and as a PSRO in any stage of development--planning, conditional, or operational.

(a) Be composed primarily of physicians practicing within the State which the organization proposes to serve and have continuing relationships with State medical and other health professional societies, agencies and organizations.

(b) Demonstrate that the physicians in the State desire technical assistance from the applicant organization.

(c) Demonstrate actual knowledge and expertise in the conduct of PSRO-like peer review activities by a description of previously provided services including for whom such services were furnished and the nature of the services and present capabilities to provide similar services to requesting groups.

(d) Demonstrate experience and competence in other areas in which the applicant Support Center proposes to furnish services.

(e) Propose to service a minimum of five (5) officially designated PSRO geographic areas. (The areas to be served by an applicant Support Center should be contiguous but need not be contained within the boundaries of a single State. An applicant Support Center need not propose to serve all the PSRO georgraphic areas in the State where the applicant Support Center is located, but the majority of areas of proposed service must be in the subject State.)

Affidavits, endorsements and other submissions of evidence relating to the basic qualifications outlined in this section may be required by the Request for Proposal as part of the Technical Proposal.

310 SUPPORT CENTER APPLICATION AND APPROVAL PROCESS

The applicant organization shall submit, in conformance with DHEW Request for Proposal requirements, a Technical Proposal setting forth the data and information on which the evaluation of proposal will be based. The Technical Proposal shall be divided into two parts: Part I shall relate to the initial tasks (described in Section 302) of educating physicians, identifying physician groups as potential PSROs, and arranging initial consultations with such physician groups to formulate individual plans whereby such groups may achieve conditional designation as a PSRO.

Part 2 shall indicate the past experience and competence of the applicant Support Center in performing types of assistance outlined in Sections 302.3 and 304. (See also Attachment D-29, Technical Proposal Instructions of attached Request for Proposal, entitled "Support for the establishment of State-wide Professional Standards Review Organization Support Centers for the purpose of accelerating the development of the Professional Standards Review Organization (PSRO) program.")

The application and selection process for Support Centers will generally parallel that outlined in PSRO Manual Chapter VI, "PSRO Application and Selection Process." Section 602.

312 PROPOSAL EVALUATION CRITERIA

Support Center proposals will be evaluated on the basis of weighted criteria as indicated in the Technical Proposal Instructions, Attachment D-29 of the Support Center Request for Proposal cited in the previous Section 310.

314 RENEWAL AND TERMINATION OF SUPPORT CENTER CONTRACTS

It is expected that future procurements will be made for Support

Center contracts as additional needs arise. Initial contracts will be let for a period of 12 months. Contract renewals are anticipated to permit the program to continue without interruption if all evaluation criteria for renewal are met.

314.1 Renewal Criteria

Renewal requests will be evaluated on the basis of (1) satisfaction of the organizations served by the Support Center; (2) the development of the PSRO program within the Support Center's geographic service area; (3) the operational success of individual PSROs served by the Support Center; (4) Support Center performance of original contract goals and obligations; and (5) projections for future Support Center progress in promoting development of operational PSROs.

314.2 Termination

Support Center - DHEW contracts may be terminated in accordance with the provisions of Federal procurement regulations [Clause 14, "Termination for Convenience of the Government," HEW - 315A (12/72) General Provisions.]

CHAPTER IV: PSRO PLANNING CONTRACTS

Chapter IV

PSRO PLANNING ORGANIZATIONS

400 INTRODUCTION

In the initial phases of the program there will be two types of PSRO organizations in operation. These are: (1) planning organizations, and (2) conditional PSROs. Chapter IV of this Manual relates to planning organizations, and Chapter V to conditional PSROs.

The major differences between planning organizations and conditional PSROs are (1) conditional PSROs must, when they apply, have as members of their organization at least 25 percent of the physicians eligible for membership whereas planning organizations, when they apply, must show a potential for obtaining this level of membership and (2) conditional PSROs must, as part of their application, submit a plan for the assumption of PSRO health care review responsibilities in their area, whereas planning organizations, must, as part of their application, evidence the support and understanding necessary to develop such a plan during the period of their planning contract. In other words, planning contracts are available to organizations who demonstrate the potential to meet the qualifications for conditional designation (See Chapter V) but who require financial assistance to complete the development of these qualifications. Organizations which feel that they meet the eligibility requirements for conditional designation specified in Chapter V may apply for such designation without first securing a planning contract.

This Chapter describes the eligibility requirements of an organization wishing to apply for a planning contract, the duties and functions of a planning organization, duration of planning contracts and the application process for such contracts.

402 ELIGIBILITY REQUIREMENTS

To qualify for a planning contract an organization must submit an acceptable plan for completing the tasks outlined in Section 405 of this Chapter and meet certain organizational and membership requirements detailed in Section 402.1 and 402.2 below.

402.1 Organizational Requirements

The applicant organization must be, or show evidence of the potential by the date of the contemplated contract award to be an incorporated, non-profit organization composed of doctors of medicine and/or osteopathy licensed to engage in practice in the PSRO area and whose primary (substantial) function is to qualify for PSRO and similar quality assurance program duties and functions. The applicant must also provide for voluntary open membership of such physicians without requirement of dues and without requirement of membership or payment of dues to any organized medical society or organization. Indications of meeting these requirements shall be:

402.11 A statement signed by the duly authorized representative of the governing body (or organizing group) that the primary (substantial) function of the organization is to qualify for conditional designation as a PSRO and subsequently to perform PSRO and similar quality assurance program duties and functions; and that the organization is non-profit and has (will) submit an application to the Internal Revenue Service requesting an exemption from Federal Corporation Tax under the Internal Revenue Code;

402.12 A statement signed by the duly authorized representative of the governing body (organizing group) that membership in the organization is open to all physicians eligible for membership under the requirements in Attachment A, Chapter V;

402.13 The names and office addresses, telephone numbers, and occupations of the directors of the governing body (or organizing group) of the applicant organization;

402.14 The following information (may be estimated) regarding numbers and types of members in the applicant organization:

(a) Licensed doctors of medicine by specialty and by county

(b) Licensed doctors of osteopathy by county

(c) Licensed doctors primarily engaged in

(1) Individual practice
(2) Group practice
(3) Institutional practice
(4) Administration
(5) Research
(6) Teaching
(7) Other

402.15 Evidence of support of the applicant organization's intent to conduct PSRO operations in the PSRO area may include endorsements from organizations such as the following:

(a) State medical society(s)

(b) County medical society(s)

(c) Medical specialty and non-physician health care practitioner organizations

(d) Health planning organizations

(e) Hospitals, medical schools, and other health care institutions

(f) Health insurance organizations

(g) Consumer health groups

402.2 Membership Requirements

The applicant organization must show potential for obtaining a substantial proportion (twenty-five percent or more) of physicians licensed to engage in practice in the PSRO area as members by the conclusion of the contract period. Evidence of such potential may include endorsements from organizations as in Section 402.15.

403 DURATION OF A PLANNING CONTRACT

As a rule, the term of a planning contract will be six months. If the applicant organization feels it requires more than six (6) months to complete their planning activities, the Department will consider such requests made in the initial contract proposal. In addition, where circumstances warrant, the Department will grant extensions to planning contracts after award. The Department anticipates that most planning organizations will be able to submit an application for conditional designation approximately 4 months after initiation of the planning contract. This will allow the Department to assess the application and work with the applicant organization to make necessary revisions during the final portion of the planning period. In addition, if it appears on initial review of the application from a planning organization for conditional designation, that the organization will obtain conditional designation, the Department will notify the organization of this tentative determination in order that it may begin to plan and organize to become a conditional PSRO. In these cases, it will also be possible for the Department during the planning period to initiate the process of notifying the PSRO area of its intent to designate the applicant organization as a conditional PSRO (see Section 606, Chapter VI, Notification and Polling).

405 DUTIES AND FUNCTIONS OF A PLANNING ORGANIZATION

Those organizations which receive a planning contract will, during the period of the contract:

405.1 Develop an organizational structure which conforms to Chapter V, "Requirements for Qualification as Conditional PSRO."

405.2 Undertake a process to enlist as members of the contractor organization a substantial proportion (twenty-five percent or more) of doctors licensed

to engage in practice in the PSRO area, such doctors to be reasonably representative of types of medical practice in the PSRO area, major medical specialities in the area, and patterns of medical practice, e.g., solo practice, group practice, institutional practice, etc. A plan for continuing recruitment of physicians is to be developed as part of this process.

405.3 Develop a detailed formal plan for the orderly assumption and implementation of Conditional PSRO duties and functions in conformance with the requirements specified in Chapter VII, "PSRO Health Care Review Responsibilities," and subsequent material to be issued by the Department related to PSRO data needs.

At a minimum the development of a formal plan shall include the following tasks and times deliverable as part of said plan:

405.31 As assessment of the designated PSRO area with respect to:

(a) the number of physicians (M.D.'s and D.O.'s) by county and by major specialty;

(b) the number of short stay hospitals, and long term care facilities; number of beds in each, and approximate estimate of the number of annual Medicare and Medicaid admissions and total number of admissions in short stay hospital;

(c) the current quality assessment/assurance and utilization review activities in each short stay hospital and the willingness of each such hospital to perform review activities in conformance with PSRO guidelines and regulations.

405.32 Development of a plan for evaluating the effectiveness of in-house review in short stay hospitals, including:

(a) the methodology necessary for the evaluation;

(b) the time required to perform such an evaluation in all short stay hospitals in the designated area;

(c) the types of individuals to be involved in each step of the evaluation;

(d) the explicit criteria to be used in the initial evaluation and in monitoring those hospitals which are performing review in short stay hospitals under a PSRO authorization;

(e) an estimate of the number of short stay hospitals where authorization by the PSRO for the hospital to conduct review for the PSRO might take place during the first year of review operations.

405.33 Development of a plan for the collection of baseline data and other data to meet the types of general Federal reporting requirements, the nature of which will be specified in material to be issued in the near future by the Department.

405.34 Development of a plan for health care review of in-patient care in short-stay hospitals and a phased plan for performance of review in long-term care settings. Chapter VII of this manual describes a system of review of in-patient short-stay hospital care consisting of admission certification, continued stay review, medical care evaluation studies and analysis of profiles. While these are the basic requirements, the Department is willing to consider alternate review mechanisms in a limited number of instances, provided that such applicants present an approach to review that has clear potential for being equally or more effective than that outlined in this Manual in ensuring that care being delivered is necessary, appropriate and consistent with acceptable professional standards. Every plan for review shall include:

(a) description of the review process;

(b) the types of individuals to be involved in each step of the review process;

(c) a timetable for phasing in review in those hospitals not performing review under an authorization from the PSRO;

(d) a plan for how the PSRO intends to work administratively with Title XVIII intermediaries and Title XIX agencies;

(e) evidence that sufficient reviewers of the types, kinds, and geographic distribution necessary to perform PSRO review will be available to assume the review duties (or an indication of support from major specialty groups within the PSRO designated area).

405.35 Formulation of a methodology to develop and/or adopt and/or modify criteria and standards; and formulation of a methodology to select norms for use in the review process. These methodologies should include an organizational structure indicating an estimate of personnel to be involved and the source of any existing criteria, standards, or norms to be used intact or to be modified by the PSRO.

405.36 Development of a plan for involvement of non-physician health care professionals in the planning and conduct of peer review and in the development and/or adoption and/or modification of criteria and standards, and in the selection of norms for care provided by their peers.

405.37 Development of a plan to train all personnel necessary to administer the PSRO and conduct required review.

405.38 Formulation of a plan for the integration of review findings into existing programs of continuing medical education.

405.39 Estimation of the type, level, and quantity of resources outside the organization necessary for performance of PSRO duties and functions under conditional designation.

405.40 Development of strategy for the acquisition of the projected organizational resources (staff, consultation, equipment, space) which would be required for performance as a conditionally designated PSRO. Determine what resources (type and level) outside the organization may be necessary.

406 CONTENT OF A PLANNING APPLICATION

Refer to Technical Proposal Instructions of RFP - HSA 105-BQA-25(4)AEI.

408 APPLICATION PROCESS

Information relating to availability of RFP for a planning contract and the processing of proposals received are detailed in Chapter VI of this Manual.

410 CRITERIA FOR EVALUATION OF PROPOSALS

Proposals shall be considered PSRO area by PSRO area, and not one area against others. The proposals will be evaluated based on four criteria as outlined in the technical proposal instruction attachment to RFP HSA 105-BQA-25(4)AEI.

412 CONTRACT REPORTING REQUIREMENTS

Structured reports of progress in completing the tasks in the scope of work shall be required. The format, frequency and quantity of these reports shall be as mutually agreed upon by the Project Officer and the contractor.

CHAPTER V: REQUIREMENTS FOR QUALIFICATION AS CONDITIONAL PSRO

Chapter V

REQUIREMENTS FOR QUALIFICATION AS A CONDITIONAL PSRO

500 INTRODUCTION

In the initial phases of the PSRO program there will be two types of PSRO organizations in operation. These are (1) planning organizations and (2) conditional PSROs. Chapter IV of this Manual relates to planning organizations. This Chapter of the PSRO Manual relates to conditional PSROs and deals with the basic requirements for conditional designation as a PSRO and the related requirements for performance of PSRO activities. The requirements for both designation and functioning as a PSRO are of two basic types: (1) organizational (including membership requirements) and (2) requirements related to performance of health care review activities.

The first portion of this Chapter briefly outlines all requirements and planned activities required for designation as a PSRO. The second portion of the Chapter describes in greater detail the organizational requirements to be designated and to function as a conditional PSRO, answering such questions as who can participate in review, how the PSRO is to relate to advisory groups and to the State PSRO Council (if present), and what are the requirements for the composition and activities of the governing body, officers, and committees. Model Articles of Incorporation and By-Laws are appended to Chapter V as examples. A detailed description of the health care review requirements of a PSRO are the subject of Chapter VII.

It should be noted that the organizational and membership requirements uniformly apply to organizations conditionally designated before January 1, 1976. After this date, organizations not meeting these organizational requirements may be conditionally designated.

Information regarding the application and selection process is contained in Chapter VI.

The major differences between planning organizations and conditional PSROs are that (1) conditional PSROs must, when they apply, have as members of their organization at least 25 percent of the physicians eligible for membership, whereas planning organizations, when they apply must show a potential for obtaining this level of membership and (2) conditional PSROs must, as part of their application, submit a plan for the assumption of PSRO health care review responsibilities in their area, whereas planning organizations must, as part of their application, evidence the support and understanding necessary to develop such a plan during the period of their planning contract.

Many organizations designated as conditional PSROs will devote the initial portion of their contract period to the further development of an organizational structure, the design of a more detailed review plan, the acquisition and education of staff, and the development of relationships with hospitals and with Medicare, Medicaid, and Maternal and Child Health agencies.

Thus an organization wishing to apply for conditional designation does not have to have the capability to initiate health care review immediately after designation. In addition, when review does begin it will likely be a phased process with a gradual increase in the number of hospitals where review is occurring, followed by a similar phasing in of review in long term care institutions.

500.1 Definitions

For the purposes of this chapter the following definitions shall apply:

500.11 Physician -- A licensed doctor of medicine or osteopathy

Licensed to practice -- Authorized under law to engage in the unrestricted practice of a specific profession, e.g., medicine, osteopathy, nursing.

500.12 PSRO member -- A physician who meets PSRO membership requirements and has voluntarily signed a written statement indicating a desire to be a PSRO member and a willingness to abide by the By-Laws and to participate in the review functions of the PSRO.

500.13 Physician professional activities -- Direct patient care and related clinical activities, administrative duties in a medical facility or other health related institution, and/or medical or osteopathic teaching or research activities.

500.14 Peer review -- The formal assessment by health care practitioners of the quality and efficiency of services ordered or performed by other health care practitioners in the same health care profession.

500.15 Substantial proportion -- A minimum of twenty-five (25) percent.

500.16 Active staff privileges -- The current eligibility of any physician to admit, perform diagnostic services, care for or treat patients in a hospital setting.

505 ELIGIBILITY FOR DESIGNATION AS A CONDITIONAL PSRO

This section describes in brief those qualifications necessary for an applicant to be eligible for designation as a conditional PSRO. In order to qualify for conditional designation, the applicant must:

505.1 Have as members at least twenty-five (25) percent of the physicians engaged in the practice of medicine or osteopathy in their designated area. (See Sections 510.16 a-h.)

505.2 Be incorporated as a non-profit organization with its substantial function to carry out PSRO and other health care review activities. (See Section 510.04.)

505.3 Have been granted or have requested exemption from Federal corporation taxes under Section 501(c) of the Internal Revenue Code. (See Section 510.04.)

505.4 Have developed by-laws* which contain specific reference to the following:

505.41 The proposed functions of the organization.** (See Section 510.08.)

505.42 Membership policy. (See Sections 510.16 - 510.36.)

505.43 Eligibility for health care review. (See Sections 520 - 520.08.)

505.44 Structure and functions of the governing body and executive committee. (See Sections 550.1 and 550.2.)

505.45 Duties of the executive director. (See Section 550.3.)

505.46 Proposed committee structure. (See Section 550.4.)

505.47 Statements on conflict of interest. (See Section 550.5.)

505.5 Develop a timetable for forming an advisory group (if applicable, see Section 550.4.)

505.6 Provide the names and addresses of the members of the governing board, executive committee, and, if known, of the executive director.

505.7 Develop and submit a formal plan for the assumption and implementation of the duties and functions of a conditional PSRO. (See Chapter VII for a more detailed description of the foregoing items related to a formal plan.)

It is anticipated that the detail of the formal plan described below will vary from applicant to applicant. Where possible, it is to describe each item in detail. In instances, however, where this is not possible, a description of how the more detailed plan will be developed after conditional designation and a projected timetable for its completion is to be provided.

* To be submitted as part of necessary documentation. See ** below.

** Documentation is necessary to substantiate compliance with this requirement.

At a minimum the formal plan shall include the following tasks and items deliverable as part of said plan.

505.71 An assessment of the designated PSRO area with respect to:

(a) the number of physicians (M.D.'s and D.O.'s) by county and by major specialty;

(b) the number of short stay hospitals, and long term care facilities, number of beds in each, an approximate estimation of the number of annual Medicare and Medicaid admissions and total number of admissions in each short stay hospital;

(c) the current quality assessment/assurance and utilization review activities in each short stay hospital and the willingness of each such hospital to perform review activities in conformance with PSRO guidelines and regulations.

505.72 Development of a plan for evaluating the effectiveness of in-house review in short stay hospitals. When developed this plan would contain:

(a) the methodology necessary for the evaluation;

(b) the time required to perform such an evaluation in all short stay hospitals in the designated area;

(c) the types of individuals to be involved in each step of the evaluation;

(d) the explicit criteria to be used in the initial evaluation and in monitoring those hospitals which are performing review in short stay hospitals under a PSRO authorization;

(e) an estimate of the number of short stay hospitals where an authorization by the PSRO for the hospital to conduct review for the PSRO might take place during the first year of operations.

505.73 Development of a plan for the collection of baseline data and data to meet the types of general Federal reporting requirements, including:

(a) kinds of data to be collected;

(b) sources for required data elements;

(c) how and where necessary aggregation of data elements will take place.

505.74 Development of a plan for health care review in short stay hospitals and a phased plan for performance of review in long term care settings. Chapter VII of this Manual describes a system of required review of in-patient short stay hospital care consisting of admission certification, continued stay review, medical care evaluation studies, and development and analysis of profiles. While these are the basic requirements, the Department is willing to consider alternate review mechanisms in a limited number of instances, provided that such applicants present an approach to review that has clear potential for being equally or more effective than that outlined in this Manual in ensuring that care being delivered is necessary, appropriate and consistent with acceptable professional standards. Every plan for review shall include:

(a) description of the process;

(b) the types of individuals to be involved in each step of the review process;

(c) a timetable for phasing in review in those hospitals not performing review under an authorization from the PSRO;

(d) a plan for how the PSRO intends to work administratively with Title XVIII intermediaries and Title XIX agencies;

(e) evidence that sufficient reviewers of the types, kinds and geographic distribution necessary to perform PSRO review will be available to assume the review duties (or an indication of support from major specialty groups within the PSRO designated area).

505.75 Formulation of a methodology to develop and/or adopt and/or modify criteria and standards; and formulation of a methodology to select norms for use in the review process. These methodologies should include an organizational structure indicating an estimate of personnel to be involved and the source of any existing criteria, standards, or norms to be used intact or to be modified by the PSRO.

505.76 Development of a plan for the involvement of non-physician health care professionals in the planning and conduct of peer review and in the development and/or adoption and/or modification of criteria and standards, and in the selection of norms for care provided by their peers.

505.77 Development of a plan to train all personnel necessary to administer the PSRO and conduct required review.

505.78 Formulation of a plan for the integration of review findings into existing programs of continuing medical education.

505.79 Development of a plan for the acquisition of the projected organizational resources (space, equipment, staff, and consultation) required for performance as a conditionally designated PSRO.

505.8 Estimation of the type, level, and quantity of resources outside the organization necessary for performance of PSRO duties and functions under conditional designation.

510 ORGANIZATIONAL REQUIREMENTS OF A CONDITIONAL PSRO

This section details those requirements which relate to a conditional PSRO's organizational structure, membership, internal operations and the roles of physicians and other health care practitioners in health care conducted under its auspices.

510.04 Incorporation

An applicant organization must be incorporated as a non-profit membership organization (no capital stock) or be a component of such incorporated organization. The organization must be authorized to operate in the State in which the PSRO area exists.

510.08 Purposes and Functions

(a) The primary function of the organization as specified in the articles of incorporation shall be to assume responsibilities for the duties and functions of Professional Standards Review Organization as specified in Title XI of the Social Security Act and related Departmental regulations and guidelines.

(b) The substantial function of the organization shall be to perform the duties and functions of a PSRO and, if desired by the organization, other related quality assurance activities.

510.12 By-Laws

The corporation's articles and by-laws must be consistent with the requirements of Title XI of the Social Security Act and related Departmental regulations and guidelines.

510.16 Conditions of Membership

(a) Any doctor of medicine or osteopathy (except when employed by the Federal government -- see Section 510.16(d)), to be eligible for membership, must hold a current and unrestricted medical or osteopathic license from, or a license recognized by, the licensing authority or authorities in the State in which the organization is located and be performing professional activities within the area.

(b) An intern or resident is eligible for membership in the organization if he/she holds, as an individual, a current and unrestricted license to engage in the practice of medicine recognized by the licensing authority in which the organization is located.

(c) A doctor of medicine or osteopathy licensed and performing professional activities in several PSRO areas shall be eligible for membership in all such areas.

(d) Physicians employed in the Federal government shall be eligible for membership in the PSRO if they are authorized to perform professional activities in the designated PSRO area and are associated with institutions performing review under the auspices of the PSRO or if a portion of their professional activities in the PSRO area is not performed in the course of their employment for the Federal government.

(e) Membership in a PSRO shall be open on a continuing basis, to all qualified doctors of medicine and osteopathy who are willing to participate in PSRO activities and such membership shall be voluntary. Every physician who wishes to become a member shall sign a statement that he wishes to become a member of the PSRO and is willing to participate in PSRO activities. The PSRO shall maintain a file of all such statements.

(f) Information on procedures and requirements for membership shall be incorporated in the by-laws of the organization and these shall be available to any physician upon request.

(g) The physician need not be a member in nor pay dues to any other organization as a requirement for PSRO membership. The organization shall allow voluntary contributions. Lack of monetary contribution shall not be a cause for suspension or termination of membership, nor for non-assignment to perform the duties and functions of the PSRO.

510.2 Recruitment of Membership

Each PSRO must devise and implement an approved plan for recruiting, on a continuing basis, physicians of all types and levels as members and reviewers.

510.24 Level of Membership

An organization's membership must include a substantial proportion of doctors engaged in the practice of medicine or osteopathy in a designated PSRO area. This is defined as membership consisting of a minimum of 25% of the physicians eligible for membership in the PSRO area.

510.28 Membership Roster

Each PSRO must devise and implement a mechanism for keeping a roster of current members, including, at a minimum, their names, current addresses, and specialties.

510.32 Rights of Membership

Each member shall be equally eligible for service as a director of the governing body or officer of the organization, and for assignment to the duties and functions of a PSRO, except where specific restrictions are provided by law.

510.36 Tenure of Membership

(a) a Physician may voluntarily elect to terminate membership at any time by serving written notice to the PSRO at its usual place of business.

(b) A physician need only continue to meet the PSRO membership requirements, exclusive of payment of voluntary contributions, to remain a member of the PSRO. No renewals of membership are required for continuing membership in the PSRO.

520 HEALTH CARE REVIEW ACTIVITIES

This section details the eligibility and restricitons of physicians and non-physician health care professionals regarding participation in PSRO review functions.

520.04 Physician Review Eligibility and Restrictions on Review

(a) Members -- All members of a PSRO are to have an equal opportunity to participate in, as appropriate, the review functions of that PSRO except where law or regulations restrict such assignment.

(b) Non-member physicians -- A PSRO shall encourage all physicians, including non-member physicians, to become involved in the review functions of PSRO.

(c) Hospital review

(1) Physicians assigned responsibility for the review of hospital care must have active hospital staff privileges in at least one hospital in a PSRO area where review is performed under PSRO auspices. Other physicians may participate in PSRO hospital review functions but may not make PSRO determinations concerning the acceptability of hospital care delivered in an individual case. This requirement does not preclude use of other physicians eligible for PSRO membership from participating in the review process, only from making final review determinations.

(2) A PSRO shall not usually assign physicians review responsibilities for hospitals in which they have active staff privileges unless the PSRO finds that assignment justified in terms of a lack of sufficient, alternate physician reviewers. Special review arrangements may be made with the approval of the Department. This provision does not preclude a physician from participating in general review activities relating to the hospital, such as working as a staff member for the review committee and working on the development of provider and/or practitioner profiles. It does preclude him from participating, in general, in individual PSRO review decisions or decisions regarding the effectiveness of in-house review. This provision does not apply to institutions operating an in-house medical care review system under a PSRO delegation. An institution is eligible for delegation of review functions only if a majority of physicians with active staff privileges are members of the PSRO and are willing to participate in the PSRO's performance of its contractual responsibilities.

(d) Self-review -- A physician may not review health care services which he provided directly or for which he was directly or indirectly responsible.

(e) Financial interests -- A physician in a PSRO may not review services provided in or by an institution, organization, or agency in which he, or any member of his family, has a direct or indirect financial interest.

(1) For purposes of this paragraph, a physician's family includes only his spouse (other than a spouse who is legally separated from him under a decree of divorce or separate maintenance), children (including legally adopted children), grandchildren, parents, and grandparents.

(2) A direct or indirect financial interest exists where the physician or a member of his family stands to gain or lose monetarily or in equity from the financial performance of a profit or non-profit making institution, organization or agency which provides health care services. An employment relationship does not, in itself, constitute a financial interest. Where as a result of these provisions, an unusual situation precludes adequate review within the PSRO area, special review arrangements may be made with the approval of the Department.

(f) Physician review -- No PSRO shall utilize the services of anyone but a duly licensed doctor of medicine or osteopathy to make final review determinations with respect to the professional conduct of any other duly licensed doctor of medicine or osteopathy in the exercise of his profession.

520.08 Non-physician Health Care Practitioner Review Eligibility and Restrictions for Review

(a) Non-physician health care practitioners must be involved in the PSRO review of care provided by their peers. Continuing recruitment of reviewers of each type shall be performed to ensure a large and representative pool of eligible reviewers. PSROs shall involve these health care practitioners in the development of standards and criteria for their peers and, to the extent it is efficient and effective, have such practitioners perform the review where the care is provided by one type of practitioner (e.g., dentist, optometrist, podiatrist).

(b) Where State licensing laws govern a health profession, the PSRO shall, to the extent possible, use such duly licensed professionals to make determinations on appropriateness of the health care services provided by such health professionals. Where the total number of practitioners of a particular type is insufficient to assure adequate and/or objective review within the PSRO area, special review arrangements may be made with the approval of the Department.

(c) Physicians are to be involved in the review of decisions on the medical appropriateness of care ordered by a physician, but delivered by other health care practitioners. Peer health care practitioners shall be involved in the review of the quality of the services delivered by practitioners of their discipline.

(d) Hospital review PSROs shall not usually assign health care practitioners to review care in hospitals where they are employed or otherwise practice their profession unless the PSRO justifies the assignment in terms of a lack of sufficient alternate peer reviewers. This restriction does not apply to institutions operating in-house medical care review systems under a PSRO delegation.

(e) Self-review -- A health professional may not review health care services which were delivered to a patient which he provided directly, or for which he was directly or indirectly responsible.

(f) Financial interest -- Same for non-physician health care practitioners as specified in Section 520.04 (e) for physicians.

530 RELATIONSHIP OF PSRO WITH STATE PROFESSIONAL STANDARDS REVIEW COUNCIL

In a State where there are three or more conditionally designated PSROs, a State PSR Council will be established. Each conditional PSRO will designate one of its members to serve on the Council.

The PSRO will utilize the resources and capabilities of the State Council in accordance with the requirements outlined in Chapter XIV of the Manual. The PSRO will cooperate with the State Council in its efforts to coordinate activities and disseminate important information among the PSROs in the State. While the State Council has no direct authority over PSROs, each PSRO will work in conjunction with the State Council to facilitate communication and cooperative arrangements among the PSROs in the State.

The State Council has a legal responsibility to assist the Secretary in evaluating local PSROs. The State Council will be given specific instructions by the Department as to its role in such evaluation. Each PSRO will cooperate with the State Council in the manner required by these instructions. Additionally, from time to time, the State Council may make requests of the PSRO in response to specific directives from the Secretary.

The PSRO shall submit reports to the State Council in accordance with the reporting requirements outlined in Chapter XIV .f this Manual. Requests for funds and required progress reports will not pass through the State Council on their way to DHEW, but rather will be directed simultaneously to the State Council and DHEW.

540 USE OF ADVISORY GROUPS

In states where a State PSR Council has been established an individual PSRO may, at its discretion, formally relate to health care institutions, organizations, or health professional associates for advice or assistance in carrying out the duties and functions of a PSRO. Reimbursable arrangements shall be subject to Departmental approval.

The PSRO legislation requires that there be established an advisory group to a PSRO in States where no State Council has been established. Chapter XV of this Manual describes the membership, organization and functions of these advisory groups.

550 INTERNAL STRUCTURE

This section elaborates requirements for the PSRO governing body, officers, committees and administrative staff.

550.1 Governing Body

550.11 Duties and Responsibilities

The governing body shall be responsible for the overall policy and operations of the PSRO. The governing body shall have the authority to make final determinations on all the major policies, review considerations, budgetary matters and other significant activities related to the on-going operations of the PSRO. Meetings of the governing body should be frequent enough to assure adequate direction to the PSRO (generally at least bi-monthly during the first year of its existence and at least quarterly thereafter).

550.12 Number of Directors

The size of the governing body is left to the discretion of the PSRO. It should be of a size (1) to allow proper representation of physicians and, at the option of the PSRO, non-physicians and (2) to allow for efficient operation (generally from 5 to 21 members).

550.13 Composition of the Governing Body and Qualifications of Directors

(a) The governing body shall be composed primarily of physicians performing professional activities in the PSRO area and may include non-physicians from the designated PSRO area. Consumer representation on the governing body is encouraged. Governing body directors shall be elected by the membership.

(b) Physician directors shall at no time comprise less than 51% of the total number of directors of the governing body.

(c) No individual shall be a director of the governing body or hold office in the PSRO solely by virtue of the office of directorship which that person holds in another organization.

(d) The chairman of the governing body shall be elected by the

governing body, shall be a member of the body, and shall be a doctor of medicine or osteophaty performing professional activities in the designated area.

(e) An initial non-elected governing body may be established for purposes of incorporation. An election for directors of the governing body must be held within 120 days of the execution of an agreement with the Secretary for conditional designation as a PSRO.

550.14 Terms of Office

The term of office of each director shall be no longer than three years, and no director shall serve more than two consecutive, three-year terms. Terms of directors shall be staggered.

550.15 Compensation

Reimbursement shall be made to a director for expenses which are reimbursable under the terms of an agreement between the PSRO and the Secretary.

550.16 Meetings

All regular and special meetings of the governing body other than meetings relating to peer review decisions, appeals, and application of sanctions shall be open for observation to all members of the organization unless special notice is given.

550.17 Voting

If non-physicians are members of the governing body, the PSRO shall develop procedures to assure that only physicians may vote on issues relating solely to the physician practice of medicine and osteopathy.

550.18 Elections

(a) A process and procedure for elections of directors shall be developed and provided to all members on entry into each organization.

(b) Nominations for directors shall be solicited and accepted from any member of the organization.

(c) Elections shall be conducted by secret, written ballot.

(d) The election process shall include a nominations procedure, specified in the by-laws, which includes a standing nominating committee composed of members from various types of practice.

550.2 Executive Committee

The governing body may appoint an executive committee to act for the governing body in the interim between its regular meetings. The executive director shall serve as staff to this committee. Executive committee meetings are to be open to any governing body member and officer.

550.3 Executive Director

550.31 Appointment

The executive director of the organization, who normally shall be a full-time employee, shall be selected, employed and supervised by the governing body, which shall determine the terms of his/her employment.

550.32 Functions

The executive director shall carry out the purposes of the organization within the framework of the legal corporate requirements, Federal statute and regulations, organizational by-laws, and the general and specific assignments given by the governing body directly or through an executive committee. The executive director is responsible for the day-to-day supervision of the other employees of the organization.

550.4 Committees

550.41 Standing Committees

The PSRO may establish certain permanent committees to carry out day-to-day business. Possible permanent committees include:

(a) Continuing Education Committee -- To plan and carry out methods for informing and educating physicians about the conduct of peer review and PSRO review findings.

(b) Nominating Committee -- To solicit names of potential nominees and to nominate individuals for vacancies as directors or officers.

(c) Grievance Committee -- To receive and consider complaints on non-review related matters.

(d) Review Committee(s) -- (See Section 520.00, Health Care Review Activities)

(e) Health Care Guidelines Committee -- To develop or to stimulate development of and to review periodically health care criteria and standards for quality and effectiveness.

(f) Finance Committee -- To develop budgets and monitor the expenditure of funds.

(g) Advisory Group Nominating Committee (For those PSROs in States without State Councils) -- To solicit and review nominations for Advisory Group membership.

550.42 Study and Ad Hoc Committees

The governing body may from time to time authorize the creation, prescribe the term, and define the powers and duties of other study and ad hoc committees to carry out the duties and functions of the PSRO. Examples may be data, systems, and evaluation committees. Reimbursement for such committee activities will be made according to Departmental regulations and agreements.

550.43 Appointment of Committee Members and Chairpersons

(a) Except as otherwise specified, the governing body shall outline for each committee its purpose, charge, objectives, projects, relationship, staffing support, and term and numbers of members (if fixed).

(b) The appointment of committee members shall be approved by the governing body. Any member is eligible for appointment to a committee unless such committee membership is restricted by law or regulations.

(c) Committee chairperson(s) shall be appointed with the approval of the governing body, except in the case of an Advisory Group Nominating Committee which shall elect its chairperson. The term of the chairperson shall not exceed two years.

(d) No staff member of the organization shall serve as a voting member of any committee.

(e) The chairperson of the governing body shall be an ex-officio (non-voting) member of all committees except the Nominating Committee.

(f) The Executive Director and other administrative staff shall serve as staff to all committees.

550.44 Powers and Duties

The committees created shall have such powers and duties as are provided for by the organization through the governing body. Except in the case of the Executive Committee, Review Committee(s), and Nominating Committee, reports of the committees shall be advisory only.

550.45 Procedures

All committee meetings, except those of the executive committee or any committee meeting which deals with individual review decisions, appeals, or sanctions, shall be open to any PSRO member for observation.

550.5 Conflicts of Interest

550.51 Abstention from Discussion or Voting

No director or committee member shall participate or vote on any matter which would involve conflicts of interest.

550.52 Announcing Conflicts of Interest

Whenever a director or committee member has cause to believe that a matter to be voted upon would involve such person in a conflict or possible conflict of interest, such person shall announce the conflicts of interest and shall abstain from both participation and voting on such matter. The question of whether an actual conflict exists shall be decided by a majority vote of the directors or committee members present, excluding said director or committee member announcing the conflict or possible conflicts of interest and excluding any other directors or committee members present who have already been disqualified from discussing or voting on the issue because of their own similar conflicts of interests.

550.6 Records and Reports

550.61 Records of Meetings

Summaries of the proceedings of all regular and other meetings of the governing body, executive committee, general committees, and general membership shall be maintained and made available to the general membership and public except where such meetings deal with the decisions on review cases, sanctions or appeals.

550.62 Reports

PSROs shall be required to maintain and/or submit reports as required by the Secretary. Specific data requirements and the rights of the Secretary to data will be part of each conditional or operational agreement or contract. General areas of reporting are:

(a) Administrative reports -- Activities which have occurred or are planned.

(b) Financial reports -- Costs incurred and justification of costs.

(c) Aggregate review findings and related actions.

(d) Work plans -- Projected activities and projected time schedule to be submitted prior to the start of each phase and prior to negotiation or renegotiation of agreements and contracts.

(e) Evaluation data reports -- Data and information required for evaluation purposes.

EXHIBIT A

The model Articles of Incorporation and By-Laws as provided are presented only as examples of how the organizational requirements under Section 1152(6)(1)(A) for conditional designation can be incorporated into these documents. These models are based on the laws of the District of Columbia. Applicants are encouraged to consult an attorney familiar with the general corporation (non-profit) laws of the jurisdiction of the PSRO area.

EXHIBIT A

Model

Articles of Incorporation

of

Washington, D.C. PSRO

To:

We, the undersigned natural persons of the age of twenty-one years or more, acting as incorporators of a corporation, adopt the following Articles of Incorporation for such corporation pursuant to the District of Columbia Non-profit Corporation Act:

ARTICLE I

The name of the corporation is_____

ARTICLE II

The period of duration of the corporation is perpetual.

ARTICLE III

The purposes for which the corporation is organized are to operate exclusively for charitable, educational, scientific, and literary purposes, within the meaning of section 501(c)(3) of the Internal Revenue Code of 1954, as amended (or corresponding provision of any subsequent federal tax laws). Consistent therewith the corporation is authorized to assume responsibilities for the duties and responsibilities of a Professional Standards Review Organization as specified in Title XI, Part B of the Social Security Act and related regulations and guidelines promulgated by the Secretary of the United States Department of Health, Education and Welfare. The corporation, in addition to assuming the substantial responsibilities of a Professional Standards Review Organization, is authorized to engage in other related quality assurance activities.

EXHIBIT A
MODEL

ARTICLE IV

The membership of the corporation shall consist of all those qualified doctors of medicine and osteopathy specified below who voluntarily elect to join as members, and who agree to abide by the Charter documents of the Corporation, as evidenced by a document so stating.

Membership in the corporation shall be open on a continuing basis to any doctor of medicine or osteopathy who holds a current and unrestricted medical or osteopathic license from, or a license recognized by, the licensing authority in Washington, D.C. and who is performing professional activities within the Washington, D.C. area, even if said doctor is a member of PSRO's in other areas. An intern or resident is eligible for membership if he/she holds, as an individual, a current and unrestricted license to engage in the practice of medicine recognized by Washington, D.C. Physicians employed by the Federal government shall be eligible for membership in the PSRO if they are authorized to perform professional activities in Washington, D.C. and are associated with institutions performing review under the auspices of the PSRO or if a portion of their professional activities in the PSRO area is not performed in the course of their employment by the Federal government.

ARTICLE V

The affairs of the corporation shall be managed by its Board of Directors. The number of directors, their qualifications, and the manner of their selection shall be fixed in the bylaws, except that there shall be not less than three directors.

ARTICLE VI

In all events and under all circumstances, and notwithstanding merger, consolidation, reorganization, termination, dissolution, winding up of this corporation, voluntary or involuntary or by operation of law, or upon amendment of the Articles of Incorporation--

(a) The corporation shall not have or exercise any power or authority either expressly, by interpretation, or by operation of law, nor shall it directly or indirectly engage in any activity that would prevent it from qualifying (and continuing to qualify) as a corporation described in the Internal Revenue Code of 1954, as amended, section 501(c)(3).

(b) No part of the assets or net earnings of the corporation shall inure to the benefit of or be distributable to its incorporators, directors,

EXHIBIT A - MODEL

officers, or other private persons having a personal or private interest in the corporation, except that the corporation shall be authorized and empowered to pay reasonable compensation for services actually rendered and to make reimbursement in reasonable amounts for expenses actually incurred in carrying out the purposes set forth in Article III hereof.

(c) No substantial part of the activities of the corporation shall consist of the carrying on of propaganda, or of otherwise attempting, to influence legislation; nor shall the corporation in any manner or to any extent participate in, or intervene in (including the publishing or distributing of statements), any political campaign on behalf of any candidate for public office.

(d) Neither the whole, nor any part or portion, of the assets or net earnings of the corporation shall be used, nor shall the corporation ever be operated, for objects or purposes other than those set forth in Article III hereof.

(e) (1) The Corporation shall distribute its income for each taxable year at such time and in such manner as not to subject it to tax on undistributed income imposed by IRC section 4942; (2) the corporation shall not engage in any act of self-dealing as defined in IRC section 4941(d); (3) the corporation shall not retain any excess business holdings as defined in IRC section 4943(c); (4) the corporation shall not make any investments in such manner as to subject it to tax under IRC section 4944; and (5) the corporation shall not make any taxable expenditures that would subject it to tax under IRC section 4945(d).

(f) Upon dissolution of the corporation, all of its assets and property of every nature and description attributable to its status as a PSRO remaining after the payment of all liabilities and obligations of the corporation (but not including assets held by the corporation upon condition requiring return, transfer, or conveyance, which condition occurs by reason of the dissolution) shall be transferred to the Department of Health, Education, and Welfare, or to such other entity as the Secretary may direct, and which are then qualified for exemption from federal income taxes as organizations described in IRC section 501(c)(3).

ARTICLE VII

The address, including street and number, of the corporation's initial registered office in the District of Columbia is _____, Washington, D.C. 20007 and the name of the corporation's initial registered agent at such address is _____.

EXHIBIT A
MODEL

ARTICLE VIII

The number of directors constituting the initial Board of Directors is___ and the names and addresses, including street and number, of the persons who are to serve as the initial directors until the first annual meeting or until their successors be elected and qualified are:

NAME	ADDRESS

EXHIBIT A
MODEL

ARTICLE IX

The name and address, including street and number, of each incorporator of the corporation is:

NAME	ADDRESS

In witness whereof, we have hereunto set our hands and seals this day of , 1974.

_____

_____

_____

EXHIBIT A
MODEL

CITY OF WASHINGTON)
) SS
DISTRICT OF COLUMBIA)

I, , a Notary Public, hereby certify that on the day of , 1974 personally appeared before me , and who, being by me first duly sworn, declared that they signed the foregoing Articles of Incorporation of , as incorporators, and that the statements therein contained are true.

Notary Public

(Notarial seal)

My Commission Expires

EXHIBIT B

Model Bylaws for Washington, D.C. PSRO

ARTICLE I

Principal Office

The principal office of the Washington, D.C. PSRO (hereinafter called the "Corporation") shall be located in Washington, D.C., with such additional offices as may from time to time be established.

ARTICLE II

Members

Section 1. - Qualifications of Members

The membership of the Corporation shall consist of all those qualified doctors of medicine and osteopathy specified below who voluntarily elect to join as members, and who agree to abide by the charter documents of the Corporation, as evidenced by a document so stating.

Membership in the Corporation shall be open on a continuing basis to any doctor of medicine or osteopathy who holds a current and unrestricted medical or osteopathic license from, or a license recognized by, the licensing authority, in Washington, D.C., even if said doctor is a member of PSROs in other areas, and who is performing professional activities within the Washington, D.C. area. An intern or resident is eligible for membership if he/she holds, as an individual, a current and unrestricted license to engage in the practice of medicine recognized by Washington, D.C. Physicians employed by the Federal government shall be eligible for membership in the PSRO if they are authorized to perform professional activities in Washington, D.C., and are associated with institutions performing review under the auspices of the PSRO or if a portion of their professional activities in the PSRO area is not performed in the course of their employment for the Federal Government.

Section 2. - Rights and Privileges of Members

Any member shall be equally eligible for service as a Director or Officer of the Corporation, and for assignment to the Corporation's duties and functions, except where specific restrictions are provided by Title XI of the Social Security Act or any regulations pursuant thereto. A member may voluntarily elect to terminate membership at any time by serving written notice on the Secretary of the Corporation.

EXHIBIT B
MODEL

A member need only to continue to meet the Corporation's membership requirements as provided in the Articles and Bylaws to remain a member of the Corporation. No renewals of membership are required.

Non-payment of voluntary contributions shall not be a cause for suspension or termination of membership, nor for non-assignment to perform the duties and functions of the PSRO.

Section 3. - Meetings of Members

Meetings of members shall be held at the principal office of the Corporation or at such other place within or without the District of Columbia as may be designated from time to time by resolution of the Board of Directors.

Section 4. - Annual Meeting

The annual meeting of the members shall be held in the month of _____ of each year at a time and place to be set by the Board of Directors and such annual meeting shall be held for the purpose of electing directors and transacting such other business as may come before said meeting.

Section 5. - Special Meetings

Special meetings may be called by the Chairman of the Board of Directors, the Executive Director of the Corporation or by members holding not less than one-twentieth of the votes entitled to be cast at such meetings. Special meetings shall be held at the principal office of the Corporation or such other location in the District of Columbia as the Executive Director may determine at such time, not to exceed twenty (20) days after the Secretary of the Corporation has been notified of the call for a special meeting, as may be ordered by resolution of the Board of Directors, or, if the Board of Directors fails to so resolve within ten (10) days after the Secretary of the Corporation has been notified of the call, then at p.m. of the first Monday following the twentieth day after the Secretary of the Corporation has been so notified of the call for special meeting.

Section 6. - Notice of Meetings

Written or printed notice stating the place, day, and hour of any meetings and, in the case of special meeting, the purpose or purposes for which the meeting is called, shall be delivered to each member personally or by mail not less than ten (10) nor more than fifty (50) days prior to the date of such meeting.

EXHIBIT B
MODEL

Section 7. - Quorum

The presence in person of members holding _____% of the voting power of the Corporation, plus one (1), constitutes a quorum for the transaction of business. If, at any meeting of the members, there shall be less than a quorum present, those present may adjourn the meeting, without further notice, from time to time until a quorum shall be present.

Section 8. - Voting

(a) Each member is entitled to one vote on each matter submitted to a vote of the members. A majority of the votes cast at a meeting, duly called and at which a quorum is present, shall be sufficient to take or authorize action upon any matter which may properly come before the meeting.

(b) Nominations for Directors will be solicited and accepted from any member.

(c) Election of Directors will be conducted by secret, written ballot.

ARTICLE III

Board of Directors

Section 1. - Number and Responsibilities of Directors

(a) The governing body shall be composed of fifteen (15) directors.

(b) The Board of Directors shall be responsible for the overall policy and operation of the Corporation and shall have authority to make final determination on all major policies, review considerations, budgetary matters and other significant activities related to the on-going operations of the Corporation.

Section 2. - Qualifications of the Directors

(a) The Board of Directors shall be composed so as to include physicians performing professional activities in the Washington, D.C. area and may include non-physicians from the Washington, D.C. area.

EXHIBIT B
MODEL

(b) Physician directors shall at no time comprise less than 51% of the total number of directors.

(c) No individual shall be a director or hold office in the Corporation solely by virtue of the office or directorship which that person holds in another organization.

Section 3. - Election of Directors

Directors, other than those named in the Articles of Incorporation, shall be elected at the annual meeting as provided for in Article II, Section 4 hereof and shall hold office until their successors are elected or until their earlier death, resignation or removal. Directors named in the Articles of Incorporation shall hold office until the election of their successors, such election to be held within 120 days of the execution of an agreement between the Corporation and the Secretary of Health, Education, and Welfare for conditional designation of the Corporation as a PSRO.

Section 4. - Terms of Office of Directors

The term of office of each director shall be no longer than three (3) years and no director shall serve more than two consecutive, three-year terms. The directors shall be divided into three classes. The term of office of those of the first class to expire at the annual meeting next ensuing; of the second class one year thereafter; of the third class two years thereafter; and at each annual election held after such classification and election, directors shall be chosen for a full term of three years.

Section 5. - Meetings

(a) The annual meeting of the Board of Directors shall be held in the month of _____, unless otherwise specified by resolution of the Board. Additional regular meetings of the Board shall be held at least bi-monthly during the first year of the Corporation's existence and at least quarterly thereafter at such time and place as may be fixed by a resolution of the Board or upon ten (10) days written notice from the Chairman of the Board at such time and place as shall be set forth in such written notice.

(b) All regular and special meetings of the Board other than meetings relating to peer review decisions, appeals and application of sanctions shall be open for observation to all members of the Corporation unless special notice is given.

(c) Special meetings of the Board of Directors shall be held whenever called, in writing, by the Chairman, by a majority of the directors or by a majority of the Executive Committee (if there shall be an Executive Committee).

EXHIBIT B
MODEL

Section 6. - Waiver of Notice

Whenever any notice of any meeting of the Board of Directors is required to be given under provisions of law or under the provisions of the Articles of Incorporation or these Bylaws, a waiver thereof in writing, signed by the person or persons entitled to such notice and filed with the records of the meeting, whether before or after the holding thereof, shall be equivalent to the giving of such notice. Presence at any meeting without objection shall also constitute waiver of required notice.

Section 7. - Quorum and Voting

(a) At any meeting of the Board of Directors, a [majority] of the directors in office shall be necessary and sufficient to constitute a quorum for the transaction of all business. A [majority] of the votes cast at a meeting of the Board of Directors, duly called and at which a quorum is present, shall be sufficient to take or authorize action upon any matter which may properly come before the meeting, unless the concurrence of a greater proportion is required for such action by published administrative procedures issued by the Secretary of HEW or by other provisions of these Bylaws. If, at any meeting of the Board of Directors, there shall be less than a quorum present, a majority of those present may adjourn the meeting, without further notice, from time to time until a quorum shall be present.

(b) Non-physician members of the governing body shall be restricted from voting on issues relating to the physician practice of medicine and osteopathy as follows: [Insert here procedures developed by the PSRO.]

(c) Any action required or permitted to be taken at a meeting of the Board of Directors may be taken without a meeting if a consent in writing, setting forth such action, is signed by all of the directors, and such written consent is filed with the minutes of proceedings of the Board. Such consent shall have the same force and effect as a unanimous vote.

Section 8. - Resignation and Removal of Directors

Any director may resign at any time. Such resignation shall be made in writing to the Board of Directors and shall take effect at the time specified therein, or if no time be specified, at the time of its receipt by the Board. The acceptance of a resignation shall not be necessary to make it effective. [Insert here procedures developed by the PSRO for removal of directors].

EXHIBIT B
MODEL

Section 9. - Compensation and Reimbursement

Reimbursement shall be made to a director for expenses which are reimbursable under the terms of the agreement with the Secretary of HEW designating the Corporation a conditional PSRO or a PSRO.

ARTICLE IV

Committees

Section 1. - Executive Committees

(a) An Executive Committee, which would act in the name of and with full power of the Board of Directors during the intervals between meetings of the Board on matters requiring action by the directors, may be created by a majority vote of the directors then in office. Once created, the Executive Committee may be dissolved by a majority vote of the directors and officers of the Corporation appointed by a majority of the Board, provided, however, that such Executive Committee shall not be composed of less than two (2) directors. The Executive Director of the Corporation shall serve as staff to the Executive Committee.

(b) Executive Committee meetings shall be open to any Board member and officer.

Section 2. - Other Committees

The Board of Directors shall create a permanent Grievance Committee to receive and review complaints on non-review related matters, including admission to membership and may create and appoint one or more other permanent and ad hoc committees, which shall serve at the pleasure of the Board.

The Board of Directors shall specify for each such committee, its purpose, charge, objectives, projects, relationship, staffing support and term and numbers of members (if fixed). Any member of the Corporation is eligible for appointment to a committee unless its membership is restricted by law or regulations of the Secretary of HEW. The Board shall appoint all committee chairpersons. Chairpersons shall be appointed to a term of no more than two years.

No member of the staff of the Corporation shall serve as a voting member of any committee. The Executive Director shall serve as a staff member of all committees except the Nominating Committee.

EXHIBIT B
MODEL

Section 3. - Powers of Committees

All committees created by the Board of Directors shall have only such powers and duties as are provided for by the Board. Reports of Committees should be advisory only except in the cases of the Executive Committee, Review Committee(s), and Nominating Committee, if such committees are appointed.

Each committee created pursuant to this Article may make and operate by its own rules or procedure, unless stated otherwise by a resolution of the Board. For each such committee, a majority of the members present of such committee shall be necessary for the adoption of any resolution. All committee meetings, except those of the Executive Committee and any committee which deals with individual review decisions, appeals, or sanctions, shall be open to any member of the Corporation for observation.

ARTICLE V

Officers

Section 1. - Specification of Officers

The officers of the Corporation shall be a Chairman of the Board of Directors, a Vice-chairman of the Board of Directors, an Executive Director, a President, one or more Vice-Presidents, a Secretary, a Treasurer and such other officers as the Board of Directors may from time to time designate. Two or more offices, except those of President and Secretary, may be held by the same person, but no officer shall execute, acknowledge, or verify any instrument in more than one capacity.

Section 2. - Election and Term of Office

(a) The Chairman and Vice-chairman of the Board of Directors shall be elected by a majority of the directors then in office from among their own members and shall be doctors of medicine or osteopathy performing professional activities in the Washington, D.C. area. The Chairman and Vice-chairman shall serve for a term of one (1) year, and thereafter until his successor(s) shall have been chosen and qualified or until his earlier death, resignation or removal.

EXHIBIT B
MODEL

(b) The Executive Director of the Corporation shall be a full-time employee who is selected, employed, and supervised by the Board of Directors, which shall determine the terms of his/her employment. The Executive Director need not be a member of the Board of Directors.

(c) The President, Vice-President, Secretary, Treasurer, and other officers designated by the Board of Directors, shall be elected by a majority of the directors then in office from among their own members and each shall serve for a term of one (1) year, and thereafter until his successor(s) shall have been chosen and qualified or until his earlier death, resignation or removal.

(d) Re-election - The officers of the Corporation may be re-elected to as many terms of office as the Board of Directors may deem advisable, so long as re-election does not conflict with Bylaw limits as Directors.

Section 3. - Duties and Powers

(a) Chairman - The Chairman of the Board of Directors shall preside at all meetings of the Board of Directors and of the Executive Committee (if there shall be an Executive Committee). (The Chairman shall be an ex-officio member of all committees of the Board of Directors).

(b) Vice-Chairman - The Vice-Chairman of the Board of Directors shall perform the duties of the Chairman in the latter's absence or disability. (The Vice-Chairman shall be an ex-officio member of all committees of the Board of Directors).

(c) Executive Director - The Executive Director shall carry out the purposes of the Corporation within the framework of the legal corporate requirements, Federal statute and regulation, the Bylaws of the Corporation, and the general and specific assignments given by the Board of Directors directly or through the Executive Committee. The Executive Director is responsible for the day-to-day supervision of the other employees of the Corporation.

(d) President - The President shall be the Chief Executive Officer of the Corporation. It shall be the duty of the President to perform such duties and to have such powers as the Board of Directors may from time to time prescribe.

(e) Vice-President - It shall be the duty of the Vice-President or, if there be more than one, the First Vice-President, to perform the duties and exercise the powers of the President in the absence or disability of the

EXHIBIT B
MODEL

President, and to perform such other duties and have such other powers as the Board or the President may from time to time prescribe.

(f) Secretary of the Corporation - It shall be the duty of the Secretary of the Corporation to attend and keep the minutes of all meetings of the Board of Directors and the Executive Committee (if there is an Executive Committee), to issue proper notices of all such meetings, to perform all other duties which are incident to the office of Secretary, and to perform such other duties and have such other powers as the Board or the President may from time to time prescribe.

(g) Treasurer - Working under the guidelines and policies established by the Board of Directors, it shall be the duty of the Treasurer to collect all monies due the Corporation, to have custody of the funds of the Corporation, to place such funds in such depositories as he sees fit, to approve payment of all bills against the Corporation, and to submit to the Board of Directors a report of the financial condition of the Corporation, including its receipts and disbursements. The Treasurer shall carry out all other duties which are incident to the office of Treasurer, and shall perform such other duties and have such other powers as the Board may from time to time prescribe.

ARTICLE VI

Seal

The Corporation may have a Seal of such design as the Board of Directors may adopt. If so adopted, the custody of the Seal shall be with the Secretary and he shall have the authority to affix the Seal to all instruments where its use is required.

ARTICLE VII

Fiscal Year

The fiscal year of the Corporation shall be determined by resolution of the Board of Directors.

EXHIBIT B
MODEL

ARTICLE VIII

Books and Records

There shall be kept at the principal office of the Corporation correct books of account of all the business and transactions of the Corporation. The Secretary of HEW or his authorized representative shall have complete access to the Corporation's books and records at all times.

ARTICLE IX

Annual Audit

An audit by independent certified public accountants selected by the Board of Directors shall be made annually of the books and accounting records of the Corporation.

ARTICLE X

Liability and Indemnification

In the absence of fraud or bad faith, the Directors of the Corporation shall not be personally liable for its debts, obligations or liabilities; and the Corporation shall indemnify any director or officer or former director or officer of the Corporation, or any person who may have served at its request as a director or officer of another corporation, whether for profit or not for profit, against expenses actually and necessarily incurred by him in connection with the defense of any action, suit, or proceeding in which he is made party by reason of being or having been such director or officer, except in relation to matters as to which he shall be adjudged in such action, suit, or proceedings to be liable for negligence or misconduct in the performance of a duty. Such indemnification shall not be deemed exclusive of any other rights to which such director or officer may be entitled, under any bylaw, agreement, vote of a duly authorized Board, or shareholders, members, or otherwise. Anything contained in this Article to the contrary notwithstanding, the Corporation shall in no event indemnify any person otherwise entitled to such indemnification, since such indemnification would constitute "self-dealing" as defined in IRS Section 4941, or corresponding provisions of any subsequent tax laws.

EXHIBIT B
MODEL

ARTICLE XI

Amendments of the Bylaws

These Bylaws may be amended, repealed, or altered, in whole or in part, and additional Bylaws may be adopted, by a majority vote of the directors then in office.

CHAPTER VI: PSRO SELECTION AND AGREEMENT PROCESS

Chapter VI

APPLICATION AND CONTRACT PROCESS FOR PLANNING PSRO CONTRACTS, CONDITIONAL PSRO CONTRACTS AND STATEWIDE PSRO SUPPORT CENTER CONTRACTS

Chapter VI,

APPLICATION AND CONTRACT PROCESS FOR PLANNING PSRO CONTRACTS, CONDITIONAL PSRO CONTRACTS AND STATEWIDE PSRO SUPPORT CENTER CONTRACTS

600 GENERAL INFORMATION

600.1 Introduction

This chapter provides information on the processes by which the Department of Health, Education, and Welfare will furnish financial support to (1) PSRO Planning Organizations, (2) Conditional PSROs, and (3) Statewide PSRO Support Centers. As appropriate, this chapter makes cross reference to Chapters III, IV, and V of the PSRO Manual, which respectively describe in detail the nature and function of PSRO Planning Organizations, Conditional PSROs, and Statewide PSRO Support Centers.

600.2 Definitions

PSRO Planning Organizations. Contracts will be awarded to organizations which demonstrate the potential to qualify for designation as a Conditional PSRO. The financial assistance will permit such organizations to satisfy the organizational and formal plan requirements that are prerequisites for conditional designation.

Conditional PSRO. Organizations which determine that they are immediately eligible for Conditional PSRO designation may submit a proposal directly for a Conditional PSRO contract. Contracts will thus be awarded to organizations that are prepared to assume PSRO medical care review responsibilities on a conditional basis.

Statewide PSRO Support Centers. Qualified organizations will be awarded contracts to provide assistance in a variety of administrative, organizational and professional matters to newly formed Planning and Conditional PSROs, and subsequently to Operational PSROs and State PSRO Councils.

In the process of requesting organizations to submit proposals for the above three categories, an announcement was published in the Commerce Business Daily, and official Requests for Proposals (RFPs) were sent to qualified organizations. Copies of these documents are contained in Chapters III, IV, and V of this Manual.

600.3 Agreements

During the current Federal fiscal year (1974), all PSRO financing is being provided under contract. It is anticipated that in fiscal year 1975 and thereafter, the Department will enter into agreements, rather than contracts, with Conditional PSROs. As Conditional PSROs become qualified to assume full Operational PSRO status, the agreement mechanism of support will also be employed.

The agreement permits the Department more flexibility and latitude in responding to unique features of the PSRO program than does strict adherence to the standard Federal Procurement System. As the Department completes policies and procedures concerning PSRO agreements, they will be incorporated in this Manual.

600.4 Notification and Polling

In the case of Conditional PSROs, the PSRO legislation provides certain notification and polling procedures to assure that potential Conditional PSROs represent physicians in the particular PSRO geographic area.

The notification process, and, if necessary, polling procedures must therefore be completed in advance of final contract arrangements between the Department and the proposing organization.

A more detailed description of the notification and polling procedures is contained in Section 606 of this chapter.

Notification and polling does not apply to Planning PSRO contracts or to Statewide PSRO Support Center contracts.

602 THE APPLICATION AND CONTRACT REVIEW PROCESS FOR PLANNING AND CONDITIONAL PSRO AND STATEWIDE PSRO SUPPORT CENTER CONTRACTS IN FISCAL YEAR 74.

This section of the Manual describes the application and contract process in fiscal year 74. Planning and Conditional PSRO proposals and Statewide PSRO Support Center proposals will also be requested by DHEW in fiscal year 75 and after. As application and contract/agreement process policies and procedures for fiscal year 75 are finalized, they will be incorporated in this Manual.

602.1 How to Apply

Notice of the availability of Requests for Proposals (RFPs) for Planning and Conditional PSRO contracts was published in Commerce Business Daily (CBD). The original notices appeared in the Commerce Business Daily on March 4, 1974 and corrected notices appeared in the March 8, 1974 issue. A second correction notice appeared for Planning PSRO contracts to announce that the deadline for submission of proposals for Planning contracts had been changed from April 15, 1974 to April 30, 1974. (The CBD notices regarding Planning PSRO contracts appear in Chapter IV and the CBD notices regarding Conditional PSRO contracts appear in Chapter V of this Manual.)

Notice of the availability of RFPs for Statewide PSRO Support Center contracts was published in the Commerce Business Daily on March 8, 1974. (This CBD notice appears in Chapter III of this Manual.)

The CBD notices briefly describe the three types of contracts and general eligibility requirements. Organizations meeting the general eligibility requirements were informed that they could request an RFP.

602.2 Where to Apply

As the Commerce Business Daily notices indicated, a copy of the RFPs can be obtained by writing to:

Health Services Administration
Procurement Branch, Room 16A-22
5600 Fishers Lane
Rockville, Maryland 20852
Attn: Contraction Officer

An organization is to request the RFP by number and, for Planning and Conditional PSRO RFPs, the organization is to indicate the PSRO area its proposal would be designed to service. The appropriate RFP numbers are as follows:

A. The PSRO Planning RFP: HSA 105-BQA-25(4) AEI
(Copy is included in Chapter IV of the Manual).

B. The Conditional PSRO RFP: HSA 105-BQA-26(4) AEI
(Copy is included in Chapter V).

C. The Statewide PSRO Support Center RFP: HSA 105-BQA-29(4) RAL
(Copy included in Chapter)

602.3 Submission of Proposals

602.31 Final Date for Receipt of Proposals for Consideration for an Award During Fiscal Year 74

Closing dates for receipt of proposals for consideration during fiscal year 74 are as follows:

A. Planning PSRO contract proposals - April 30, 1974.

B. Conditional PSRO contract proposals - April 30, 1974

C. Statewide PSRO Support Center contract proposals - April 30, 1974.

602.32 Mailing

A. Five copies of the proposal shall be sent to the address mentioned in section 602.2 above.

B. Three copies of the proposal are to be simultaneously sent to the appropriate DHEW Regional Office as mentioned in an attachment of the RFPs. A list of DHEW Regional Office PSRO focal points is also contained in Appendix A of this Chapter.

602.4 Contract Proposal Review, Negotiation and Award

A diagram of this process is contained in Appendix B of this Chapter. The dates in Appendix B and subsequent parts of this section are outside points for accomplishing the various phases of contract proposal review, negotiation and award process. It is expected that many proposals will be processed within a shorter period.

602.41 Contract Proposal Review Process

Responsibility for managing the contract proposal review process, as well as negotiation and award process resides with the Department of Health, Education and Welfare. The contract proposal review process is essentially a two part process: a technical review and a business review. The technical review focuses upon the offeror's understanding of the scope of work, while the business review is primarily concerned with the cost aspects of the proposals. Chapters III, IV and V of the manual respectively include a description of the criteria for evaluation of Statewide PSRO Support Center proposals, PSRO planning proposals and Conditional PSRO proposals.

See section 604ff of this Chapter for a description of State and local government review procedures and their applicability to Conditional PSRO contracts.

It is expected that by May 20, 1974 all proposal reviews will have been completed and contract negotiations begun for fiscal year 74 projects.

602.42 Contract Negotiation and Award

Contract negotiations are to be completed by June 20, 1974 and awards made as soon as possible thereafter.

For Conditional Designation PSRO contracts, there is an additional step which must take place between completion of negotiations and award of the contract. Under section 1152(f) of the Act, when the Secretary intends to enter into a Conditional PSRO designation contract with an organization, he must notify the doctors of medicine or osteopathy in the PSRO area of his intention. If more then 10 percentum of the doctors object on the ground that the organization is not representative of doctors in the area, the Secretary must conduct a poll of the doctors in the area to determine whether or not the organization is representative. If more than 50 percentum of the doctors responding to the poll object, the Secretary may not enter into the proposed contract. (See section 606ff for greater detail on the notification and polling process.)

If it is not possible to complete a contract award until after the end of fiscal year 74 (6/30/74), the organization will not need to submit a new proposal.

All organizations submitting proposals for Planning and Conditional PSRO contracts and Statewide PSRO Support Center contracts will be notified in writing of the Secretary's decision regarding their proposal.

604 STATE AND LOCAL GOVERNMENT REVIEW PROCEDURES

604.1 General Information

In order to further the objectives of the Intergovernmental Cooperation Act of 1968 for the encouragement of coordination of Federal or federally assisted projects and programs with State, area-wide, and local planning for orderly growth and development, the procedures detailed in Part I of the Office of Management and Budget Circular A-95 apply to any organizations intending to submit a proposal for Conditional or final operational designation as a PSRO.

Organizations submitting a proposal during fiscal year 74 will not be required to follow the steps set forth in section 604.2ff prior to the submission of a proposal. However, during the first six months of the contract period the organization is expected to consult with the State and develop for DHEW review any appropriate modifications to the approved contract.

For organizations applying for consideration after fiscal year 74, (6/30/74), Federal government review of proposals will not begin until the steps in section 604.2ff below have been completed.

The State and local review process generally takes a minimum of 60 days to complete.

604.2. Procedures

(Appendix C of this Chapter contains a flow chart of the State and local government project notification and review process.)

604.21 Notification

The State or areawide planning clearinghouse in the jurisdiction where the project is to be located is to be notified on the intent to submit a proposal for Conditional or final designation. Notification will include a summary description of the proposal and will include the following information, as appropriate and available.

A. Identification of the proposing organization.

B. Geographic jurisdiction for the program. A map should be provided, if appropriate.

C. A brief description of the program by type, purpose, general size or scale, estimated cost, beneficiaries, or other characteristics which will enable the clearinghouse to identify agencies of State or local government having plans, programs, or projects that might be affected by the proposed program.

D. The general program title and number and agency under which assistance will be sought as indicated in Attachment D of the latest Catalogue of Federal Domestic Assistance, which is issued annually in the spring and is updated periodically during the year.

E. The estimated date the organization expects to formally file a proposal.

Many clearinghouses have developed notification forms and instructions. Proposing organizations are urged to contact their clearinghouse for such information in order to expedite the clearinghouse review. In order to assure maximum time for effective coordination and so as not to delay the timely submission of the completed application to the funding agency, notifications containing the preliminary information indicated above should be sent at the earliest feasible time.

604.22 Consultation and Review

After receipt of a project notification State and areawide clearinghouses have up to 30 days in which to inform State agencies and local or regional governments or agencies that may be affected by the proposed project and arrange, as may be necessary, to consult with the applicant. During this period and during the period in which the proposal is being completed, the clearinghouse may work with the proposing organization in the resolution of any problems raised by the proposed project.

Clearinghouses may have, if necessary, an additional 30 days to review the completed proposal and to transmit to the proposing organization any comments or recommendations the clearinghouse (or others) may have. Written comments submitted to a clearinghouse by other jurisdictions, agencies, or parties will be included as attachments to the comments of the clearinghouse when they are at variance with the clearinghouse comments. Others from whom comments were solicited should be listed.

Proposing organizations will include with the completed proposals as submitted to the Federal Agency any comments and recommendations made by or through clearinghouses, along with a statement that such comments have been considered prior to submission of the proposal or that the above described procedures have been followed and that no comments or recommendations have been received.

604.23 Subject Matter of Comments and Recommendations

Comments or recommendations may include, but need not be limited to, information about the extent to which the program/project:

A. Duplicates, runs counter, to, or needs to be coordinated with other projects or activities being carried out in or affecting the area;

B. Might be revised to increase its effectiveness or efficiency; or

C. Contributes to the achievement of State, areawide, and local objectives and priorities relating to natural and human resources and economic and community development as specified in section 401 of the Intergovernmental Cooperation Act of 1968.

606 NOTIFICATION AND POLLING

Section 1152(f) of the Social Security Act provides that, in the case of contracts and agreements entered into prior to January 1, 1976, under Part B of Title XI of the Social Security Act under which any organization is designated by the Secretary of Health, Education and Welfare as the Professional Standards Review Organization for any area, the Secretary shall, prior to entering into such contract or agreement, inform the doctors of medicine or osteopathy who are in active practice in such area of his intention. If within a reasonable period of time following the service of such notice, more than 10 percentum of such doctors object to the Secretary's entering into the proposed contract or agreement with such organization on the ground that the organization is not representative of doctors in the area, the Secretary shall conduct a poll. If no, or fewer objections are received, the Secretary, by law, may conclude his contract or agreement with the organization.

In such instances where a poll is required, the Secretary shall conduct a poll of such doctors in the area to determine whether or not the organization is representative of such doctors in the area. If more than 50 percentum of the doctors responding to the poll indicate that the organization is not representative of such doctors in the area, the Secretary may not enter into the intended contract or agreement. Otherwise, the Secretary may conclude the contract or agreement at this point.

APPENDIX A

PSRO FOCAL POINTS IN THE HEW REGIONAL OFFICES

Region I Maine, Vermont, New Hampshire, Massachusetts, Connecticut, and Rhode Island

William Beck, Ph.D.
John F. Kennedy Federal Building
Government Center - Room 1400
Boston, Massachusetts 02203
(617) 223-6863

Region II New York, New Jersey, Puerto Rico, and Virgin Islands

Lawrence Clare, M.D.
Federal Building
26 Federal Plaza
New York, New York 10007
(212) 264-4490

Region III Pennsylvania, Maryland, Delaware, Virginia, West Virginia, and District of Columbia

Clyde Couchman
Post Office Box 13716
Philadelphia, Pennsylvania 19101
(215) 597-6670

Region IV Alabama, Georgia, Mississippi, South Carolina, North Carolina, Tennessee, Kentucky, and Florida

Charles Coker, D.D.S.
Peachtree-Seventh Building
50 Seventh Street, N.E.
Atlanta, Georgia 30323
(404) 526-3342

PSRO FOCAL POINTS IN THE HEW REGIONAL OFFICES

Continued

Region V Illinois, Indiana, Ohio, Michigan, Wisconsin, and Minnesota

Robert Goodnow
300 South Wacker Drive
Chicago, Illinois 60607
(312) 353-1385

Region VI Louisiana, Arkansas, Oklahoma, Texas, and New Mexico

Kenneth Schneider, M.D.
1114 Commerce Street
Dallas, Texas 75202
(214) 749-7477

Region VII Missouri, Iowa, Kansas, and Nebraska

Kenneth Mayfield
Federal Office Building
601 East 12th Street
Kansas City, Missouri 64106
(816) 374-5103

Region VIII Colorado, Utah, Wyoming, South Dakota, North Dakota, and Montana

Leonard Hellman, M.D.
Federal Office Building
19th and Stout Streets
Denver, Colorado 80202
(303) 837-3172

Region IX California, Nevada, Arizona, Guam, Hawaii, and Samoa

Robert Harper
Federal Office Building
50 Fulton Street
San Francisco, California 94102
(415) 556-3100

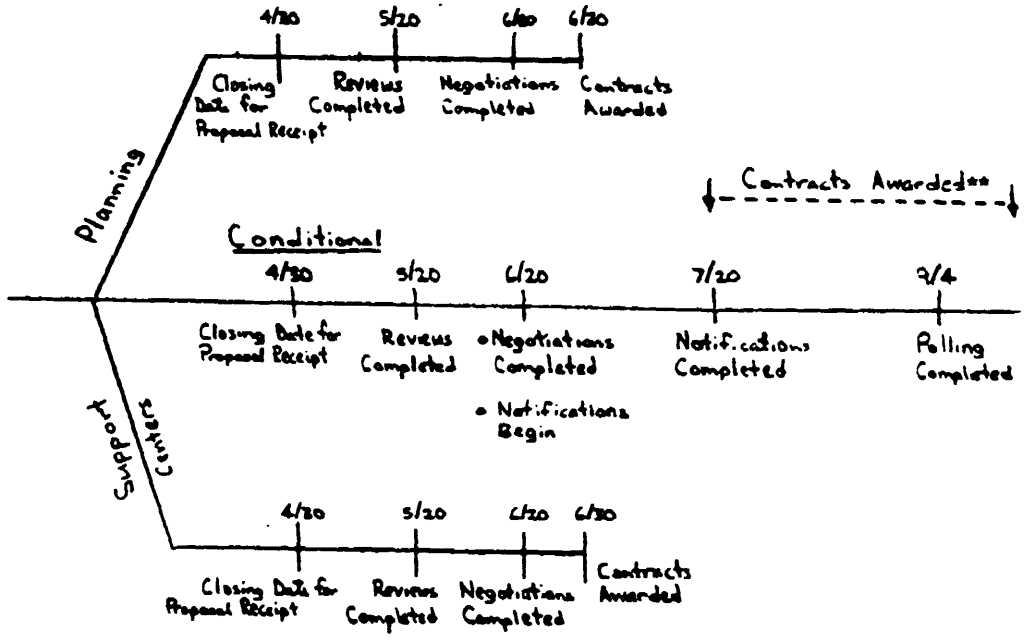
PSRO FOCAL POINTS IN THE HEW REGIONAL OFFICES

Continued

Region X Washington, Oregon, Idaho, and Alaska

Richard Marquardt
1321 Second Avenue
Seattle, Washington 98101
(206) 442-0432

CRITICAL DATES IN PSRO CONTRACTING PROCESS



** Whether an award is made and its actual date is dependent upon the outcomes of the notification and polling processes.

The dates on this chart are the outside points for accomplishing the identified tasks.

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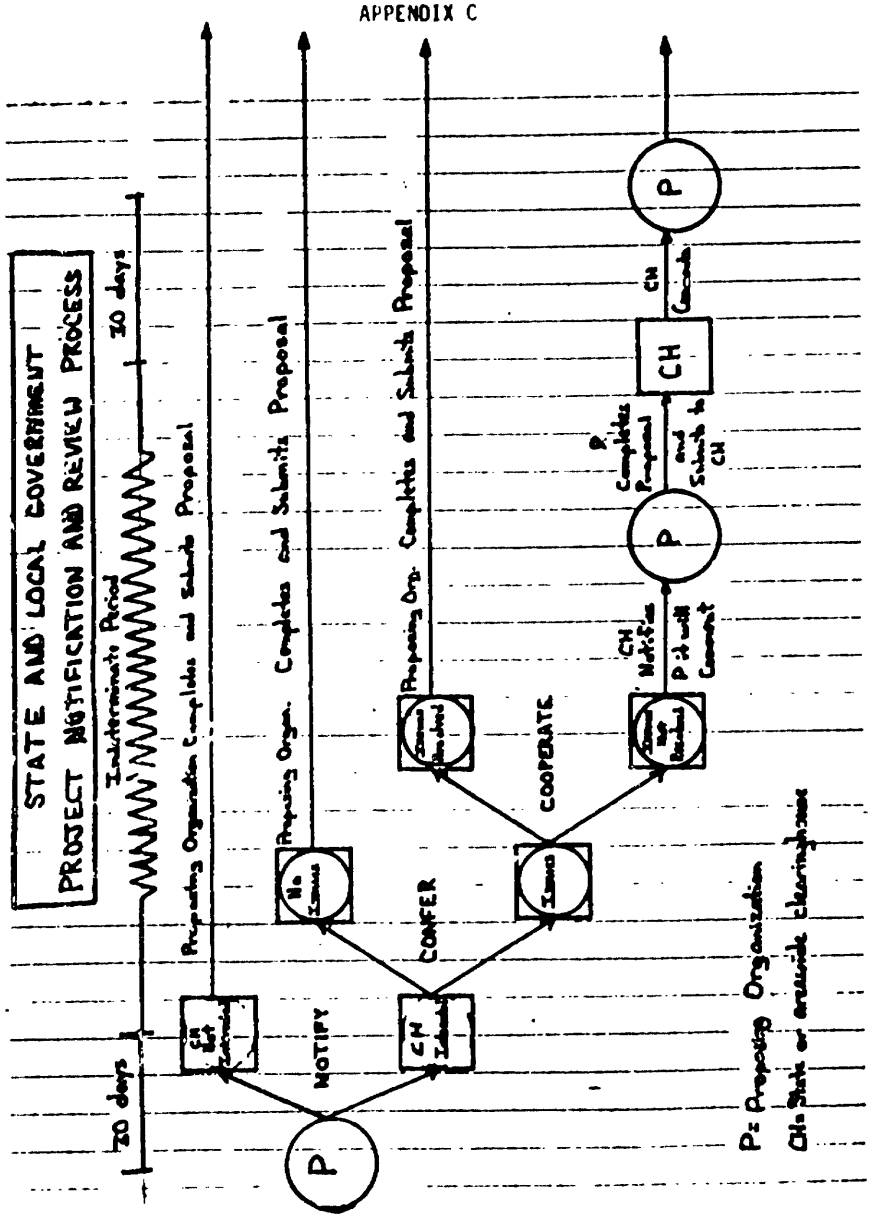
APPENDIX C


STATE AND LOCAL GOVERNMENT
PROJECT NOTIFICATION AND REVIEW PROCESS
Indeterminate Period
30 days
30 days
Preparing Organization Completes and Submits Proposal
Preparing Organ. Completes and Submits Proposal
Preparing Org. Completes and Submits Proposal
P
CH Receives
CH
P Completes Proposal and Submits to CH
P
CH Notifies P it will Comment
COOPERATE
CONFER
NOTIFY
P
P= Preparing Organization
CH= State or areawide clearinghouse

CHAPTER VII: OPERATIONAL RESPONSIBILITIES OF PSRO'S

Chapter VII

PSRO HEALTH CARE REVIEW RESPONSIBILITIES

PSRO HEALTH CARE REVIEW RESPONSIBILITIES

700 INTRODUCTION

Professional Standards Review Organizations will review the health care provided to patients under the Medicare, Medicaid and Maternal and Child Health programs and make judgements on the medical necessity and quality of the care. In addition, PSROs will determine whether care is proposed to be provided or has been provided at a level of care which is most economical, consistent with the patient's medical care needs. Specifically:

700.1 The PSRO is required, over time to review the care provided in health care institutions which participate in the Medicare, Medicaid, and Maternal and Child Health programs. This includes care provided in short-stay general hospitals, mental health institutions, tuberculosis hospitals, skilled nursing facilities, and intermediate care facilities.

700.2 The PSRO may review non-institutional care if it requests to do so and if the Department approves its request.

700.3 Initially, the PSRO should, at a minimum, establish a system for review of care provided to in-patients in short-stay general hospitals and develop a phased plan for the performance of review in long-term care settings. If it demonstrates capability in the review of in-patient short-stay general hospital and long-term care, the PSRO may develop review systems for care provided in other types of institutions and for non-institutional care. PSROs may request authority to perform review of ambulatory care provided they are able to meet review responsibilities in short-stay general hospitals. The Department will, in the near future, issue guidelines related to review in long-term care settings and criteria for the approval of applications requesting authority to perform review of non-institutional care.

701 THE PSRO HOSPITAL REVIEW SYSTEM

Professional Standards Review Organizations are responsible for developing and operating a quality assurance system based on peer review and continuing education.

This Chapter describes the requirements of this system for hospital review. The PSRO hospital review system is an integrated one based on three major review mechanisms. These are (a) concurrent admission certification and continued care review, (b) medical care evaluation studies and (c) analysis of hospital, practitioner, and patient profiles.

The components of the PSRO review system are interrelated. Together they result in a comprehensive quality assurance system that will improve quality, assure

appropriate utilization of health care services and provide ongoing feedback about the effectiveness of the entire system.

Within each designated geographic area, PSROs will implement this review system gradually depending on the size of the area, the number of hospitals and physicians involved and the sophistication of existing review programs. Once in place, the PSRO assumes full responsibility for assuring the quality, necessity and appropriateness of services provided under the Medicare, Medicaid and Maternal and Child Health programs, and replaces existing third party payment review mechanisms.

The components of the review system are interdependent yet each is designed to achieve a specific objective. The purpose of the concurrent review mechanism is to assure (a) the necessity of hospital admissions, (b) the appropriateness of hospital stays and (c) the effectiveness of discharge planning. The concurrent admission certification and continued stay review component removes the need for retrospective claims review.

The purpose of medical care evaluation studies is to improve quality through an organized and systematic process designed to (a) identify deficiencies in the quality of health care and in the organization, and administration of its delivery, (b) correct such deficiencies through education and administrative change and, (c) periodically reassess performance to assure that improvements have been maintained.

Medical care evaluation studies provide a means to determine the effectiveness of the concurrent review component and to identify areas where concurrent review should be instituted, intensified or is no longer required. They also assist in validating criteria, norms, and standards or provide evidence helpful in their revision.

The purpose of profile analysis is to (a) monitor the effectiveness of the other components of the PSRO review system and (b) provide indications where they might best be directed on a priority basis. Profile analysis also contributes to the overall evaluation of the PSRO program.

For each of the components in the PSRO review system, norms, criteria and standards are used to assist in making the review more objective and in screening from a number of cases those requiring more in-depth review. The criteria and standards which are used should be based upon the medical literature or best judgments available and upon experience with their use. Those criteria and standards used in medical care evaluation studies will generally be most well conceived and therefore, a subset of such criteria and standards should be used in the PSRO's admission certification and continued stay review programs.

The development of criteria is a fundamental PSRO activity that cuts across all components of the PSRO review system and involves the PSRO physicians in the

difficult task of defining the critical required elements of quality care. While criteria development integrates the three major PSRO review mechanisms, the components are mutually dependent in other ways as well. Profile analysis, for example, provides a mechanism to judge the effectiveness of a PSRO's or hospital's review program by comparing similar data over time. In addition, by distinguishing between normal and consistently aberrant practice patterns, profile analysis allows the PSRO or hospital to modify their admission certification and continued stay review programs to focus on defined problem situations. The concurrent review component, itself, frequently identifies potential problems with health care administration and delivery. These can be topics for more detailed medical care evaluation studies. Through the performance of quality studies and the analysis of profiles, PSROs will be able to determine those areas of practice that would benefit most from ongoing intensive concurrent review. In this way they will be able to devote their review resources to priority areas while simultaneously monitoring the effectiveness of the entire system. Thus the PSRO review system is comprehensive in that it simultaneously pursues the assessment and assurance of quality across a spectrum of disease entities, service and service delivery problems while also operating an ongoing mechanism to assure appropriate utilization of services.

The PSRO review system will be maintained and operated cooperatively by the hospitals in the area and the PSRO. Hospital medical staffs who participate in activities of the PSRO and have the capability and willingness to carry out PSRO review responsibilities will assume such responsibilities provided they continue to perform effectively.

Once the PSRO review system is established, the responsibilities currently held by Medicare contractors and Medicaid State agencies with respect to determination of medical necessity and quality will be relinquished to the PSRO. Medicare and Medicaid through their fiscal agents will continue to retain responsibility for determination of eligibility, definition of coverage, and determination of the appropriateness of charges. PSROs however, will assume full responsibility for all decisions having to do with quality, appropriateness and necessity of services. When a PSRO is carrying out its review responsibilities there will be no retroactive review potentially leading to the denial of payment. The concurrent and quality study system described in this Chapter will replace all current programs which examine necessity and appropriateness of services on a retrospective prepayment basis.

When a conditional PSRO is operating a comprehensive review system to the satisfaction of the Secretary he will waive all existing review requirements in favor of the PSRO system and designate the PSRO as a fully operational organization. Re-institution of other review requirements would only be directed if the PSRO were not performing effectively.

As noted above the review system described in this Chapter requires establishment and maintenance of several review mechanisms. There is considerable

flexibility as to the scope, extent, location and conduct of the review procedures, but the mechanisms themselves are required. Alternative approaches developed by applicant PSROs will be reviewed and may be found acceptable provided they have the potential to result in the establishment and operation of an equally or more effective review system than that outlined in this manual for assuring that care provided is necessary, appropriate and of a quality which meets acceptable professional standards. Such alternate approaches might include mixtures of the requirements contained in this Chapter with such approaches as the screening of claims on a retrospective basis using PSRO developed norms, criteria and standards with referral of aberrant claims to the PSRO or hospital for peer review. If such approaches are to be proposed, it is preferrable that they not be relied upon for purposes of prepayment review with the potential of retroactive denial. Instead, they should be used to direct concurrent review efforts that can impact services prior to or at the time they are provided.

702 RESPONSIBILITY OF A PSRO FOR ITS REVIEW SYSTEM

When an organization is designated a conditional PSRO it assumes responsibility for all aspects of the planning, organization, implementation, and on-going operation of the review which it is authorized to perform. It exercises this responsibility within the guidelines and regulations issued by the Department. It may delegate certain of its functions to other individuals or groups but, when this occurs, the PSRO retains responsibility to assure the effective performance of these individuals or groups. This is exemplified by the following:

702.1 As discussed above, a PSRO is responsible, in its initial stages, for the performance of admission certification, continued stay review and medical care evaluation studies of in-patient short-stay hospital care. It will delegate such review to hospitals which the PSRO finds are capable of and willing to perform such review and which submit a plan for review which is acceptable to the PSRO. When such delegation occurs, the PSRO continues to be responsible for assuring that the review performed by the hospital is effective. Thus, the PSRO will monitor and periodically evaluate the hospital's performance in a manner consistent with PSRO program criteria and guidelines. If the hospital fails to perform effectively the PSRO would withdraw the delegation and conduct review in another manner.

702.2 In each of its review activities the PSRO will use norms, criteria, and standards which are useful in identifying possible instances of misutilization of health care services or of the delivery of care of substandard quality. The PSRO is responsible for the development and on-going modification of the criteria and standards and the selection of the norms to be used in its area. While PSROs may structure themselves in many ways to perform these duties, the overall responsibility for the development, modification and content of norms, criteria and standards rests with the PSRO. (See Section 709.4.)

702.3 While other examples could be cited, these serve to point out the nature of the responsibility of a PSRO. The Department will provide all possible assistance to the PSRO as it assumes this responsibility. If, however, the PSRO fails, either by not performing effectively itself or by not requiring effective performance from those to whom it delegates certain of its functions, the Department would terminate the PSRO's contract and either revert to existing mechanisms of review or select another organization to perform PSRO review.

705 PSRO PLAN FOR REVIEW OF IN-PATIENT SHORT-STAY HOSPITAL CARE

The PSRO's plan for review of in-patient, short-stay hospital care must include plans for concurrent admission certification and continued stay review and retrospective medical care evaluation studies. The requirements for these types of review and a general description of each are outlined below.

When the capacity exists to develop them in their area, PSROs will be required to review practitioner, patient, hospital and diagnosis profiles. As the Department defines the content of these profiles, the period of time which they will encompass, the mode by which they will be generated, the frequency of analysis and the general nature of the norms, criteria and standards to be used, guidelines will be issued to assist PSROs in organizing and performing profile analysis.

705.1 Admission Certification

705.11 Definition

Admission certification is a form of medical care review in which an assessment is made of the medical necessity of a patient's admission to a hospital.

705.12 Objectives

(a) To assure that patients requiring a hospital level of care are admitted to a hospital.

(b) To assure that diagnostic or therapeutic care which could be provided at a non-hospital level of care is not provided on a hospital in-patient basis without appropriate justification (e.g., lack of trained personnel, geographic constraints, etc.).

(c) To assure that hospital admissions are not being inappropriately delayed.

(d) When an admission is certified, to assure assignment of a diagnosis-specific or problem-specific length of stay certification period. In addition, where problems in post-discharge care are anticipated, discharge planning should be initiated as soon as possible after admission.

705.13 Timing of the Certification

Admission certification will be performed during the initial

portion of the hospital stay (concurrent admission certification). At the option of the PSRO admission certification for elective admission can be performed prior to admission (pre-admission certification -- see Section 705.14b). When performing concurrent admission certification for elective and emergency admissions, the initial screening review will occur within the first working day following admission. For elective surgery, certification should be confirmed before surgery is performed. If the admission is certified as medically necessary, an initial length of stay will be assigned. Medicare and Medicaid payment terminates at the end of this period unless recertification takes place (see Section 705.24 for recertification process). If, however, review indicates that admission is not medically necessary, the attending physician will be notified within two working days of admission in order to afford him an opportunity to present his view prior to the point when a final determination is made. If the final determination is that the medical necessity for the admission has not been shown, the review committee shall verbally notify the hospital, the patient, the attending physician, and in the case of a Medicaid patient, the State agency, within two working days following admission. Written confirmation of the committee's decision must be sent to the patient, the attending physician, the institution, and in the case of a Medicaid patient, to the Medicaid State agency or its designee, or, in the case of Medicare, the Medicare intermediary, as soon as possible thereafter.

705.14 Elective Admission Certification

(a) Concurrent Admission Certification of Elective Admissions

(1) Initially, concurrent certification of elective admission will be performed on all elective admissions unless the PSRO can clearly identify in their review plan diagnoses (or problems) or physicians which do not require such review. For example, it may not be necessary for a PSRO to certify the necessity of admissions for term delivery. Data which would indicate that such review was not indicated might include (a) the length-of-stays for term deliveries were within the PSRO standards and, (b) the fetal and maternal morbidity and mortality rates were within acceptable ranges. In addition, where the volume of admissions or manpower available prohibit 100 percent review prohibitive, a less extensive approach would be considered.

Except as indicated below (705.14b) all PSROs will initially perform admission certification on a concurrent basis.

(2) Over time, as the PSRO performs concurrent admission certification it will identify physicians, diagnoses (or problems), and/or institutions which no longer require admission certification. Such could be indicated by (a) absence of admission denials, (b) absence of inappropriate lengths of stay, (c) absence of the delivery of diagnostic or therapeutic services inappropriate to the hospital level of care and/or (d) results of medical care evaluation studies which indicate that the health outcomes of

patients hospitalized for a particular diagnosis meet locally developed standards. When this occurs such physicians, diagnoses (or problems), or institutions would not be subjected to admission certification (although continued stay review could still be performed). Conversely, when data and experience indicated that admission certification was necessary for a particular physician, diagnoses (or problem), or institution, it would be instituted. The objective here is to assure the efficient and effective operation of the admission certification process by focusing attention on defined problem areas.

(3) If a hospital currently employs admission classifications other than elective and emergency, (e.g., urgent and semi-urgent) those admissions otherwise classified shall be subject to the elective admissions certification process.

(b) Pre-admission Certification of Elective Admissions

At the option of the PSRO, pre-admission certification could be used in any of at least the following instances.

(1) Where the PSRO felt that, for certain situations (by diagnosis, physician, institution or procedure), pre-admission certification would be more effective, from the beginning, than concurrent admission certification.

(2) Where a hospital has had an effective pre-admission certification program and has been delegated review authority by the PSRO including PSRO approval to continue pre-admission certification in lieu of concurrent admission certification.

(3) Over time, in those situations (by diagnosis, physician, institution or procedures) when concurrent admission certification has failed to prevent medically unnecessary admissions.

The PSRO can develop the pre-admission certification process which it wishes to employ. In some instances the PSRO may ask that the patient under review be seen in consultation by another physician to obtain an independent assessment of a patient's need for hospitalization. While the choice of a consulting physician should be left to the attending physician and the patient, the PSRO may wish to approve the choice made.

705.15 Emergency Admission Certification

(a) Initially, certification of emergency admissions will be performed either on all emergency admissions or on a random sample or selective basis which must include a substantial proportion of emergency admissions to each hospital in the PSRO area. For these purposes, "substantial proportion" means that the review would, in a reasonable period of time, cover all types of physicians and all major diagnoses.

In selecting diagnoses or physicians for emergency admission certification the PSRO should, to the extent data is available, focus on instances where assessment of patient outcomes indicates that medically inappropriate admissions have frequently occurred or that care of substandard quality has been delivered. It would be possible to combine random sampling of emergency admissions with more extensive review of selected diagnoses, physicians or institutions.

(b) Over time the PSRO will eliminate areas not needing admission certification and will add others so that the admission certification process should become an efficient and effective process which assures the medical necessity of emergency admissions. Information which would indicate that it was unnecessary to certify certain emergency admissions is listed above in 705.14a(1).

705.16 Use of Criteria

Criteria specifying indications for admissions, the appropriate nature of a pre-admission work-up and/or the types of services which should be provided at a hospital level of care will be used to screen admissions in order to select those requiring further review. For a discussion of the development and use of criteria refer to section 709.

705.17 Use of Norms

For all patients whose admission was certified as being medically necessary, length-of-stay norms will be used to assign an initial certification period. These norms will be developed by the PSRO as discussed in section 709 of this chapter. They will relate to the patient's primary diagnosis(es) with the initial length-of-stay assignment usually being the 50th percentile of the average total length of stay for patients with the same diagnosis and of the same age grouping. Where no diagnosis has been established or where a patient had multiple diagnoses, the initial length-of-stay certification period should relate to the nature of the patient's medical problem and the projected point in time when a diagnosis might be established or when the problem should begin to resolve.

705.18 Data Needs for Admission Certification

(a) Concurrent Admission Certification

The following are the minimum data elements needed for each patient:

Data	Source(s)
--Patient identification	Medical record or admission office
--Payment program	
--Physician identification	
--Diagnosis(es) or problem(s)	Medical record
--Selected signs, symptoms and/or results of previous testing	Medical record

The precise data needed in the last category will depend upon the admission criteria established by the PSRO. Such data should allow an initial assessment of the medical necessity for admission. If the medical necessity of the admission is questioned, additional pertinent data would be obtained from the medical record and/or the patient's attending physician.

(b) Pre-admission Certification

As noted in section 705.14b there are several situations in which a PSRO could decide to institute pre-admission certification. In such cases the data mentioned above for concurrent admission certification should be obtained.

705.19 Data Required for Local Reporting

(a) The PSRO or the hospital should document its actions in the patient's medical record and in addition, should maintain, at a minimum, the following aggregate statistics.

(1) The number of elective and emergency admissions reviewed.

(2) The number of elective and emergency admissions certified.

(3) The number of elective and emergency admissions referred for peer review:

a. The number of elective and emergency admissions certified after peer review;

b. The number of elective and emergency admissions denied. And for each instance, the coded identification of the patient and of his physician.

(4) For admission certification of emergency admission, the sampling frame and nature of areas selected for more extensive review.

This information will be used to fulfill the reporting requirements to be specified in this Manual.

(b) The PSRO or hospital will, as a part of reporting the results of its review of individual cases to claims payment agents, indicate that an admission has been approved or denied.

705.2 Continued Stay Review (CSR)

705.21 Definition

Continued stay review is a form of medical care review which occurs during a patient's hospitalization and consists of an assessment of the medical necessity of a patient's need for continued confinement at a hospital level of care and may also include a detailed assessment of the quality of care being provided.

705.22 Objectives

(a) To assure that payment is made only for health care which should be delivered at a hospital level of care unless otherwise justified (e.g., no lower level of care available, geographic constraints, etc.).

(b) To assure that the health services provided to a patient are efficacious, meet locally developed standards of quality, and are delivered at a time most consistent with his needs.

(c) To perform effective pre-discharge planning.

(d) Where necessary, collect data needed for use in medical care evaluation studies.

705.23 Requirement for Continued Stay Review

Initially, continued stay review will be performed on all patients which have undergone admission certification. Over time, continued stay review could be performed in the absence of admission certification if the PSRO felt such was warranted. Over time, as the PSRO performs continued stay review it will identify physicians, diagnoses (or problems), and/or institutions which no longer require continued stay review. Data which might indicate that continued stay review was not necessary might include any or all of the following: (a) results of medical care evaluations or audits which indicate that the health outcomes of hospitalization for patients with a particular diagnosis meet professionally developed standards, (b) that length-of-stays for patients with a particular diagnosis were within PSRO standards, or (c) that the services provided were necessary, appropriate and of a quality which meet locally developed standards.

705.24 General Outline of Continued Stay Review

In general, continued stay review will consist of a periodic reassessment of a patient's need for continued stay at the hospital level of care. The first such reassessment should occur on or before the day initially assigned during the admission certification process. The review coordinator will use screening criteria developed by the PSRO to make an initial assessment. The nature of these criteria are discussed below. If, on the basis of criteria, the review coordinator determines that further stay is justified, (s)he will assign another certification period. On or before that day (s)he will again reassess the patient's need for further stay. If the review coordinator questions whether further stay is indicated (s)he will refer the case to the next level of review as defined by the PSRO (or authorized hospital). If, after consulting with the patient's attending physician, the reviewer(s) find that further stay in the hospital is not appropriate, notice of such finding will be given to the hospital, the attending physician, the patient and, in the case of a Medicaid patient, the Medicaid State agency. Except under unusual circumstances, this notice will be given prior to the expiration of the certified period.

705.25 Criteria Used for Continued Stay Review

Criteria which a PSRO will develop for use by the review coordinator in continued stay review screening will take one of three general forms.

(a) Criteria specifying indications for discharge (criteria specifying anticipated outcomes of hospitalization).

(b) Criteria indicating the types of services (e.g., physician, nursing, diagnostic radiology, therapeutic radiology, laboratory) which can only be provided at a hospital level of care.

(c) In those instances where a PSRO wishes to perform in-depth concurrent assessment of the quality of care, criteria specifying the critical indicated and contraindicated diagnostic and therapeutic services (including their frequency, timing and quantity).

705.26 Norms for Use in CSR

Length-of-stay norms will be used to assign subsequent certification periods (as described above). These norms will be developed by the PSRO as discussed in section 709 of this chapter. They will relate to the patient's primary diagnosis(es) with the second certification period usually based upon the 75th percentile of the average length-of-stay for patients with the same diagnosis and of the same age grouping as the patient. Where no

diagnosis is yet established, or where the patient has multiple diagnoses, the certification period assigned should relate to the nature of the patient's medical problem(s) and the projected point in time when a diagnosis might be established or when the problem(s) should begin to resolve.

705.27 Data Needs for CSR

From the admission certification process, the reviewer will have the patient's identification, the attending physician(s) identification, and the program involved. In the process of reassessment, the reviewer will become aware of changes in diagnosis or the establishment of a diagnosis. Additional data which is necessary relate to the criteria specified above. These are screening criteria which will be used by the review coordinator. If physician review is required, the necessary additional data will be obtained from the medical record or from the patient's physician(s) and will relate to that patient's medical condition.

705.28 Data Required for Local Reporting

(a) The PSRO or hospital will document its actions in the patient's medical record and, in addition should, at a minimum, maintain the following aggregate statistics:

(1) The number of cases reviewed

(2) The number of extensions granted

(3) The number of extensions referred for peer review

a. The number of extensions granted after peer review

b. The number of extensions denied and for each instance the coded identification of the patient and of his physician

(4) Indication, in those situations where concurrent quality assessment has been performed, whether the services provided conformed to criteria.

For the PSRO, this information will be used to meet the reporting requirements to be specified in this Manual. For the hospital, this will be used to meet the reporting requirements specified in section 720 of this chapter.

(b) The PSRO or hospital should, as a part of reporting the results of review of individual cases to claims payment agents, indicate the total number of days of hospitalization which were approved.

705.29 Discharge Planning

Where problems in post-discharge care or discharge placement are anticipated, discharge planning should be initiated as soon as possible after admission to the short-stay hospital. Discharge planning should include both preparation of the patient for the next level of care and arrangement for placement in the appropriate care setting.

Information needed for the discharge planning process include:

(a) Prior health care status of patient (i.e., was patient receiving care in his home or in some type of long-term care facility?)

(b) Current level of care needed

(c) Projected level(s) of care needed

(d) Projected time frame for moving patient to next level of care

(e) Therapy(ies) and teaching that must be accomplished prior to hospital discharge

(f) Available resources for post-hospital care

(g) Mechanisms for facilitating transfer to other levels of care.

705.3 Medical Care Evaluation Studies (MCE)

705.31 Definition

Medical care evaluation studies are a type of retrospective medical care review in which in-depth assessment of the quality and/or the nature of the utilization of health care services is made.

705.32 Objectives

(a) To assure that health care services are appropriate to the needs of a patient and are of acceptable quality.

(b) To assure that health care organization and administration support the timely provision of quality care.

705.33 Requirements for MCE Studies

Each PSRO or each hospital delegated PSRO review will be required to be performing at least one MCE study at any point in time. The

suggested medical audit procedure contained in the Joint Commission on Accreditation of Hospital's current addition of the Manual for Trustees, Administrators and Physicians Institutes and in the current addition of Chapter 12 of the American Hospital Association's "Quality Assurance Program for Medical Care in the Hospital" fulfill the medical care evaluation study requirements for a hospital which has received delegation from a PSRO to perform such studies.

705.34 General Characteristics of MCE Studies

MCE studies have the following characteristics.

(a) They are specifically designed in-depth studies focusing on particular potential problem areas.

(b) They are usually of short duration.

(c) They may be prompted by cases in which screening parameters have indicated possible instances of substandard quality. Alternatively, they may focus on subjectively perceived instances of medical care administrative inefficiency or substandard quality.

(d) They may be performed by a single hospital, or where common problems exist, by a group of hospitals in a coordinated effort.

(e) For the most part, they do not deal with an individual patient or practitioner, but will require information related to the care provided by a number of practitioners to a number of patients.

(f) They constitute an important link to the continuing education aspects of the PSRO effort. The results of MCE studies should be used by a hospital or PSRO in the development of curriculum for and in the monitoring of the effectiveness of its continuing education efforts.

(g) The results of MCE studies can be used to monitor the effectiveness of admission certification and continued stay review and identify areas (diagnoses or physicians) where admission certification and/or continued stay should be instituted or intensified.

(h) The results of some MCE studies will often identify needed changes in the organization and administration of health care delivery. When such is the case, the PSRO or hospital should provide this information to those responsible for making such changes and help to assure that necessary action is taken.

(i) Data necessary for MCE studies may be collected retrospectively and/or by the review coordinator during a patient's confinement in the hospital. Analysis of the data is done retrospectively.

705.35 Norms, Criteria and Standards for MCE Studies

Since medical care evaluation studies vary widely in their characteristics, no specific set of criteria, norms, or standards can be cited. Rather, they will relate to the objective of the study. Examples of such studies include:

(a) A detailed analysis of the process of care for a particular diagnosis or problem. The criteria used in such studies would be based on scientifically derived evidence of the efficacy of a given diagnostic or therapeutic procedure. If such evidence did not exist, they would be based on the best judgment of experts.

(b) A study of the use of combination antibiotics with the criteria specifying the indications and contraindications for their use.

(c) Examination of the length of time between the ordering and provision of a given radiologic procedure.

(d) A study of the outcome of hospitalization for a given diagnosis with the criteria for such studies specifying appropriate health status just prior to discharge and the optimal time needed to achieve such status.

(e) Exploration of the length of pre- and post-operative confinement with criteria specifying the optimal intervals.

705.36 Data Needs and Sources for MCE Studies

The data needed to conduct MCE studies will vary depending upon the nature of the study. It will relate directly to the problem under study and to the norms, criteria and standards which have been developed for it. If, for example, the purposes of the study were to determine the outcome of patients hospitalized for myocardial infarction and to identify and correct the causes of apparently inappropriate outcomes, it would be necessary to do the following with reference to study data:

(a) Identify the medical records of those patients with myocardial infarction;

(b) Collect data which related to patient outcomes; and

(c) If the actual outcomes did not conform to the stated expectations of the hospital or PSRO committee, data would be collected which related to the medical care process criteria developed by these committees.

The source of the data will also vary depending upon the nature of the study and the resources available to the hospital or PSRO. Data can be obtained from three basic sources:

(a) Medical or other hospital records or internal information systems.

(b) Organizations external to hospitals which currently compile statistics, design profiles and produce other comparative data for one or more hospitals in the area; and

(c) The fiscal agents for Medicare or Medicaid.

707 RETROSPECTIVE INDIVIDUAL CLAIMS REVIEW

(a) Definition

For purposes of PSRO, retrospective review of individual hospital claims is a type of medical care review in which an assessment is made of the medical necessity and quality of care and of the appropriateness of the setting in which care was delivered. No assessment will be made by PSROs of practitioner or institutional charges, patient eligibility or of the coverages for the services received.

(b) Retrospective review of individual hospital claims is not an initially required PSRO review mechanism. It will be used only when required forms of review have not been implemented or, where implemented, have not been performed effectively.

(c) In the near future, the Department will issue guidelines for this form of review, including those related to the appropriate timing of its implementation and its relationship with other PSRO review mechanisms.

709 DEVELOPMENT AND USE OF NORMS, CRITERIA AND STANDARDS

The following are the definitions to be used by the PSRO program for the terms norms, criteria and standards.

Norms - Medical care appraisal norms are numerical or statistical measures of usual observed performance.

Standards - Standards are professionally developed expressions of the range of acceptable variation from a norm or criterion.

Criteria - Medical care criteria are predetermined elements against which aspects of the quality of a medical service may be compared. They are developed by professionals relying on professional expertise and on the professional literature.

Norms are derived from aggregate information related to the health care provided to a large number of patients over time.

Norms, criteria, and standards should be used in each type of PSRO review. They should, at least, be used for the initial screening of cases to select those cases requiring more in-depth review. In-depth review should be performed by peers using a combination of more detailed norms, criteria and standards and an assessment of a patient's individual clinical and social situation and the resources of the institution in which care is being provided.

709.1 PSRO Development of Norms, Criteria, and Standards

709.11 The National Professional Standards Review Council will provide, through the Department, sample sets of norms and criteria to each PSRO, when such sample sets are available.

709.12 As early as is feasible, each conditional PSRO should establish an appropriate committee or set of committees to review these model sets of norms and criteria in order to adopt or adapt them for their use. Alternatively this committee(s) may wish to develop its own criteria and standards and/or select its own norms. In selecting members for these committees, the PSRO should attempt to provide balanced representation from the medical staffs of hospitals in their area. To the extent possible, the committee(s) should be so constituted as to allow each major medical speciality to review the norms and criteria for its speciality. Those specialities which provide care to a wide variety of patients (e.g., radiology) might be asked to develop the criteria and standards for its specialty. Those specialties which provide care to a wide is treated by several specialities, the PSRO should assure that the norms and criteria for such conditions are reviewed jointly by the involved specialities.

In addition to using its established committee(s), a PSRO may ask a particular organized speciality group, the medical staff of an institution(s) or other appropriate group, to assist in the development of certain criteria or standards or the selection of certain norms.

709.13 Over time, norms, criteria and standards should be developed for each major diagnosis, health problem or procedure which will come under review. Since this will take time, the PSRO should initially focus attention on high priority situations. Priorities should be set on the basis of (a) the frequency with which the diagnosis, problem or procedure is seen in or performed on hospitalized patients, (b) the degree to which health can be improved by the identification and treatment of particular medical problems, and (c) the degree to which subjective or objective evidence indicates inappropriate utilization of services or the delivery of care of substandard quality. Admission certification and continued stay review could, during the initial period of a PSRO's operation, be performed without the use of criteria, norms or standards. When this is done, however, the PSRO or hospital must show evidence that such

parameters are under development and will be used when developed. MCE studies should not be performed without the use of norms, criteria, and standards.

709.14 Criteria are usually developed with reference to a particular diagnosis or health problem. These criteria usually encompass the following categories and should result in the identification of those elements critical to the health care of the patient.

(a) Findings of history, physical examination or diagnostic procedures which confirm the diagnosis.

(b) Indications for admission to a hospital.

(c) Diagnostic or therapeutic services (including timing, frequency and quantity) which should be provided to a patient with the specified diagnosis.

(d) Contraindicated diagnostic or therapeutic services.

(e) Projected length-of-stay.

(f) Indications for discharge from the hospital (expected health status at the time of discharge).

(g) Necessary post-hospital care.

Which of these criteria will be utilized in review depend upon the type of review to be performed. In admission certification and continued stay review, the review coordinator will be attempting to screen from a large number of cases those which require physician review. Thus, the review coordinator will need only a small subset of the total list of criteria developed for a diagnosis. This subset would consist of those criterion which will best enable the coordinator to select for physician review those cases in which admission or continued stay is inappropriate. The more detailed list of criteria would be used in medical care evaluation studies to enable an in-depth, objective assessment of the quality of care which has been rendered.

While it is possible to develop the criteria for admission certification and continued stay review separately from those for MCE studies such an approach could foster an inappropriate separation of the assessment of utilization from the assessment of quality. Thus, it is recommended that to the extent possible, a full set of criteria be developed for each diagnosis or problem under consideration. An appropriate subset can be used in concurrent review and the full set employed in medical care evaluation studies.

709.15 The PSRO committees will be responsible initially for selecting the norms and developing criteria and standards to be used for

admission certification and continued stay review. These will result from:

(a) the review and modification of the sample sets of norms and criteria mentioned above (e.g., for norms, PAS length of stay norms for the region, MADOC length of stay norms, or length of stay norms based on regional abstracting services, and, for criteria, those developed by medical speciality organizations participating in the work of the AMA Guidelines Task Force);

(b) the review of local norms, criteria or standards if such are available (e.g., norms and standards for length of stay by diagnosis); and/or

(c) the local development of these parameters.

Note: Those hospitals performing PSRO review which have developed criteria and standards and selected norms for admission certification and continued stay review prior to their development or selection by the PSRO may utilize these parameters until the PSRO establishes committees for this purpose. Such PSRO committee(s), when formed, can then either accept the hospital's norms, criteria or standards or require changes in them which are consistent with the parameters developed by the PSRO committee(s). In addition, where a PSRO committee has not developed criteria or standards or selected norms for particular diseases, problems or procedures, the hospital may develop or select such parameters and use them if the PSRO approves.

709.16 As the capability exists for the generation and analysis of profiles, the PSRO will be responsible for developing the norms, criteria and standards to be used for the screening of physician, patient, practitioner and diagnosis profiles.

709.17 In those instances where a PSRO is performing medical care evaluation studies, the PSRO will be responsible for developing, prior to the initiation of the study, the norms, criteria and/or standards to be used. (See below for hospital development of these parameters.)

709.18 The PSRO will be expected to utilize non-physician health practitioners for the development of the criteria and standards and the selection of the norms to be used for the review of the care provided by such practitioners. For those conditions in which care is often provided by physician and non-physician practitioners, the norms, criteria and standards should be jointly developed.

709.2 Dissemination of Norms, Criteria and Standards

709.21 When the PSRO has completed and approved its initial set of norms, criteria and standards for admission certification and continued stay review, it will be responsible for their dissemination to the health care practitioners and hospitals in its area.

709.22 When the PSRO performs medical care evaluation studies, the norms, criteria and standards used in the studies should be made available to practitioners and hospitals in their area.

709.23 As the PSRO develops norms, criteria and standards for profile analysis these should be disseminated to health care practitioners and hospitals in its area.

709.24 If a PSRO performs retrospective individual claims review, the norms, criteria and standards for such review should be disseminated to health care practitioners and hospitals in its area.

709.3 Modification of Norms, Criteria and Standards

709.31 As new medical information is developed, or as data is available which would indicate the need for revision of norms, criteria, and standards, it is anticipated that the PSRO's norms, criteria, and standards will need to be modified.

709.32 The PSRO should develop a plan for periodic modification of norms, criteria and standards.

709.33 Any modifications should be made available to practitioners and hospitals in the PSRO area.

709.4 Hospital Development of Criteria and Standards and Selection of Norms

709.41 As discussed in section 700 of this manual, the PSRO will delegate review activities to hospitals which have the capability to perform review effectively.

709.42 Except as indicated in 709.15 (NOTE) above the hospital which receives a delegation will be required to utilize the norms, criteria, and standards developed by the PSRO for admission certification and continued stay review. In those instances where a hospital feels there is valid reason for exceptions to these parameters, the hospital must receive approval from the PSRO prior to making such modification.

709.43 When a hospital performs medical care evaluation studies, it will develop the criteria and standards to be used in such studies. When a PSRO coordinates a medical care evaluation study which involves several hospitals, each hospital will participate in the development of the criteria and standards to be utilized. The hospital should provide the PSRO with the norms, criteria and standards used in its medical care evaluation studies in order that the PSRO may share these with other hospitals contemplating such studies.

710 THE HOSPITAL-PSRO RELATIONSHIP WITH RESPECT TO MEDICAL CARE REVIEW

Section 705 of this chapter dealt with the requirements for medical care review which are to be followed by a conditional PSRO. This section of the chapter specifies the nature of the relationship between a PSRO and a hospital to which the PSRO has delegated review.

710.1 Assessment of the Hospital's Review Capability

Section 720 of this chapter describes the process by which a PSRO initially assesses the capability of a hospital which wishes to be delegated PSRO review activities as well as the mechanism by which a PSRO will perform on-going monitoring of the effectiveness of a hospital's review.

710.2 PSRO Review Which Can Be Delegated to a Hospital

710.21 If the PSRO deems it capable, a hospital will be allowed to perform (a) admission certification, (b) continued stay review, and/or (c) medical care evaluation studies. In addition, as profiles are developed for a PSRO, a capable hospital will be asked by the PSRO to review and take necessary action on any of its hospital profiles which are selected for review by the application of screening norms, criteria, or standards.

710.22 The requirements made of the PSRO in sections 705.14a, 705.15, 705.23, and 705.33 of this chapter (Admission Certification, Continued Stay Review, and Medical Care Evaluation Studies) are the same for a hospital which is delegated these types of review.

710.23 The hospital and PSRO will mutually agree upon the organization of the hospital's review activities. For example, the hospital might structure its review such that it is performed by the hospital's personnel and committee(s). Alternatively, one or more types of review might be performed using a combination of personnel and committee(s) of the hospital and the PSRO.

710.24 The hospital should inform the PSRO of the subject of its medical care evaluation studies, the study design and methods, the norms, criteria and standards used, the general nature of the results and how the results were utilized. The hospital could participate with other hospitals in joint medical care evaluation studies coordinated by the PSRO.

710.3 Development of Norms, Criteria and Standards

The method for development of criteria and standards and the selection of norms is discussed in section 709 of this chapter.

710.31 A hospital is required to utilize the norms, criteria, and standards developed or selected by the PSRO for admission certification,

continued stay review, profile analysis and individual claims review unless it requests a modification(s) which is approved by the PSRO.

710.32 The hospital should develop the criteria, or standards ... select the norms which it will use in its medical care evaluation studies. The hosptial should provide the PSRO with these norms, criteria and standards as models which the PSRO can provide to other hospitals contemplating performance of similar studies. The hospital should also review model sets of MCE norms, criteria and standards and study designs and methods on file with the PSRO which relate to MCE studies the hospital may wish to undertake.

720 EVALUATION OF IN-HOUSE REVIEW

A PSRO is required to utilize the services of and accept the findings of the review committees of hospitals to the extent that the hospital's review would aid the PSRO in the performance of its duties and responsibilities. The major tenets which will guide this portion of the PSRO/hospital relationship are as follows:

720.01 PSROs are responsible for assuring the effectiveness of all medical care review which it is authorized to perform. Thus, while a PSRO may delegate review functions to effective institutional review committees, it retains responsibility for assuring the continued effectiveness of that review.

720.02 A PSRO shall accept the findings of in-house review committee(s) when the committee(s) has demonstrated its capability to perform effectively and in a timely manner.

720.03 A hospital may organize its review activities utilizing one or more of its standing committees (UR, audit, etc.) as long as its review continues to be effective. Stated differently, the delegation of review should not be viewed as limited to a delegation to the Utilization Review Committee. Since PSRO review will encompass utilization review and MCE studies, the function delegated to a hospital should be organized to match the expertise existing on a variety of hospital health care review committees.

720.04 In order to assure the broadest possible participation in PSRO activities by physicians in its area, in-house review activities will be accepted by a PSRO only if the physicians of the hospital participate in the overall review activities conducted by the PSRO (e.g., PSRO review, PSRO criteria development).

720.05 The PSRO must, from the beginning, work closely with interested hospitals in their efforts to develop effective review systems.

720.06 The focus of PSRO evaluation of in-house review will shift over time from the medical care review process and its organization to its effectiveness.

720.07 The Secretary, with good cause, can disapprove or over rule the PSRO's delegation of review to a hospital.

720.08 Hospitals may appeal delegation decisions made by the PSRO.

720.09 Note

Reimbursement methods are being developed and will be included in a subsequent version of this manual. In general, where a hospital has been delegated PSRO review activities, the Department will assume financial responsibility only for those in-house review and continuing education activities which are unique requirements made by the PSRO program and which will need to be initiated as a supplement to present hospital activities. Reimbursement for such hospital based activities will, in general, be made using current reimbursement mechanisms rather than through reimbursement from the PSRO.

720.1 Steps in the Initial Assessment and On-going Evaluation and Monitoring of Hospital Review Committees

In most instances, there will be three phases to a PSRO's development -- the planning, conditional, and operational phases. The major objective of the planning phase is to develop a formal plan for review which, if accepted, will be used during the PSRO's conditional phase to initiate review. Part of the formal plan will include an approximate assessment of the number of hospitals in the PSRO area in which the PSRO will perform review and the number in which the hospital's medical staff will perform review during the conditional phase.

The following represent the series of steps which should be taken by a PSRO and hospital in order to make an initial determination of whether or not review should be delegated to a hospital committee and if it is, the steps in on-going evaluation and monitoring. For this discussion, the assumption has been made that a hospital delegated PSRO review will be:

(a) required to perform admission certification, continued stay review and retrospective medical care evaluation (MCE) studies;

(b) allowed, for elective admissions, to exempt physicians, diagnoses or procedures from admission certification and continued stay review, if approved by the PSRO;

(c) required to perform admission certification of emergency admissions on at least a random sample or selected basis.

(d) required to be performing at least one MCE study at any given time and that it may develop the criteria or standards and select the norms to be used in these studies.

(e) required (except as indicated in 709.15 - "Note") to use the PSRO's norms, criteria, and standards for admission certification, continued stay review and profile analysis unless they can present the PSRO with valid reasons why these parameters should be modified for their institution.

To the extent possible, STEPS 1 and 2 specified below should be completed during the PSRO's planning phase in order that the PSRO's formal plan may generally state the "division of labor" between the PSRO and the hospital. STEPS 3 and 4 can occur after conditional designations. No review will be funded, however, prior to the acceptance of the PSRO's formal plan.

720.2 STEP 1 - Initial Assessment

720.21 An initial assessment of the present capability and willingness of a hospital's medical staff to perform review should be conducted during the potential PSRO's planning phase. This could include:

(a) Review by the potential PSRO of information from the Medicare State Survey Agency and appropriate Medicare intermediaries concerning the hospital's past performance in Medicare utilization review.

(b) Review by the potential PSRO of information from the Medicaid State Agency concerning past performance of the hospital in Medicaid review.

(c) Review of information received from the hospital concerning other types of review taking place in the hospital (medical audit, tissue committee, QAP, JCAH audit program, etc.).

(d) Collection by the hospital of information which characterizes a hospital (e.g., number of beds, total admissions/year, Medicare, Medicaid and Maternal and Child Health admissions/year, type of ownership, teaching affiliations, size and type of medical staff, etc.).

Such information will allow the potential PSRO to make an initial assessment of past review performance and potential capability of a hospital to perform review.

720.3 STEP 2 - Initial Expression of Interest

The potential PSRO should request from each hospital in its area which is interested in performing review a memorandum of understanding or other suitable document which states that the hospital is willing to work with the potential PSRO to plan, organize and establish a medical care review system that meets the PSRO's requirement. This memorandum should indicate official interest on the part of the medical staff, the board of directors and the hospital's administration. It should also state a willingness to allow the

potential PSRO to evaluate and monitor the effectiveness of the hospital's review.

720.4 STEP 3 - Joint Development of a Review Plan

720.41 In those hospitals which appear to have the capability (STEP 1) and the willingness (STEP2) to perform review, the PSRO and hospital will jointly develop a review plan which conforms to Departmental guidelines. This effort should include the widest possible participation by the hospital's:

(a) Medical staff -- especially the chairman of the Utilization Review, medical audit, and other committees;

(b) Non-physician health practitioners;

(c) Medical record personnel;

(d) Director of Medical Education (or equivalent);

(e) Administrative staff;

(f) Board of Trustees.

Where necessary and appropriate, this activity would be aided by technical assistance available to the PSRO.

720.5 STEP 4 - Approval by the PSRO of the Hospital's Review Plan:

720.51 STEP 3 will result in a plan for the review of care in a hospital. This plan must be approved by the PSRO prior to its (the plan's) initiation. The plan should conform to Departmental guidelines and include the following elements:

(a) Description of organization of the review effort including the:

(1) number and types of hospital personnel to be used for each type of review;

(2) levels of review (e.g., review coordinator, review physician, review committee(s) for each type of review);

(3) relationship with claims payment agencies;

(4) relationship with data collection agencies;

(5) functions to be performed by PSRO personnel.

(b) Description of the types of review to be performed including for each type:

(1) phasing in schedule;

(2) intensity of review (100 percent, random sample, selected sample);

(3) nature and source of data to be collected.

(c) Development and use of norms, criteria, and standards including:

(1) for admission certification and continued stay review, requested deviations from PSRO parameters;

(2) the method of development for MCE studies;

(3) mechanisms for modification over time.

(d) The content and frequency of reports to be generated for:

(1) PSRO evaluation and monitoring;

(2) internal monitoring and management;

(3) modification of norms, criteria, and standards.

(e) Methods by which review findings will be used in continuing education.

(f) Types of technical assistance and education needed to implement the plan.

(g) The number of physicians on the hospital's medical staff which are or will be participating in PSRO review activities.

This plan should be submitted by the hospital's medical staff with the official approval of the hospital's Board and administrator.

720.6 STEP 5 - Implementation of the Hospital's Approved Review Plan

720.61 If the PSRO approves the hospital's plan for review and if the PSRO is granted conditional status, the hospital's plan is then implemented. The PSRO has the responsibility to assure that the hospital's plan is put in place according to the agreed upon schedule. The PSRO should provide technical assistance if it is needed. The PSRO might also assist hospitals in its area

by aiding in the recruitment of necessary personnel and in the training of review coordinators, medical record personnel and review physicians.

720.62 The hospital and PSRO will jointly work with the Medicaid State agency and Medicare agents. Such discussions should result in memoranda of understanding between the hospital, PSRO and the Medicare, Medicaid and Maternal and Child Health agents which specify:

(a) The point in time when the hospital's review findings will be accepted for payment purposes.

(b) The data to be submitted by the hospital to the Medicare, Medicaid and Maternal and Child Health agents.

(c) The role of the Medicaid, Medicare and Maternal and Child Health agents in data processing and reporting.

(d) The mechanisms to be used by Medicare, Medicaid and Maternal and Child Health agents for post-payment monitoring of a hospital's review. This would include general specification of the findings a Medicare, Medicaid or Maternal and Child Health agent could use to question a hospital's review capability. If problems arise they are to be discussed jointly with the hospital and PSRO.

720.7 STEP 6 - On-going Monitoring by the PSRO

720.71 Discussion

After implementation of a hospital review plan, the PSRO is responsible for assuring that the hospital continues to perform review effectively. The nature of the PSRO's on-going monitoring role will change over time from an assessment of the organization and process of review to an evaluation of its impact. Initially, the PSRO will monitor whether review is being performed and if the process of review conforms to Departmental guidelines. Over time, monitoring will focus on the types of decisions being made by the review committee, and the impact of these decisions on the quality of care and the utilization of services.

The discussion below illustrates the types and sources of information which a PSRO might need to monitor and evaluate the performance of a hospital delegated PSRO review activities.

A. Is review being performed?

1. Data necessary

   a. Admission certification

      1) Elective admissions reviewed

      2) Elective admissions certified

      3) Elective admissions denied

      4) Sampling frame or situations selected for certification of emergency admissions

      5) Emergency admissions reviewed

      6) Emergency admissions denied

      7) Request for changes in admission certification criteria

      8) Frequency of referral to review levels above review coordinator

      9) Request to drop certain areas from admission certification

   b. Continued stay review

      1) Extensions requested

      2) Extensions denied

      3) Extensions granted

      4) Request for changes in criteria

      5) Frequency of referral to review levels above review coordinator

      6) Request to drop certain areas from Continued Stay Review and justification

      7) Non-physician health professionals involved in review

   c. Medical care evaluation studies (MCES)

      1) Number and subject of MCES completed since last report

2) Number and subject of newly initiated MCES

3) Criteria used for each completed study

4) Summary of results of each study and actions taken

5) Types of non-physician health professionals involved in review

2. Sources of Data

Virtually all of the admission certification and continued stay review data noted above can be easily obtained by manual tabulation. The only exceptions relate to requests for changes in the scope or focus of concurrent review. These will come to the PSRO as special requests.

The data for MCE studies will be obtained by direct reports from the hospital to the PSRO.

B. What types of decisions are being made?

While this is covered to some extent in the data above, further questions are more appropriately asked on a selective or sample basis.

1. Data necessary

a. Admission certification

1) Are admissions being granted appropriately?

2) Are denials appropriate?

b. Continued stay review

1) Are extensions being granted appropriately?

2) Are denials of extensions appropriate?

3) What are the reasons for granting extensions (e.g., continues to need hospital level of care, no lower level beds available, diagnostic and/or therapeutic procedures not completed)?

4) Do the decisions made conform to the medical care criteria?

c. Medical care evaluation studies

How are the findings of MCE studies being utilized?

2. Data sources

The data related to admission certification and continued stay review would be obtained by the PSRO review of medical records.

The data related to MCE studies could be obtained from reports to the PSRO from the hospital or by discussions between the PSRO and the hospital's review committee.

C. What is the impact of review decisions?

1. Data necessary

a. Admission certification

1) Medicare emergency and elective admission rates

2) Medicaid emergency and elective admission rates

3) Readmission rates

b. Continued stay review

1) Length-of-stay by diagnosis - Medicare and Medicaid.

2) Readmission rates

c. Medical care evaluation studies

1) Results of reaudit to determine impact of the hospital's educational program

2. Data Sources

For admission certification and continued stay review, data could be obtained from aggregation of relevant Medicare, Medicaid, and Maternal and Child Health data.

The data related to MCE studies could be obtained from a report to the PSRO from the hospital.

730 INVOLVEMENT OF NON-PHYSICIAN HEALTH CARE PRACTITIONERS IN PSRO REVIEW

Health care is provided by practitioners of a wide variety of health care disciplines. Review of care provided by non-physician health care practitioners should be performed by their peers. Thus, while the PSRO retains ultimate responsibility for the decisions made under its aegis, it should seek the participation of all health care practitioners in the development of criteria and standards and the selection of norms for their professions, in the establishment of mechanisms to review the care provided by each type of practitioner, and in the actual review of that care. The PSRO's formal plan shall contain a plan for the involvement of non-physician health care practitioners in the PSRO's review system.

730.2 Definition

Non-physician health care practitioners are those health professionals which (a) do not hold a Doctor of Medicine or Doctor of Osteopathy degree, (b) are qualified by education, experience and/or licensure to practice their profession, and (c) are involved in the delivery of direct patient care or services which are directly or indirectly reimbursed by the Medicare, Medicaid or Maternal and Child Health programs.

730.3 Development and On-going Modification of Norms, Criteria, and Standards

730.31 PSRO Responsibility

The PSRO is responsible for assuring, over time, that non-physician health care practitioners are involved in the establishment and on-going modification of norms, criteria and standards for their discipline. This is true both for PSRO direct development and when development is delegated to hospitals.

730.32 When care provided by non-physician health care practitioners will be assessed under any of the types of review to be performed by a PSRO or a hospital delegated PSRO review, non-physician health care practitioners of the appropriate discipline should work with committee(s) of the hospital or PSRO which are developing the criteria and standards and selecting the norms for these types of review.

730.33 Non-physician health care practitioners should work with the committee(s) of a hospital or PSRO which are responsible for on-going revision of norms, criteria or standards. This will assure the continual updating of the parameters as they relate to all involved health care disciplines.

730.4 Development of Review Mechanisms

730.41 PSRO Responsibility

The PSRO shall assure the active involvement of non-physician health care practitioners in all phases of the development and implementation of those review mechanisms which will be used to assess the performance of non-physician health care practitioners.

730.42 Hospital Responsibility

Any hospital which receives delegation of review activities from a PSRO is expected to involve non-physician health care practitioners in all phases of the development and implementation of those review mechanisms which will be used to assess the performance of non-physician health care practitioners.

730.5 Health Care Review

730.51 PSRO Responsibility

The PSRO is responsible for assuring that non-physician health care practitioners are involved in the actual review of care provided by their peers.

730.52 Hospital Responsibility

Any hospital which performs review under delegation from the PSRO is responsible for assuring that, where such review involves assessment of the care of non-physician health care practitioners, non-physician health care practitioners perform the assessment of their peers.

730.53 Where care is provided jointly by physician and non-physician health care practitioners, the assessment of such care will be performed jointly by peer physician and non-physician practitioners.

730.54 Where care is provided exclusively by one type of non-physician health care practitioners, the assessment of such care will be performed by peer non-physician practitioners. The decisions made during such review would be reported through the mechanisms established for review decisions related to physician care.

730.55 Only physicians will be allowed to make final decisions on the care provided by physicians.

730.6 Continuing Education

Those types of non-physician health care practitioners whose care is being reviewed under the aegis of a PSRO are responsible for developing mechanisms by which the results of review are utilized in the continuing education of such practitioners.

730.7 Organization

Where appropriate, the organizational structure established to provide for involvement of non-physician health care practitioners in the activities listed above should be the same structure established for the performance of these activities by physicians. For example, committee(s) should include physician and non-physician practitioners.

730.8 PSROs must show evidence over time of adherence to the guidelines listed above.

Appendix E

Statutory Language of PSRO—Bold Type for Emphasis Requested by Senator Carl T. Curtis

Statutory Language of the PSRO Provision

"TITLE XI—GENERAL PROVISIONS AND PROFESSIONAL STANDARDS REVIEW

"PART A—GENERAL PROVISIONS"

(b) Title XI of such Act is further amended by adding the following:

"PART B—PROFESSIONAL STANDARDS REVIEW

"DECLARATION OF PURPOSE

* * * * * * *

"DESIGNATION OF PROFFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"SEC. 1152. (a) The Secretary shall (1) not later than January 1, 1974, establish throughout the United States appropriate areas with respect to which Professional Standards Review Organizations may have be designated, and (2) at the earliest practicable date after designation of an area enter into an agreement with a qualified organization whereby such an organization shall be conditionally designated as the Professional Standards Review Organization for such area. If, on the basis of its performance during such period of conditional designation, the Secretary determines that such organization is capable of fulfilling, in a satisfactory manner, the obligations and requirements for a Professional Standards Review Organization under this part, he shall enter into an agreement with such organization designating it as the Professional Standards Review Organization for such area.

"(b) For purposes of subsection (a), the term 'qualified organization' means—

"(1) when used in connection with any area—

"(A) an organization (i) which is a nonprofit professional association (or a component organization thereof), (ii) which is composed of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area, (iii) the membership of which includes a substantial proportion of all such physicians in such area, (iv) which is organized in a manner which makes available professional competence to review health care services of the types and kinds with respect to which Professional Standards Review Organizations have review responsibilities under this part, (v) the membership of which is voluntary and open to all doctors of medicine or osteopathy licensed to engage in the practice of medicine or surgery in such area without requirement of membership in or payment of dues to any organized medical society or association, and (vi) which does not restrict the eligibility of any member for services as an officer of the Professional Standards Review Organization or eligibility for and assignment to duties of such Professional Standards Review Organization, or, subject to subsection (c)(1),

"(B) such other public, nonprofit private, or other agency or organization, which the Secretary determines, in accordance with criteria prescribed by him in regulations, to be of professional competence and otherwise suitable; and

"(2) an organization which the Secretary, on the basis of his examination and evaluation of a formal plan submitted to him by the association, agency, or organization (as well as on the basis of other relevant data and information), finds to be willing to perform and capable of performing, in an

effective, timely, and objective manner and at reasonable cost, the duties, functions, and activities of a Professional Standards Review Organization required by or pursuant to this part.

"(c)(1) The Secretary shall not enter into any agreement under this part under which there is designated as the Professional Standards Review Organization for any area any organization other than an organization referred to in subsection (b)(1)(A) prior to January 1, 1976, nor after such date, unless, in such area, there is no organization referred to in subsection (b)(1)(A) which meets the conditions specified in subsection (b)(2).

"(2) Whenever the Secretary shall have entered into an agreement under this part under which there is designated as the Professional Standards Review Organization for any area any organization other than an organization referred to in subsection (b)(1)(A), he shall not renew agreements with such organization if he determines that—

"(A) there is in such area an organization referred to in subsection (b)(1)(A) which (i) has not been previously designated as a Professional Standards Review Organization, and (ii) is willing to enter into an agreement under this part under which such organization would be designated as the Professional Standards Review Organization for such area;

"(B) such organization meets the conditions specified in subsection (b)(2); and

"(C) the designation of such organization as the Professional Standards Review Organization for such area is anticipated to result in substantial improvement in the performance in such area of the duties and functions required of such organizations under this part.

"(d) Any such agreement under this part with an organization (other than an agreement established pursuant to section 1154) shall be for a term of 12 months; except that, prior to the expiration of such term such agreement may be terminated—

"(1) by the organization at such time and upon such notice to the Secretary as may be prescribed in regulations (except that notice of more than 3 months may not be required); or

"(2) by the Secretary at such time and upon such reasonable notice to the organization as may be prescribed in regulations but only after the Secretary has determined (after providing such organization with an opportunity for a formal hearing on the matter) that such organization is not substantially complying with or effectively carrying out the provisions of such agreement.

"(e) In order to avoid duplication of functions and unnecessary review and control activities, the Secretary is authorized to waive any or all of the review, certification, or similar activities otherwise required under or pursuant to any provision of this Act (other than this part) where he finds on the basis of substantial evidence of the effective performance of review and control activities by Professional Standards Review Organizations, that the review, certification, and similar activities otherwise so required are not needed for the provision of adequate review and control.

"(f)(1) In the case of agreements entered into prior to January 1, 1976, under this part under which any organization is designated as the Professional Standards Review Organization for any area, the Secretary shall, prior to entering into any such agreement with any organization for any area, inform (under regulations of the Secretary) the doctors of medicine or osteopathy who are in active practice in such area of the Secretary's intention to enter into such an agreement with such organization.

"(2) If, within a reasonable period of time following the serving of such notice, more than 10 per centum of such doctors object to the Secretary's entering into such an agreement with such organization on the ground that such organization is not representative of doctors in such area, the Secretary shall conduct a poll of such doctors to determine whether or not such organization is representative of such doctors in such area. If more than 50 per centum of the doctors responding to such poll indicate that such organization is not representative of such doctors in such area the Secretary shall not enter into such an agreement with such organization.

"REVIEW PENDING DESIGNATION OF PROFESSIONAL STANDARDS REVIEW ORGANIZATION

"SEC. 1153. Pending the assumption by a Professional Standards Review Organization for any area, of full review responsibility, and pending a demonstra-

tion of capacity for improved review effort with respect to matters involving the provision of health care services in such area for which payment (in whole or in part) may be made, under this Act, any review with respect to such services which has not been designated by the Secretary as the full responsibility of such organization, shall be reviewed in the manner otherwise provided for under law.

"TRIAL PERIOD FOR PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"SEC. 1154. (a) The Secretary shall initially designate an organization as a Professional Standards Review Organization for any area on a conditional basis with a view to determining the capacity of such organization to perform the duties and functions imposed under this part on Professional Standards Review Organizations. Such designation may not be made prior to receipt from such organization and approval by the Secretary of a formal plan for the orderly assumption and implementation of the responsibilities of the Professional Standards Review Organization under this part.

"(b) During any such trial period (which may not exceed 24 months), the Secretary may require a Professional Standards Review Organization to perform only such of the duties and functions required under this part of Professional Standards Review Organization as he determines such organization to be capable of performing. The number and type of such duties shall, during the trial period, be progressively increased as the organization becomes capable of added responsibility so that, by the end of such period, such organization shall be considered a qualified organization only if the Secretary finds that it is substantially carrying out in a satisfactory manner, the activities and functions required of Professional Standards Review Organizations under this part with respect to the review of health care services provided or ordered by physicians and other practitioners and institutional and other health care facilities, agencies, and organizations. Any of such duties and functions not performed by such organization during such period shall be performed in the manner and to the extent otherwise provided for under law.

"(c) Any agreement under which any organization is conditionally designated as the Professional Standards Review Organization for any area may be terminated by such organization upon 90 days notice to the Secretary or by the Secretary upon 90 days notice to such organization.

"DUTIES AND FUNCTIONS OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"SEC. 1155. (a)(1) Notwithstanding any other provision of law, but consistent with the provisions of this part, it shall (subject to the provisions of subsection (g)) be the duty and function of each Professional Standards Review Organization for any area to assume, at the earliest date practicable, responsibility for the review of the professional activities in such area of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under this Act for the purpose of determining whether—

"(A) such services and items are or were medically necessary;

"(B) the quality of such services meets professional recognized standards of health care; and

"(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a differnt type.

"(2) Each Professional Standards Review Organization shall have the authority to determine, in advance, in the case of—

"(A) any elective admission to a hospital, or other health care facility, or

"(B) any other health care service which will consist of extended or costly courses of treatment.

whether such service, if provided, or if provided by a particular health care practitioner or by a particular hospital or other health care facility, organization, or agency, would meet the criteria specified in clauses (A) and (C) of paragraph (1).

"(3) Each Professional Standards Review Organization shall, in accordance with regulations of the Secretary, determine and publish from time to time, the the types and kinds of cases (whether by type of health care or diagnosis involved, or whether in terms of other relevant criteria relating to the provision of health care services) with respect to which such organization will, in order most effectively to carry out the purposes of this part, exercise the authority conferred upon it under paragraph (2).

"(4) Each professional Standards Review Organization shall be responsible for the arranging for the maintenance of and the regular review of profiles of care and services received and provided with respect to patients, utilizing to the greatest extent practicable in such patient profiles, methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation consistent with the purposes of this part. Profiles shall also be regularly reviewed on an ongoing basis with respect to each health care practitioner and provider to determine whether the care and services ordered or rendered are consistent with the criteria specified in clauses (A), (B), and (C) of paragraph (1).

"(5) Physicians assigned responsibility for the review of hospital care may be only those having active hospital staff privileges in at least one of the participating hospitals in the area served by the Professional Standards Review Organization and (except as may be otherwise provided under subsection (e)(1) of this section) such physicians ordinarily should not be responsible for, but may participate in the review of care and services provided in any hospital in which such physicians have active staff privileges.

"(6) No physician shall be permitted to review—

"(A) health care services provided to a patient if he was directly or indirectly involved in providing such services, or

"(B) health care services provided in or by an institution, organization, or agency, if he or any member of his family has, directly or indirectly, any financial interest in such institution, organization, or agency.

For purposes of this paragraph, a physician's family includes only his spouse (other than a spouse who is legally separated from him under a decree of divorce or separate maintenance), children (including legally adopted children), grandchildren, parents, and grandparents.

"(b) To the extent necessary or appropriate for the proper performance of its duties and functions the Professional Standards Review Organization serving any area is authorized in accordance with regulations prescribed by the Secretary to—

"(1) make arrangements to utilize the services of persons who are practitioners of or specialists in the various areas of medicine (including dentistry(, or other types of health care, which persons shall, to the maximum extent practicable, be individuals engaged in the practice of their profession within the area served by such organization;

"(2) undertake such professional inquiry either before or after, or both before and after, the provision of services with respect to which such organization has a responsibility for review under subsection (a)(1);

"(3) examine the pertinent records of any practitioner or provider of health care services providing services with respect to which such organization as a responsibility for review under subsection (a)(1); and

"(4) inspect the facilities in which care is rendered or services provided (which are located in such area) of any practitioner or provided.

"(c) No Professional Standards Review Organization shall utilize the services of any individual who is not a duly licensed doctor of medicine or osteopathy to make final determinations in accordance with its duties and functions under that part with respect to the professional conduct of any other duly licensed doctor of medicine or osteopathy, or any act performed by any duly licensed doctor of medicine or osteopathy in the exercise of his profession.

"(d) In order to familiarize physicians with the review functions and activities of Professional Standards Review Organizations and to promote acceptance of such functions and activities by physicians, patients, and other persons, each Professional Standards Review Organization, in carrying out its review responsibilities, shall (to the maximum extent consistent with the effective and timely performance of its duties and functions)—

"(1) encourage all physicians practicing their profession in the area served by such Organization to participate as reviewers in the review activities of such Organizations;

"(2) provide rotating physician membership of review committees on an extensive and continuing basis;

"(3) assure that membership on review committees have the broadest representation feasible in terms of the various types of practice in which physicians engage in the area served by such Organization; and

"(4) utilize, whenever appropriate, medical periodicals and similar publications to publicize the functions and activities of Professional Standards Review Organizations.

"(e)(1) Each Professional Standards Review Organization shall utilize the services of, and accept the findings of, the review committees of a hospital or other operating health care facility or organization located in the area served by such organization, but only when and only to the extent and only for such time that such committees in such hospitals or other operating health care facility or organization have demonstrated to the satisfaction of such organization their capacity effectively and in timely fashion to review activities in such hospital or other operating health care facility or organization (including the medical necessity of admissions, types and extent of services ordered, and lengths of stay) so as to aid in accomplishing the purposes and responsibilities described in subsection (a)(1), except where the Secretary disapproves, for good cause, such acceptance.

"(2) The Secretary may prescribe regulations to carry out the provisions of this subsection.

"(f)(1) An agreement entered into under this part between the Secretary and any organization under which such organization is designated as the Professional Standards Review Organization for any area shall provide that such organization will—

"(A) perform such duties and functions and assume such responsibilities and comply with such other requirements as may be required by this part or under regulations of the Secretary promulgated to carry out the provisions of this part; and

"(B) collect such data relevant to its functions and such information and keep and maintain such records in such form as the Secretary may require to carry out the purposes of this part and to permit access to and use of any such records as the Secretary may require for such purposes.

"(2) Any such agreement with an organization under this part shall provide that the Secretary make payments to such organization equal to the amount of expenses reasonably and necessarily incurred, as determined by the Secretary, by such organization in carrying out or preparing to carry out the duties and functions required by such agreement.

"(g) Notwithstanding any other provision of this part, the responsibility for review of health care services of any Professional Standards Review Organization shall be the review of health care services provided by or in institutions, unless such Organization shall have made a request to the Secretary that it be charged with the duty and function of reviewing other health care services and the Secretary shall have approved such request.

"NORMS OF HEALTH CARE SERVICES FOR VARIOUS ILLNESSES OR HEALTH CONDITIONS

"SEC. 1156. (a) Each Professional Standards Review Organization shall apply professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice in its regions (including typical lengths-of-stay for institutional care by age and diagnosis) as principal points of evaluation and review. The National Professional Standards Review Council and the Secretary shall provide such technical assistance to the organization as will be helpful in utilizing and applying such norms of care, diagnosis, and treatment. Where the actual norms of care, diagnosis, and treatment in a Professional Standards Review Organization area are significantly different from professionally developed regional norms of care, diagnosis, and treatment approved for comparable conditions, the Professional Standards Review Organization concerned shall be so informed, and in the event that appropriate consultation and discussion indicate reasonable basis for usage of other norms in the area concerned, the Professional Standards Review Organization may apply such norms in such area as are approved by the National Professional Standards Review Council.

"(b) Such norms with respect to treatment for particular illnesses or health conditions shall include (in accordance with regulations of the Secretary)—

"(1) the types and extent of the health care services which, taking into account differing, but acceptable, modes of treatment and methods of organizing and delivering care are considered within the range of appropriate diagnosis and treatment of such illness or health condition, consistent with professionally recognized and accepted patterns of care;

"(2) the type of health care facility which is considered, consistent with such standards, to be the type in which health care services which are medically appropriate for such illness or condition can most economically be provided.

"(c)(1) The National Professional Standards Review Council shall provide for the preparation and distribution, to each Professional Standards Review Organization and to each other agency or person performing review functions with respect to the provision of health care services under this Act, of appropriate materials indicating the regional norms to be utilized pursuant to this part. Such data concerning norms shall be reviewed and revised from time to time. The approval of the National Professional Standards Review Council of norms of care, diagnosis, and treatment shall be based on its analysis of appropriate care and adequate data.

"(2) Each review organization, agency, or person referred to in paragraph (1) shall utilize the norms developed under this section as a principal point of evaluation and review for determining, with respect to any health care services which have been or are proposed to be provided, whether such care and services are consistent with the criteria specified in section 1155(a)(1).

"(d)(1) Each Professional Standards Review Organization shall—

"(A) in accordance with regulations of the Secretary, specify the appropriate points in time after the admission of a patient for inpatient care in a health care institution, at which the physician attending such patient shall execute a certification stating that further inpatient care in such institution will be medically necessary effectively to meet the health care needs of such patient; and

"(B) require that there be included in any such certification with respect to any patient such information as may be necessary to enable such organization properly to evaluate the medical necessity of the further institutional health care recommended by the physician executing such certification.

"(2) The points in time at which any such certification will be required (usually, not later than the 50th percentile of lengths-of-stay for patients in similar age groups with similar diagnoses) shall be consistent with and based on professionally developed norms of care and treatment and data developed with respect to length of stay in health care institutions of patients having various illnesses, injuries, or health conditions, and requiring various types of health care services or procedures.

"SUBMISSION OF REPORTS BY PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"SEC. 1157. If, in discharging its duties and functions under this part, any Professional Standards Review Organization determines that any health care practitioner or any hospital, or other health care facility, agency, or organization has violated any of the obligations imposed by section 1160, such organization shall report the matter to the Statewide Professional Standards Review Council for the State in which such organization is located together with the recommendations of such Organization as to the action which should be taken with respect to the matter. Any Statewide Professional Standards Review Council receiving any such report and recommendation shall review the same and promptly transmit such report and recommendation to the Secretary together with any additional comments or recommendations thereon as it deems appropriate. The Secretary may utilize a Professional Standards Review Organization, in lieu of a program review team as specified in sections 1862 and 1866, for purposes of subparagraph (C) of section 1862(d)(1) and subparagraph (F) of section 1866(b)(2).

"REQUIREMENT OF REVIEW APPROVAL AS CONDITION OF PAYMENT OF CLAIMS

"SEC. 1158. (a) Except as provided for in section 1159, no Federal funds appropriated under any title of this Act (other than title V) for the provision of health

care services or items shall be based (directly or indirectly) for the payment, under such title or any program established pursuant thereto, of any claim for the provision of suc hservices or items, unless the Secretary, pursuant to regulation determines that the claimant is without fault if—

"(1) the provision of such services or items is subject to review under this part by any Professional Standards Review Organization, or other agency; and

"(2) such organization or other agency has, in the proper exercise of its duties and functions under or consistent with the purposes of this part, disapproved of the services or items giving rise to such claim, and has notified the practitioner or provider who provided or proposed to provide such services or items and the indivdual who would receive or was proposed to receive such services or items of its disapproval of the provision of such services or items.

"(b) Whenever any Professional Standards Review Organization, in the discharge of its duties and functions as specified by or pursuant to this part, disapproves of any health care services or items furnished or to be furnished by any practitioner provider, such organization shall, after notifying the practitioner, provider, or other organization or agency of its disapproval in accordance with subsection (a), promptly notify the agency or organization having responsibility for acting upon claims for payment for or on account of such services or items.

"HEARINGS AND REVIEW BY SECRETARY

"SEC. 1159. (a) Any beneficiary or recipient who is entitled to benefits under this Act (other than title V) or a provider or practitioner who is dissatisfied with a determination with respect to a claim made by a Professional Standards Review Organization in carrying out its responsibilities for the review of professional activities in accordance with paragraphs (1) and (2) of section 115(a) shall, after being notified of such determination, be entitled to a reconsideration thereof by the Professional Standards Review Organization and, where the Professional Standards Review Organization reaffirms such determination in a State which has established a Statewide Professional Standards Review Council, and where the matter in controversy is $100 or more, such determination shall be reviewed by professional members of such Council and, if the Council so determined, revised.

"(b) Where the determination of the Statewide Professional Standards Review Council is adverse to the beneficiary or recipient (or, in the absence of such Council in a State and where the matter in controversy is $100 or more), such beneficiary or recipient shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 205(b), and, where the amount in controversy is $1,000 or more, to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g). The Secretary will render a decision only after appropriate professional consultation on the matter.

"(c) Any review or appeals provided under this section shall be in lieu of any review, hearing, or appeal under this Act with respect to the same issue.

"OBLIGATIONS OF HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES; SANCTIONS AND PENALTIES; HEARINGS AND REVIEW

"SEC. 1160. (a)(1) It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this Act, to assure that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this Act—

"(A) will be provided only when, and to the extent, medically necessary; and

"(B) will be of a quality which meets professionally recognized standards of health care; and

"(C) will be supported by evidence of such medical necessity and quality in such form and fashion and at such time as may reasonably be required by the Professional Standards Review Organization in the exercise of its duties and responsibilities;

and it shall be the obligation of any health care practitioner in ordering, authorizing, directing, or arranging for the provision by any other person (including a hospital or other health care facility, organization, or agency), of health care services for any patient of such practitioner, to exercise his professional responsibility with a view to assuring (to the extent of his influence or control over such patient, such person, or the provision of such services) that such services or items will be provided—

"(D) only when, and to the extent, medically necessary; and

"(E) will be of a quality which meets professionally recognized standards of health care.

"(2) Each health care practitioner, and each hospital or other provider of health care services, shall have an obligation, within reasonable limits of professional discretion, not to take any action, in the exercise of his profession (in the case of any health care practitioner), or in the conduct of its business (in the case of any hospital or other such provider), which would authorize any individual to be admitted as an inpatient in or to continue as an inpatient in any hospital or other health care facility unless—

"(A) inpatient care is determined by such practitioner and by such hospital or other provider, consistent with professionally recognized health care standards, to be medically necessary for the proper care of such individual; and

"(B)(i) the inpatient care required by such individual cannot, consistent with such standards, be provided more economically in a health care facility of a different type; or

"(ii) (in the case of a patient who requires care which can, consistent with such standards, be provided more economically in a health care facility of a different type) there is, in the area in which such individual is located, no such facility or no such facility which is available to provide care to such individual at the time when care is needed by him.

"(b)(1) If after reasonable notice and opportunity for discussion with the practitioner or provider concerned, any Professional Standards Review Organization submits a report and recommendations to the Secretary pursuant to section 1157 (which report and recommendations shall be submitted through the Statewide Professional Standards Review Council, if such Council has been established, which shall promptly transmit such report and recommendations together with any additional comments and recommendations thereon as it deems appropriate) and if the Secretary determines that such practitioner or provider, in providing health care services over which such organization has review responsibility and for which payment (in whole or in part) may be made under this Act has—

"(A) by failing, in a substantial number of cases, substantially to comply with any obligation imposed on him under subsection (a), or

"(B) by grossly and flagrantly violating any such obligation in one or more instances,

demonstrated an unwillingness or a lack of ability substantially to comply with such obligations, he (in addition to any other sanction provided under law) may exclude (permanently for such period as the Secretary may prescribe) such practitioner or provider from eligibility to provide such services on a reimbursable basis.

"(2) A determination made by the Secretary under this subsection shall be effective at such time and upon such reasonable notice to the public and to the person furnishing the services involved as may be specified in regulations. Such determination shall be effective with respect to services furnished to an individual on or after the effective date of such determination (except that in the case of institutional health care services such determination shall be effective in the manner provided in title XVIII with respect to terminations of provider agreements), and shall remain in effect until the Secretary finds and gives reasonable notice to the public that the basis for such determination has been removed and that there is reasonable assurance that it will not recur.

"(3) In lieu of the sanction authorized by paragraph (1), the Secretary may require that (as a condition to the continued eligibility of such practitioner or provider to provide such health care services on a reimbursable basis) such practitioner or provider pay to the United States in case such acts or conduct involved the provision or ordering by such practitioner or provider of health care services which were medically improper or unnecessary, an amount not in

excess of the actual or estimated cost of the medically improper or unnecessary services so provided, or (if less) $5,000. Such amount may be deducted from any sums owing by the United States (or any instrumentality thereof) to the person from whom such amount is claimed.

"(4) Any person furnishing services described in paragraph (1) who is dissatisfied with a determination made by the Secretary under this subsection shall be entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g).

"(c) It shall be the duty of each Professional Standards Review Organization and each Statewide Professional Standards Review Council to use such authority or influence it may possess as a professional organization, and to enlist the support of any other professional or governmental organization having influence or authority over health care practitioners and any other person (including a hospital or other health care facility, organization, or agency) providing health care services in the area served by such review organization, in assuring that each practitioner or provider (referred to in subsection (a)) providing health care services in such area shall comply with all obligations imposed on him under subsection (a).

"NOTICE TO PRACTITIONER OR PROVIDER

"SEC. 1161. Whenever any Professional Standards Review Organization takes any action or makes any determination—

"(a) which denies any request, by a health care practitioner or other provider of health care services, for approval of a health care service or item proposed to be ordered or provided by such practitioner or provider; or

"(b) that any such practitioner or provider has violated any obligation imposed on such practitioner or provider under section 1160,

such organization shall, immediately after taking such action or making such determination, give notice to such practitioner or provider of such determination and the basis therefor, and shall provide him with appropriate opportunity for discussion and review of the matter.

"STATEWIDE PROFESSIONAL STANDARDS REVIEW COUNCIL; ADVISORY GROUPS TO SUCH COUNCILS

"SEC.1162. (a) In any State in which there are located three or more Professional Standards Review Organizations, the Secretary shall establish a Statewide Professional Standards Review Council.

"(b) The membership of any such Council for any State shall be appointed by the Secretary and shall consist of—

"(1) one representative from and designated by each Professional Standards Review Organization in the State;

"(2) four physicians, two of whom may be designated by the State medical society and two of whom may be designated by the State hospital association of such State to serve as members on such Council; and

"(3) four persons knowledgeable in health care from such State whom the Secretary shall have selected as representatives of the public in such State (at least two of whom shall have been recommended for membership on the Council by the Governor of such State).

"(c) It shall be the duty and function of the Statewide Professional Standards Review Council for any State, in accordance with regulations of the Secretary, (1) to coordinate the activities of, and disseminate information and data among the various Professional Standards Review Organizations within such State including assisting the Secretary in development of uniform data gathering procedures and operating procedures applicable to the several areas in a State (including, where appropriate, common data processing operations serving several or all areas) to assure efficient operation and objective evaluation of comparative performance of the several areas and, (2) to assist the Secretary in evaluating the performance of each Professional Standards Review Organization, and (3) where the Secretary finds it necessary to replace a Professional Standards Review Organization, to assist him in developing and arranging for a qualified replacement Professional Standards Review Organization.

"(d) The Secretary is authorized to enter into an agreement with any such Council under which the Secretary shall make payments to such Council equal to the amount of expenses reasonably and necessarily incurred, as determined by the Secretary, by such Council in carrying out the duties and functions provided in this section.

"(e)(1) The Statewide Professional Standards Review Council for any State (or in a State which does not have such Council, the Professional Standards Review Organizations in such State which have agreements with the Secretary) shall be advised and assisted in carrying out its functions by an advisory group (of not less than seven nor more than eleven members) which shall be made up of representatives of health care practitioners (other than physicians) and hospitals and other health care facilities which provide within the State health care services for which payment (in whole or in part) may be made under any program established by or pursuant to this Act.

"(2) The Secretary shall by regulations provide the manner in which members of such advisory group shall be selected by the Statewide Professional Standards Review Council (or Professional Standards Review Organizations in States without such Councils).

"(3) The expenses reasonably and necessarily incurred, as determined by the Secretary, by such group in carrying out its duties and functions under the subsection shall be considered to be expenses necessarily incurred by the Statewide Professional Standards Review Council served by such group.

"NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

"SEC. 1163. (a)(1) There shall be established a National Professional Standards Review Council (hereinafter in this section referred to as the 'Council') which shall consist of eleven physicians, not otherwise in the employ of the United States, appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service.

"(2) Members of the Council shall be appointed for a term of three years and shall be eligible for reappointment.

"(3) The Secretary shall from time to time designate one of the members of the Council to serve as Chairman thereof.

"(b) Members of the Council shall consist of physicians of recognized standing and distinction in the appraisal of medical practice. A majority of such members shall be physicians who have been recommended by the Secretary to serve on the Council by national organizations recognized by the Secretary as representing practicing physicians. The membership of the Council shall include physicians who have been recommended for membership on the Council by consumer groups and other health care interests.

"(c) The Council is authorized to utilize, and the Secretary shall make available, or arrange for, such technical and professional consultative assistance as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Council such secretarial, clerical and other assistance and such pertinent data prepared by, for, or otherwise available to, the Department of Health, Education, and Welfare as the Council may require to carry out its functions.

"(d) Members of the Council, while serving on business of the Council, shall be entitled to receive compensation at a rate fixed by the Secretary (but not in excess of the daily rate paid under GS–18 of the General Schedule under section 5332 of title 5, United States Code), including traveltime; and while so serving away from their homes or regular places of business, they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in Government service employed intermittently.

"(e) It shall be the duty of the Council to—

"(1) advise the Secretary in the administration of this part;

"(2) provide for the development and distribution, among Statewide Professional Standards Review Council and Professional Standards Review Organizations of information and data which will assist such review councils and organizations in carrying out their duties and functions;

"(3) review the operations of Statewide Professional Standards Review Councils and Professional Standards Review Organizations with a view to determining the effectiveness and comparative performance of such review councils and organizations in carrying out the purposes of this part; and

"(4) make or arrange for the making of studies and investigations with a view to developing and recommending to the Secretary and to the Congress measures designed more effectively to accomplish the purposes and objectives of this part.

"(f) The National Professional Standards Review Council shall from time to time, but not less often than annually, submit to the Secretary and to the Congress a report on its activities and shall include in such report the findings of its studies and investigations together with any recommendations it may have with respect to the more effective accomplishments of the purposes and objectives of this part. Such report shall also contain comparative data indicating the results of review activities, conducted pursuant to this part, in each State and in each of the various areas thereof.

"APPLICATION OF THIS PART TO CERTAIN STATE PROGRAMS RECEIVING FEDERAL FINANCIAL ASSISTANCE

"SEC. 1164. (a) In addition to the requirements imposed by law as a condition of approval of a State plan approved under any title of this Act under which health care services are paid for in whole or part, with Federal funds, there is hereby imposed the requirement that provisions of this part shall apply to the operation of such plan or program.

"(b) The requirement imposed by subsection (a) with respect to such State plans approved under this Act shall apply—

"(1) in the case of any such plan where legislative action by the State legislature is not necessary to meet such requirement, on and after January 1, 1974; and

"(2) in the case of any such plan where legislative action by the State legislature is necessary to meet such requirement, whichever of the following is earlier—

"(A) on and after July 1, 1974, or

"(B) on and after the first day of the calendar month which first commences more than ninety days after the close of the first regular session of the legislature of such State which begins after December 31, 1973.

"CORRELATION OF FUNCTIONS BETWEEN PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS AND ADMINISTRATIVE INSTRUMENTALITIES

"SEC. 1165. The Secretary shall by regulations provide for such correlation of activities, such interchange of data and information, and such other cooperation consistent with economical, efficient, coordinated, and comprehensive implementation of this part (including, but not limited to, usage of existing mechanical and other data-gathering capacity) between and among—

"(a)(1) agencies and organizations which are parties to agreements entered into pursuant to section 1816, (2) carriers which are parties to contracts entered into pursuant to section 1842, and (3) any other public or private agency (other than a Professional Standards Review Organization) having review or control functions, or proved relevant data-gathering procedures and experience, and

"(b) Professional Standards Review Organizations, as may be necessary or appropriate for the effective administration of title XVIII, or State plans approved under this Act.

"PROHIBITION AGAINST DISCLOSURE OF INFORMATION

"SEC. 1166. (a) Any data or information acquired by any Professional Standards Review Organization, in the exercise of its duties and functions, shall be held in confidence and shall not be disclosed to any person except (1) to the extent that may be necessary to carry out the purposes of this part or (2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care

"(b) It shall be unlawful for any person to disclose any such information other than for such purposes, and any person violating the provisions of this section shall, upon conviction, be fined not more than $1,000, and imprisoned for not more than six months, or both, together with the costs of prosecution.

"LIMITATION ON LIABILITY FOR PERSONS PROVIDING INFORMATION, AND FOR MEMBERS AND EMPLOYEES OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS, AND FOR HEALTH CARE PRACTITIONERS AND PROVIDERS

"SEC. 1167. (a) Notwithstanding any other provision of law, no person providing information to any Professional Standards Review Organization shall be held, by reason of having provided such information, to have violated any criminal law, or to be civilly liable under any law, of the United States or of any State (or political subdivision thereof) unless—

"(1) such information is unrelated to the performance of the duties and functions of such Organization, or

"(2) such information is false and the person providing such information knew, or had reason to believe, that such information was false.

"(b)(1) No individual who, as a member or employee of any Professional Standards Review Organization or who furnishes professional counsel or services to such organization, shall be held by reason of the performance by him of any duty, function, or activity authorized or required of Professional Standards Review Organizations under this part, to have violated any criminal law, or to be civilly liable under any law, of the United States or of any State (or political subdivision thereof) provided he has exercised due care.

"(2) The provisions of paragraph (1) shall not apply with respect to any action taken by any individual if such individual, in taking such action, was motivated by malice toward any person affected by such action.

"(c) No doctor of medicine or osteopathy and no provider (including directors, trustees, employees, or officials thereof) of health care services shall be civilly liable to any person under any law of the United States or of any State (or political subdivision thereof) on account of any action taken by him in compliance with or reliance upon professionally developed norms of care and treatment applied by a Professional Standards Review Organization (which has been designated in accordance with section 1152(b)(1)(A)) operating in the area where such doctor of medicine or osteopathy or provider took such action but only if—

"(1) he takes such action (in the case of a health care practitioner) in the exercise of his profession as a doctor of medicine or osteopathy (or in the case of a provider of health care services) in the exercise of his functions as a provider of health care services, and

"(2) he exercised due care in all professional conduct taken or directed by him and reasonably related to, and resulting from, the actions taken in compliance with or reliance upon such professionally accepted norms of care and treatment.

"AUTHORIZATION FOR USE OF CERTAIN FUNDS TO ADMINISTER THE PROVISIONS OF THIS PART

"SEC. 1168. Expenses incurred in this administration of this part shall be payable from—

"(a) funds in the Federal Hospital Insurance Trust Fund;

"(b) funds in the Federal Supplementary Medical Insurance Trust Fund; and

"(c) funds appropriated to carry out the health care provisions of the several titles of this Act;

in such amounts from each of the sources of funds (referred to in subsections (a), (b), and (c)) as the Secretary shall deem to be fair and equitable after taking into consideration the costs attributable to the administration of this part with respect to each of such plans and programs.

"TECHNICAL ASSISTANCE TO ORGANIZATIONS DESIRING TO BE DESIGNATED AS PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"SEC. 1169. The Secretary is authorized to provide all necessary technical and other assistance (including the preparation of prototype plans of organization and operation) to organizations described in section 1152(b)(1) which—

"(a) express a desire to be designated as a Professional Standards Review Organization; and

"(b) the Secretary determines have a potential for meeting the requirements of a Professional Standards Review Organization;

to assist such organizations in developing a proper plan to be submitted to the Secretary and otherwise in preparing to meet the requirements of this part for designation as a Professional Standards Review Organization.

"EXEMPTIONS OF CHRISTIAN SCIENCE SANATORIUMS

"SEC. 1170. The provisions of this part shall not apply with respect to a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts."

Appendix F

Informational Material Distributed to the Medical Profession by the Department of Health, Education, and Welfare

PSRO Questions and Answers

The Professional Standards Review program has given rise to a great deal of confusion in the minds of physicians who are uncertain about its purpose, about how it will work, and about its effect on their ability to provide responsible care for their patients.

I believe that as this uncertainty is dispelled and as facts begin to take the place of conjecture, PSRO will come to be recognized as a program of importance, and potentially of significant benefit, to the health professions, to health care institutions, and to the people they serve. By providing a uniform basis for professional review of the institutional care paid for under Medicare, Medicaid, and Maternal and Child Health programs, PSRO willl enable physicians themselves to determine that such care is necessary and of recognized quality, that it properly meets the needs of the patient, and that it is provided in the most appropriate setting.

Most practitioners are striving to meet these objectives through the exercise of professional judgment and in cooperation with peer review committees in institutions throughout the country. Perhaps for that very reason many members of the profession are deeply concerned about the impact of a Federal PSRO law that calls for practices willingly and conscientiously adhered to by the majority of physicians. Even those who regard PSRO as an important new opportunity for the health professions to improve the quality and effectiveness of care want and need information about how PSROs will be formed, how they will function, how confidentiality will be preserved, and how PSROs will affect the work of practicing physicians.

This booklet is an attempt to provide answers to those and other questions about the PSRO program. While it cannot provide exhaustive information nor treat every question that might be raised, it does address the major issues that all of us recognize have to be examined and understood if the PSRO movement is to succeed.

We are embarking on a major new venture in the efforts of government and the health professions to improve the quality of health care, one in which the major responsibility falls—as it must—on the physicians who seek to meet the health needs of their patients. I hope that the information presented in this booklet, brief though it is, will give you a sense of the direction the PSRO movement is taking and the opportunity it offers to all of us who are concerned with the health of the American people.

Charles C. Edwards, M.D.,
Assistant Secretary for Health.

December 1973.

What is a PSRO?

Professional Standards Review Organization (PSRO) is a program organized, administered and controlled by local physicians to evaluate the necessity and quality of medical care delivered in their area under Medicare, Medicaid and Maternal and Child Health programs.

Who will be members of a PSRO?

PSRO membership is open only to licensed, practicing doctors of medicine or osteopathy in the PSRO area. The PSRO cannot require membership in or dues to any other organized medical society or association. Any member is eligible to serve as an officer of the PSRO and to participate in the PSRO's activities.

How will PSRO affect a physician's practice of medicine?

PSRO will cause little change in the way most physicians practice medicine. The PSRO program does require that the services a physician provides in institutions to Medicare and Medicaid patients be subject to review by his peers in the local PSRO. The PSRO will only review care delivered in institutions and will not cover care delivered in a physician's office, clinic, or other ambulatory setting unless the physicians in a PSRO request that it do so. As long as a physician's

pattern of practice falls generally within the norms and criteria which he will help establish for his PSRO, his practice will not be significantly affected.

Will PSRO mean more work for physicians?

All physicans will be encouraged to participate in the review activities of the PSRO. The amount of time spent by a physician in peer review will depend upon the number of physician and the specialty distribution within the PSRO, the patient load, and the degree to which the physician chooses to participate in the PSRO activities.

The physician's time will be concentrated on matters requiring professional medical judgment. Other health personnel can be used to do the preliminary screening and much of the paper work which will be kept to a minimum through greater uniformity and standardization in the collection and recording of medical care data.

Will the PSRO's tell physicians how to practice medicine?

The local physicians who make up each PSRO will establish the standards and criteria to be used in determining the necessity and quality of care. No standard or criteria can be applicable in every situation. There will be instances in which a physician's clinical judgment will require him to deviate from the established standards and criteria without objection from the PSRO.

If a physician's peers in the PSRO disapprove a proposed procedure or service or an extension of a length of stay, the immediate effect would be that the government would not pay for those services. The physician is still free to provide the care and services he chooses, and he can appeal the determination of his local PSRO to the Statewide Professional Standards Review Council and to HEW.

How will standards and criteria of care to be used by a PSRO be established?

Each PSRO will establish standards and criteria of care that reflect acceptable patterns of practice in the PSRO's area and that will lend themselves to local review. It is expected that the standards and criteria used by a PSRO will be modified as experience is gained and developments in medicine warrant their modification. Norms, standards and criteria will take into account the professional personnel, facilities and equipment available. The National Professional Standards Review Council must approve norms used by a PSRO that are significantly different from professionally developed regional norms.

The national specialty societies are preparing model criteria which will be made available to the PSRO's and which they can adopt or adapt to meet local circumstances.

Will the confidentiality of patient and physician information be protected?

Any data or information collected by a PSRO is to be held in strict confidence. The PSRO legislation contains strong penalties for breaches of confidentiality by any reviewer or employee of a PSRO.

Why PSRO?

PSRO is an effort to make review of Federally funded medical services more effective through greater participation by the physicians themselves. The Federal Government spend $17 billion a year on the Medicare and Medicaid programs and has a responsibility to see that the medical care paid for with public funds is necessary and that it meets quality standards. The entire thrust of the program is based upon the premise—which has been borne out by experience—that physicians are best qualified to determine the necessity and quality of medical services. Local physicians will set the standards and criteria of care, monitor to see that they are applied and take corrective action when they are not.

Is the purpose of PSRO to assure ouality or control cost?

The primary emphasis of the PSRO program is on assuring the quality of medical care. Providing quality care may increase health services for some patients in certain areas and could increase costs in those circumstances.

PSRO will be concerned also with whether medical care is necessary and delivered in the proper setting. If overuse or uneconomical use of services are identified and eliminated, cost savings will result.

A PSRO will not concern itself in any way with the fees for services charged by physicians or institutions.

What will be the responsibilities of a PSRO?

The PSRO will determine whether services provided are medically necessary, of proper quality, and delivered in the most appropriate setting for the proper length of time. The PSRO will have the authority to approve in advance the medical necessity of elective admissions to institutions as well as extended or costly services. In carrying out its responsibilities, the PSRO will consult with other health care practitioners, such as dentists and podiatrists, for assistance in reviewing services which these practitioners provide.

What will be the relationship between the PSRO and internal review activities in institutions?

The PSRO will accept the review performed by utilization review committees whenever the PSRO determines that such review is effective and that the physicians of the institution participate in the overall review activities of the PSRO.

What will the PSRO do about unnecessary or improper health care services?

The purpose of the PSRO program is to improve the quality of care not to discipline physicians. If a physician's pattern of practice indicates that he is delivering excessive or insufficient health care or otherwise improperly treating his patients, his peers in the PSRO will advise the physician and recommend appropriate remedies, such as professional consultation and education. Only in rare cases would sanctions provided by law be imposed, such as suspension or termination of Medicare and Medicaid payments. Appeal mechanisms from any sanctions recommended by the PSRO are also provided by law.

Where will PSRO's be established?

PSRO's will be established throughout the entire country with priority to be given to organizations at local levels so that the program is organized, administered and controlled by local, practicing physicians. Guidelines have been developed by HEW for designating PSRO areas. Among the factors which were considered in developing the guidelines was the need to designate areas that while assuring broad, diverse representation of all medical specialties would not encompass so large a number of practicing physicians as to preclude the possibility of active physician participation in the review activities of the PSRO.

This means that there will have to be more than one PSRO in all States except those that are small or sparsely populated. In States with multiple PSRO's, organizations, such as a medical society or a medical care foundation, could serve as a technical, professional resource center for the local PSRO's and provide advice and assistance in the development, implementation and evaluation of a PSRO and its activities.

When will PSRO's be established?

By January 1, 1974, HEW must designate PSRO geographic areas throughout the United States. Once the areas have been designated, HEW will enter into an agreement with a qualified organization in each area to be the PSRO. Until January 1, 1976, only a nonprofit professional association representing most of the practicing physicians in an area can qualify as a PSRO. If such an organization does not apply to a PSRO by that date, HEW can designate another organization, such as a health department or medical school, that has the professional medical competence to be a PSRO. In no case could any determinations about the provisions of care by a physician be made by anyone except another qualified physician.

How will the PSRO areas be designated?

Information gathered through research and consultation with the health community in each State was used as the basis for the preliminary designation of PSRO areas. These tentative designations were published in the *Federal Register* along with a statement of the guidelines and criteria which were applied in establishing the area or areas in each State. Comments from all interested parties on both the guidelines and the specific area designations will be accepted for a minimum of 30 days. Each comment will be analyzed and evaluated to determine if modification in specific PSRO areas should be made. Following the analysis and any necessary modifications, the PSRO area designations will be published again in the *Federal Register* and will become effective after 60 days.

How may individuals and organizations comment on the proposed PSRO areas?

All comments will be welcomed, and HEW will informally accept them at any time and in any form. The notice in the *Federal Register* contains general instructions concerning the format and content of formal, written comments and requests that they be forwarded to the Director, Office of Professional Standards Review, Room 17-64, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20852. The Department's regional office staff will assist individuals and organizations in preparing comments and will continue to consult informally with any interested parties during this period.

Will the final PSRO areas be permanent?

The law makes it clear that these areas would be tentative and may be altered at any time changes seem desirable.

How will a PSRO be selected?

An organization that wishes to be a PSRO must submit to HEW a formal plan of operation, based on guidelines formulated by the Department. HEW will provide consultation and technical assistance in the development of the plan. Once a

plan has been approved, HEW will contract with the organization to serve as a PSRO on a conditional basis for up to 24 months. During this initial period as the PSRO develops and expands its review capacity, exsiting Medicare and Medicaid review operations will continue, in the event the PSRO encounters difficulties or is terminated. If, at the end of the conditional period, the PSRO is performing satisfactorily, HEW will enter into an agreement with it for a period of 12 months. These agreements will be renewable on an annual basis and can be terminated by HEW or the PSRO.

How will a PSRO be supported?

HEW will provide funding to the PSRO to cover all necessary expenses involved in carrying out its functions, including the reimbursement of physicians for time spent participating in review activities.

What is the role and structure of the Statewide Professional Standards Review Council?

The principal responsibilities of the Statewide Council include the review of appeals from a PSRO's adverse decision and assisting HEW in the dissemination of information and data to the PSRO, the coordination of data gathering procedures within the PSRO areas of the State and the evaluation of PSRO effectiveness. The Council will consist of one representative from each PSRO in the State; four physicians, two of whom may be designated by a State medical society and two by a State hospital association; and four persons knowledgeable in health care selected by HEW to represent the public (at least two of whom are recommended by the Governor of the State.)

What is the role and structure of the National Professional Standards Review Council?

The National Council advises HEW on PSRO program matters. It will help provide data and information to Statewide Councils and PSRO's to aid them in carrying out their functions, review the norms used by a PSRO if they differ significantly from professionally developed regional norms of care, and aid in the review of the Operations of Statewide Councils and PSRO's with regard to their effectiveness and comparative performance.

The National Council consists of 11 physicians of recognized standing and distinction in the appraisal of medical practice who are appointed by the Secretary of HEW. A majority of the members are selected from nominees of national organizations representing practicing physicians. The Council also includes physicians nominated by consumer groups and other health care interests. Members are appointed or re-appointed for 3-year terms.

[OPSR Memo, November 1973]

OFFICE OF PROFESSIONAL STANDARDS REVIEW,
DEPARTMENT OF HEALTH, EDUCATION AND WELFARE,
Rockville, Md.

As the Professional Standards Review Organization efforts moves into the important phase of PSRO area designation, I feel it is extremely important that we in the Federal Government take every appropriate opportunity to give members of the medical profession the information they need in order to involve themselves in the work of local PSRO's as they are being planned and formed. The Office of Professional Standards Review has begun publication of the OPSR MEMO, the first issue of which contains a comprehensive policy statement on the designation of PSRO area. Subsequent iss ies of the OPSR MEMO will provide information on major PSRO developments of importance of all physicians.

Professional standards review is a major challenge to the American medical profession. While we in government have the task of developing and supporting the mechanism that will enable PSRO's to operate effectively, it is the local practicing physicians of the country who bear the ultimate responsibility for the national PSRO effort.

We invite your guidance and your help.

CHARLES C. EDWARDS, M.D.
Assistant Secretary for Health.

PSRO ACTIVITIES IN HEW

A number of agencies with HEW are involved in the implementation of the PRSO program—the Social Security Administration's Bureau of Health Insurance because of its responsibility for Medicare, the Social and Rehabilitation Service's Medical Service Administration with its responsibility for Medicaid and the Health Service Administration's Bureau of Quality Assurance with its responsibilities in the area of maintaining the quality of services provided through the public financed health programs. The Office of Professional Standards Review, which is located within the Office of the Assistant Secretary for Health, directs and coordinates the PSRO activities of these agencies. Within the HEW Regional Offices, the Regional Health Administrators have been given the lead responsibility for PSRO and have appointed PSRO representatives within their offices.

HEW REGIONAL OFFICES AND STATES COVERED

Region I: Maine, Vermont, New Hampshire, Massachusetts, Connecticut and Rhode Island—John F. Kennedy Federal Building, Government Center, Boston, Mass.

Region II: New York, New Jersey, Puerto Rico and Virgin Islands—Federal Building, Federal Plaza; New York, N.Y.

Region III: Pennsylvania, Maryland, Delaware, Virginia, West Virginia, and District of Columbia—Post Office Box 13716, Philadelphia, Pa.

Region IV: Alabama, Georgia, Mississippi, South Carolina, North Carolina, Tennessee, Kentucky and Florida—Peachtree-Seventh Building, Atlanta, Ga.

Region V: Illinois, Indiana, Ohio, Michigan, Wisconsin and Minnesota—Chicago, Ill.

Region VI: Louisiana, Arkansas, Oklahoma, Texas, and New Mexico—Dallas, Tex.

Region VII: Missouri, Iowa, Kansas and Nebraska—Federal Office Building, Kansas City, Mo.

Region VIII: Colorado, Utah, Wyoming, South Dakota, North Dakota, and Montana—Federal Office Building, Denver, Colo.

Region IX: California, Nevada, Arizona, Guam, Hawaii and Samoa—Federal Office Building, San Francisco, Calif.

Region X: Washington, Oregon, Idaho and Alaska—Arcade Building, Seattle, Wash.

POLICY STATEMENT ON AREA DESIGNATION

The need for an explicit statement of the Department's policy on the question of designating PSRO service areas has been made clear in the past several weeks by the apparently contradictory interpretations that have been placed on statements eminating from Congressional and Departmental sources. In reality, of course, the Department has consistently pursued an area designation policy, enunciated earlier this year, that was derived from the statutory language and the clearly expressed intent of the Congress as embodied in the Senate Finance Committee Report. That policy is based on several fundamental premises:

1. The law contemplates the establishment of a fairly substantial number of PSRO areas and, in many instances, the designation of three or more areas within a single State.

2. While the size of a PSRO service area is not specifically addressed by the legislation, it is clear from the Committee Report language that priority in designation as a PSRO is to be given to organizations established at local levels representing the practicing physicians in the local areas.

3. There is a very strong emphasis both in the legislation and the Committee Report on local responsibility and autonomy in the conduct of peer review activities.

4. There are several other critical factors, apart from the absolute size of a PSRO area, that need to be fully assessed in arriving at appropriate area designations. Included among these factors are the following:

(*a*) The designated area should encompass a medical service area and assure broad, diverse representation of all medical specialties.

(*b*) The area should not encompass so large a number of practicing physicians as to preclude the possibility of active physician participation in the review activities of the PSRO.

(c) The existing boundaries of current local peer review organizations and health planning areas should be taken into account.

Based on these assumptions, the Department developed and disseminated guidelines for the designation of PSRO areas and initiated a widespread process of consultation with State and local physician and medical care organizations. While there has been considerable nationwide discussion of the Department's guidelines, particularly that one which attempted to provide some reasonable direction on the appropriate size of a PSRO service area, neither the need for nor the general validity of these guidelines has been challenged. For some, however, the guideline on the size of a PSRO area has created confusion, in part because it was erroneously assumed that the figure included in the guideline was an absolute limit, in part because of a belief that smaller areas, and consequently smaller local organizations would lack the administrative capacity and competence to undertake the tasks of a PSRO, and in part because in large States there was the misconception that Statewide organizations would be precluded from participation in the PSRO program.

It was never the intent of this guideline to exclude experienced State organizations from a role in the PSRO effort. It is recognized that in many cases newly emerging local PSRO organizations will not have the resources or experience to initially organize themselves and undertake without assistance the many activities required. In such circumstances, it would be necessary and desirable for the local organization to turn to a Statewide organization for assistance, guidance, and support. Such a Statewide organization, serving as an administrative, technical resource center, could provide substantial guidance and aid to the local organizations within the State on a variety of organizations, administrative and professional matters. Arrangements of this sort have always been contemplated as fully consistent with the Department's policy, in that such arrangements assure local autonomy and responsibility, provide opportunities for existing Statewide organizations to extend the benefits of their experience, knowledge and capacity to the local organizations, and present opportunities for involving all the organizations in the State in a way that is consistent with the intent of the Congress and the objectives of the legislation.

Thus, the Department's policy is to strive for the designation of multiple PSRO areas within a State and to designate an entire State as a PSRO area only in those States that conform to the Departmental guidelines; to enter into separate agreements with each local PSRO; and to assure satisfactory arrangements by the PSRO's with those State organizations that will be providing technical and administrative support to the local PSRO's. The Department is, therefore, continuing to proceed with the area designation process on the basis of this general policy and will seek to arrive at judgments consistent with the published guidelines and the advice that has been furnished by State and local organizations during the course of the numerous consultation meetings that have been conducted.

PSRO AREA DESIGNATION GUIDELINES

The guidelines developed by the Department for designating appropriate PSRO service areas are as follows:

1. In general, a PSRO area should not cross State lines.—The basis for this guideline is the provision of the law relating to the creation of Statewide councils and the several references in the Senate Finance Committee Report to areas established on a multi-county or State basis. In addition, the Medicaid program is organized on a State-by-State basis.

2. In general, a PSRO area should not divide a county.—Considerations of administrative practicability serve as the basis for this guideline. However, in instances of larger geographic areas or large county populations, it may be necessary and appropriate to divide a county.

3. Existing boundaries of local medical review organizations and health planning areas should be considered.—Since the Senate Finance Committee Report recognizes the existence of local professional medical review organizations, the current boundaries of these organizations should be considered. In addition, established health planning areas need to be considered as possible precedents.

4. A PSRO area should, to the extent possible, coincide with a medical service area and assure broad, diverse representation of all medical specialities.—The PSRO area should be drawn to include, to the extent possible, the existing

medical service or medical trade areas. Consideration should be given to existing medical centers and to natural geographic barriers. In addition, effective peer review is attainable only if the review body has available to it the necessary range of professional expertise.

5. A PSRO area should generally include a minimum of approximately 300 licensed, practicing physicians. While the maximum can be expected to vary with local circumstances, generally, it should not exceed 2,500 licensed, practicing physicians.—The purpose of an approximate limitation on the maximum size of an area's physician population is to emphasize the statutory concepts of local peer review responsibility and the active participation of local practicing physicans in the activities of the PSRO.

6. The designation of a PSRO area should take into account the need to allow effective coordination with Medicare/Medicaid fiscal agents.—This principle is stated in the statute and the Senate Finance Committee Report. Since the PSRO is involved in the Medicare and Medicaid programs, it will have a significant effect on the claims process.

ROLE OF STATEWIDE MEDICAL ORGANIZATIONS IN THE PROFESSIONAL STANDARDS REVIEW PROGRAM

Although the law contemplates the emergence of locally autonomous peer review organizations and includes provision for a Statewide PSR Council in a larger State, there is nothing in the legislative history or intent to preclude other capable Statewide physician or medical organizations from providing advice and assistance on an appropriate basis to local PSRO's. Indeed, the statute clearly assumes that many local PSRO's will need technical and professional assistance and requires the Secretary, through whatever means he deems necessary and appropriate, ". . . to provide all necessary technical and other assistance . . ." to organizations to help them meet the responsibilities of a PSRO.

Thus, a capable Statewide organization, such as a State Medical Society or a State Medical Care Foundation, could serve as the technical, professional PSRO resource center for the several local PSRO's within the State and provide the following types of services:

1. Advice and assistance in the development and evaluation of medical care criteria and professional norms.
2. Advice on the development, implementation and evaluation of peer review methods.
3. Advice and assistance in establishing the PSRO's organizational structure; e.g., designing by-laws, written membership policies, methods for involving physicians in the PSRO's review activities, accounting systems, reports management systems, etc.
4. Assistance in designing and implementing professional educational activities to be performed by PSRO's.
5. Consultation and advice on the organizational and management aspects of PSRO operations.
6. Other types of services mutually agreed upon.

In establishing such an arrangement between a PSRO and a State resource center, the relationship would be one under which the PSRO would retain autonomy with respect to its activities in connection with the review of services within its area, while relying upon the resource center for such advice and assistance as it requires. The Secretary would enter into an agreement with each local PSRO and assure satisfactory arrangements with those State organizations that will be providing technical and administrative support to the local PSRO's.

The concept of a Statewide resource center relates primarily to the role of State medical organizations in larger States with multiple PSRO areas. In these smaller or more sparsely populated States where the area designation is expected to be Statewide, State Medical Societies or Foundations are the logical sponsors of the PSRO's in those States.

ROLE OF THE STATEWIDE PROFESSIONAL STANDARDS REVIEW COUNCIL

Under the law, the Secretary is required to establish a Statewide PSR Council in each State having three or more PSRO areas. The principal responsibilities of the Statewide Council, as prescribed by law, include the review of appeals

from a PSRO's adverse decisions, the dissemination of such information and data as may be determined appropriate by the Secretary to PSRO's, assist the Secretary in the evaluation of PSRO effectiveness and, to the extent provided for by the Secretary, assure the coordination of data gathering procedures applicable to the areas within the State.

While some have expressed concern over the possible overlapping of functions between the Statewide resource center and the Statewide Council, it is clear that the statute makes appropriate provision for the participation of both types of organizations in the implementation of the PSRO program, and for the exercise of subsantial administrative discretion by the Secretary in the determination of the functions to be performed by these organizations.

NATIONAL PSR COUNCIL MEETING

The National Professional Standards Review Council will hold its next meeting November 26 in Room 5051 of the HEW North Building in Washington, D.C., from 9:00 a.m. to 5:00 p.m. Meetings of the Council Subcommittees are scheduled as follows: Policy Development Subcommittee, November 13, 10:00 a.m., Room 17-64 Parklawn Building, Rockville, Maryland; Evaluation Subcommittee, November 25, 8:00 p.m., Mayflower Hotel, Washington, D.C.; Data and Norms Subcommittee, November 26, 7:00 p.m., Mayflower Hotel, Washington, D.C., and November 27, 9:00 a.m., Room 5131 HEW North Building, Washington, D.C. All meetings are open to the public on a space available basis.

(Additional information on items appearing in the MEMO can be obtained from OPSR, Room 17-64, 5600 Fishers Lane, Rockville, Maryland 20852. Your comments on any of the items herein are most welcomed. We would appreciate the assistance of organizations receiving the MEMO in bringing this information to the attention of their members through their newsletters, journals, or by whatever other means they deem appropriate.)

[OPSR Memo, No. 2, December 1973]

OFFICE OF PROFESSIONAL STANDARDS REVIEW,
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Rockville, Md.

PROPOSED PSRO AREA DESIGNATIONS

HEW Secretary Caspar W. Weinberger has designated proposed geographical areas for the establishment of Professional Standards Review Organizations (PSRO')s. The designations were published in the December 20 Federal Register, a copy of which is attached.

The designation of area represents a major step in implementing the 1972 Amendments to the Social Security Act calling for the creation of PSRO's. One hundred and eighty-two (182) areas are proposed. Twenty-five States, the District of Columbia, Puerto Rico and the Virgin Island were each designated as single PSRO's, mainly because of their limited physician populations. The other 25 States had multiple PSRO areas designated.

Major metropolitan areas have been designated as single PSRO's with the understanding that the PSRO for the area will establish a DHEW-approved subdistricting pattern under which the review activities will be carried on by the local physicians in each subdistrict.

The guidelines used in designating PSRO areas also are included in the Federal Register notice.

Once PSRO areas have been established, the next step is the conditional designation of a PSRO for each area. HEW will encourage local physician-sponsored organizations to form the PSRO for their area and will provide assistance to them in meeting the requirements for designation as a PSRO and for carrying out the functions of a PSRO once an organization is no designated.

Until January 1, 1976, only a nonprofit, professional association representing the practicing physicians in an area can qualify as a PSRO. If such an organization does not apply to be a PSRO by that date, HEW can designate another organization, such as a health department or medical school, that has the professional medical competence to be a PSRO. However, even after January 1, 1976, physician organizations must be given priority for designation as a PSRO.

Interested ndividuals and organizations have until January 21 to submit written comments and suggestions on or objections to the proposed area designations. All comments should be forwarded to the Director, Office of Professional Standards Review, Room 17—64 Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20852.

NATIONAL PSR COUNCIL MEETING

The National Professional Standards Review Council will hold its next meeting January 21–22 in Room 5051 of the HEW North Building, Washington, D.C., from 9:00 a.m. to 5:00 p.m. the first day and from 9:00 a.m. to 3:00 p.m. the second day. Meetings of the Council Subcommittees are scheduled as follows: Data and Norms Subcommitte, January 4, 1:00 p.m., to 10:00 p.m. and January 5, 9:00 a.m. to 1:00 p.m., Hyatt-Regency Hotel, Chicago, Illinois; Policy Development Subcommittee, January 14, 11:00 a.m. to 4:00 p.m., Conference Room L, Parklawn Building, Rockville, Maryland: Evaluation Subcommittee, January 20, 7:00 p.m., Mayflower Hotel, Washington, D.C. All meetings are open to the public on a space-available basis.

[OPSR Memo, No. 3, March 1974]

OFFICE OF PROFESSIONAL STANDARDS REVIEW,
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Rockville, Md.

PSRO CONTRACT APPLICATIONS AVAILABLE

The Department of Health, Education, and Welfare has announced that it is now ready to receive applications for contracts from physician organizations seeking to participate in the Professional Standards Review Organization program.

The announcement represents an important step in the implementation of the PSRO law, part of the Social Security Amendments of 1972. Local physician organizations now have the opportunity to take the leadership role in establishing peer review groups to assure that institutional medical care provided under the Medicare, Medicaid and Maternal and Child Health program is necessary, of acceptable quality, and rendered in the most appropriate setting.

HEW will contract with qualified physician organizations to plan PSRO's, to begin operation of PSRO's on a conditional basis, or to establish statewide organizations to provide support services to local PSRO's.

Under the law, HEW was required to designate PSRO geographical areas by January 1, 1974. The proposed areas were published in the December 20 issue of the *Federal Register*, and comments were received from interested individuals individuals and organizations. After reviewing all comments and making necessary adjustments in the PSRO area boundaries, HEW announced final PSRO areas in early March. (Details will be published in the next issue of OPSR Memo.)

Physician organizations in each area can now apply to be the PRSO. Contract requirements are detailed in the PSRO Manual which will accompany the Requests for Proposals.

Until January 1, 1976, only a non-profit, professional association representing the practicing physicians in an area can qualify as a PSRO. If such an organization does not apply to be a PSRO by that date, HEW can designate another organization, such as a health department or medical school, that has the professional medical competence to be a PSRO.

Under the law, an organization, before it can be designated the PSRO for an area, must be designated on a conditional basis for up to 24 months. If, at the end of the conditional period, the PSRO is performing satisfactorily, HEW will enter into an agreement with it for a period of 12 months. These agreements will be renewable on an annual basis and can be terminated by HEW or the PSRO.

Three types of contracts will be awarded:

PLANNING CONTRACTS

These contracts will require an organization to design a formal plan for assuming the duties and functioning of a PSRO in a designated area. The plan will have to include a formal review system, including peer review, to assess

medical care, and organizational structure and membership requirements to carry out the plan in conformance with Departmental guidelines.

In order to be eligible for a planning contract, an organization must meet the following requirements:

1. Be a professional physician association whose membership is open to all doctors of medicine and osteopathy licensed to practice in the PSRO area;
2. Be legally incorporated as a non-profit organization by the time the contracts are scheduled to be awarded;
3. Have a membership which is representative of the physicians in the area, and
4. Have a membership which is composed of at least 25% of the physicians in the area, or demonstrate a potential for achieving such membership.

Although more than one organization is a PSRO area may appiy for a planning contract only one organization per PSRO area will ultimately be conditionally designated as the PSRO.

CONDITIONAL DESIGNATION CONTRACTS

These contracts will require an organization to implement a system for reviewing the quality, necessity and appropriateness of medical care provided to Medicare, Medicaid and Maternal and Child Health program beneficiaries. An organization, in order to be eligible for a conditional PSRO designation contract, must meet the following requirements:

1. Be a professional physician association whose membership is open to all doctors of medicine and osteopathy licensed to practice in the PSRO area;
2. Be legally incorporated as a non-profit organization by the time the contracts are scheduled to be awarded;
3. Have a membership which is representative of the physicians in the area;
4. Have a membership which is composed of at least 25% of the physicians in the area and
5. Have developed an acceptable formal plan for the gradual assumption of review operations, including:
   - (*a*) Development and initiation of review in short-stay hospitals.
   - (*b*) Timetable for phasing in review of long-term care institutions.
   - (*c*) Performance by the organization or by the hospitals given review authority of retrospective medical care evaluation studies.
   - (*d*) Development of mechanism by which review findings can be integrated into existing programs of continuing medical education.
   - (*e*) Plan for evaluation of the inhouse review capability of all hospitals performing review in the PSRO area.
   - (*f*) Plan for the involvement of non-physician health care practitioners in the PSRO's review system.

STATEWIDE PSRO SUPPORT CENTER CONTRACTS

In the December 20, 1973, *Federal Register*, proposed PSRO Area Designations were announced for the entire country. In the "Notice of Proposed Rule-Making," the Department indicated arrangements were being developed for existing organizations to provide assistance in a variety of administrative, organizational and professional matters to newly formed Professional Standards Review Organizations. Statewide PSRO Support Centers will be established through competitive contracting to accomplish this purpose.

PURPOSE OF STATEWIDE PSRO SUPPORT CENTERS

The general purpose of Support Centers shall be to stimulate and support the development and operation of the PSRO program and the local PSROs in a manner consistent with the legislative intent and the policies of the Secretary. Support Centers could thus provide professional administrative and technical support to assist local PSROs in carrying out their standard setting and peer review responsibilities. DHEW contracts with Support Centers would be let on a competitive basis and the tasks to be performed under all contracts and subcontracts would be subject to HEW approval.

ACTIVITIES OF STATEWIDE PSRO SUPPORT CENTERS UNDER DHEW CONTRACT

The Support Centers' initial task would be to provide, as necessary, encouragement to physicians in the local PSRO areas in organizing for the purpose of applying for designation as a conditional PSRO. The DHEW contract would call for the Support Center to:

1. Educate physicians about the PSRO program, peer review and quality assurance.
2. Identify physician groups who desire assistance in meeting the organizational and membership requirements of a PSRO.
3. Assist the physicians in the PSRO areas in meeting the organizational and membership requirements of a PSRO, including but not limited to:
   (*a*) Developing an organizational format and structure as a nonprofit corporation consistent with DHEW rules, regulations, and guidelines.
   (*b*) Developing by-laws that conform to guidelines set forth in the PSRO manual.
   (*c*) Organizing programs to recruit broad physician membership on a continuing basis.

Also, upon request of a candidate PSRO, the Support Center may provide to such an emergent organization technical and professional assistance in the devolpment of a formal plan, such as:

1. Assistance in the development of review procedures, including methods for selection and rotation of reviewing health care professionals.
2. Assistance in familiarizing the PSRO with the options for peer review techniques based on PSRO Manual guidelines.
3. Assistance in planning for the application of medical criteria and standards to the review of institutional care in short-stay hospitals and/or in long-term care institutions.
4. Assistance in the identification of specialists for recruitment as reviewers.
5. Assistanec in formulating a plan for the evaluation of in-house review mechanisms.

ROLE OF SUPPORT CENTERS IN ASSISTING CONDITIONAL AND OPERATIONAL PSROS

Support Centers may also provide needed forms of technical and professional assistance to conditional and operational PSROs upon their request, such as:

1. Assistance in the further development and elaboration of review procedures.
2. Assistance in the continuing recruitment of all types of physicians to ensure a broad base of physician reviewers.
3. Assistance in developing procedures for development of special criteria necessary for the conduct of medical care evaluation studies.
4. Assistance with the analysis and use of data to support PSRO review activities.
5. Assistance in planning programs to train physicians to perform review activities, to conduct medical care evaluation studies, and to interpret aggregate data related to review.
6. Assistance in developing data output formats to measure objectively the effectiveness of review efforts of individual institutions and of the PSRO.
7. Provide common professional and technical services to PSROs as appropriate.
8. Assist the Secretary and PSRO State Councils in coordination and evaluation of PSROs.

ROLE OF SUPPORT CENTERS IN ASSISTING STATE PSRO COUNCIL

Support Centers may enter into contracts with a State PSRO Council at the latter's request. Under such agreements the Support Center may:

1. Assist in the dissemination of information among PSROs.
2. Assist in ensuring sufficient expertise for specialty review in all PSROs within the State.
3. Assist in coordinating the data requirements of PSROs in line with the responsibilities of the State Council.

4. Assist in fostering cooperation between PSROs and appropriate health planning bodies.

5. Assist in developing relationships between individual PSROs and Statewide health and health-related agencies.

STATEWIDE PSRO SUPPORT CENTERS' FUNDAMENTAL QUALIFICATIONS

To qualify as a Support Center an organization must:

1. Be composed primarily of physicians practicing within the State which the organization proposes to serve and have continuing relationships with State medical and other health professional societies, agencies and organizations.

2. Demonstrate that the physicians in the State desire technical assistance from the applicant organization.

3. Demonstrate knowledge of and expertise in the conduct of PSRO-like peer review activities.

4. Demonstrate experience and competence in other areas in which they propose to furnish services.

5. Demonstrate that the workload proposed by the Support Center will be sufficient to require a direct contract with DHEW, particularly in terms of the number of PSROs served.

REQUESTS FOR PROPOSALS

Requests for Proposals on these contracts and copies of the PSRO Manual must be requested in writing from the Contracting Officer, Health Services Administration, Room 16A-30, 5600 Fishers Lane, Rockville, Maryland 20852.

Organizations desiring to apply for planning contracts should request a copy of the Request for Proposal No. HSA 105-BQA-25(4). Those organizations that feel they can qualify for the conditional designation contracts should request a copy of the Request for Proposal No. HSA 105-BQA-26(4). Those organizations that desire to apply for Statewide PSRO Support Center contracts should request a copy of the Request for Proposal No. HSA 105-BQA-29(4). Requests should indicate the PSRO area that the proposal will be designed to serve.

The deadline for submission of proposals for planning contracts will be April 15, 1974. Deadline for conditional designation contract proposals and for contract proposals to serve as Support Centers will be April 30, 1974.

Technical assistance will be available to eligible organizations and will be coordinated through the HEW Regional Offices.

PSRO FOCAL POINTS IN THE HEW REGIONAL OFFICES

Region I: Maine, Vermont, New Hampshire, Massachusetts, Connecticut, and Rhode Island—William Beck, Ph.D., John F. Kennedy Federal Building, Government Center, Boston, Mass.

Region II: New York, New Jersey, Puerto Rico, and Virgin Islands—Lawrence Clare, M.D., Federal Building, Federal Plaza, New York, N.Y.

Region III: Pennsylvania, Maryland, Delaware, Virginia, West Virginia, and District of Columbia—Clyde Couchman, Post Office Box 13716, Philadelphia, Pa.

Region IV: Alabama, Georgia, Mississippi, South Carolina, North Carolina, Tennessee, Kentucky, and Florida—George Reich, M.D., Peachtree-Seventh Building, Atlanta, Ga.

Region V: Illinois, Indiana, Ohio, Michigan, Wisconsin, and Minnesota—Robert Goodnow, Chicago, Ill.

Region VI: Louisiana, Arkansas, Oklahoma, Texas, and New Mexico—Kenneth Schneider, M.D., Dallas, Tex.

Region VII: Missouri, Iowa, Kansas, and Nebraska—Kenneth Mayfield, Federal Office Building, Kansas City, Mo.

Region VIII: Colorado, Utah, Wyoming, South Dakota, North Dakota, and Montana—Leonard Hellman, M.D., Federal Office Building, Denver, Colo.

Region IX: California, Nevada, Arizona, Guam, Hawaii, and Samoa—Robert Harper, Federal Office Building, San Francisco, Calif.

Region X: Washington, Oregon, Idaho, and Alaska—Richard Marquardt, Seattle, Wash.

[OPSR Memo, No. 4, April 1974]

OFFICE OF PROFESSIONAL STANDARDS REVIEW,
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Rockville, Md.

PSRO—ISSUES AND ANSWERS

The implementation of the Professional Standards Review Organization (PSRO) program involves a number of issues that have generated questions from the public, the press and, most importantly, the medical profession. The questions relate to issues such as the confidentiality of patient records, the development and use of norms, standards and criteria of care and whether the PSRO program is primarily concerned with the cost or with the quality of medical care.

These questions arise from a number of concerns. Some of that concern is legitimate. Much of it, however, is based on misinformation and a misunderstanding of the PSRO program.

The American Medical Association recently distributed an information package entitled, "PSRO—Deleterious Effects" for dissemination to the public, the press and the medical profession.

HEW Assistant Secretary for Health Dr. Charles C. Edwards sent a telegram to the AMA voicing objection to the materials in the package. The telegram stated, in part:

"We recognize your concern and your opposition to the PSRO law. But we are deeply disturbed to find that the information in the documents expressing your position is not only factually incorrect but is also incomplete and misleading in its overall presentation.

"Both the Department and the AMA are aware of the fact that there are significant and serious problems which must be addressed in the quality of care being delivered in this country today. Yet many physicians and the public know very little about the PSRO law which was enacted to help improve the quality of care. Therefore, we believe it behooves Government and organized medicine to try to increase public and professional understanding of PSRO and not aggravate the situation through misinformation."

In order to assist the public, the press and the medical profession obtain basic, accurate information about the PSRO program, the Office of Professional Standards Review has prepared and forwarded to the AMA a detailed response on the major issues raised in the materials included in the AMA package. That response follows:

GENERAL COMMENTS

The AMA's PSRO Task Force, as well as AMA staff, have worked closely with HEW personnel and have been generous in their efforts to assist in the development of rational sensitive PSRO program policies. From the beginning, virtually all of the issues raised by the AMA in the materials in this package have been freely discussed and constructive suggestions from affected organizations have been solicited.

Many of the points raised in the AMA package are specifically addressed in the PSRO Program Manual which was prepared by HEW over the last several months. Drafts of the Manual were reviewed in public sessions by the National Professional Standards Review Council and its subcommittees. Drafts were provided also to major professional groups—including the AMA—for comment. The comments of the AMA were reviewed in detail by the Department and many were incorporated into the final draft of the Manual.

As the AMA is aware also, the PSRO Program Manual contains interim guidelines, not final Departmental regulations. The purpose of providing program policies in this form is to permit revision based on the constructive comments of appropriate organizations and on the early experiences of the program as it becomes operational.

However, the information materials developed by the AMA do not appear to have drawn upon the knowledge which the AMA has had about PSRO programmatic guidelines. The materials in the package are totally negative in tone. Aside from our concern that much of the information provided is factually inaccurate and misleading, we do not believe that the majority of American physicians share the views expressed in the package. Indications of support for the program have come to us from a number of individual physicians—many of whom are members

of the AMA—and from physician organizations, including a number of the medical specialty societies and State and county medical societies.

It should be noted also from the outset that many of the review functions which a PSRO is expected to perform were authorized under the Social Security Act prior to the PSRO legislation. The purpose of the PSRO legislation was to give practicing physicians priority in undertaking the review of care provided rather than have the review performed by those outside the medical profession.

DEVELOPMENT AND USE OF NORMS, CRITERIA AND STANDARDS

The AMA raises the question, "Who would have the right to set norms and how would they be determined?" The PSRO Program Manual clearly answers this question in Section 702.2.

"In each of its review activities the PSRO will use norms, criteria, and standards which are useful in identifying possible instances of misutilization of health care services or of the delivery of care of substandard quality. The PSRO is responsible for the development and on-going modification of the criteria and standards and the selection of the norms to be used in its area. While PSRO's may structure themselves in many ways to perform these duties, the overall responsibility for the development, modification and content of norms, criteria and standards rests with the PSRO."

The AMA material also states that "norms could lead to cookbook medicine." Again the PSRO Program Manual addresses this issue in Section 709.

"Norms, criteria, and standards should be used in each type of PSRO review. They should, at least, be used for the initial screening of cases to select those cases requiring more in-depth review. In-depth review should be performed by peers using a combination of more detailed norms, criteria and standards and an assessment of a patient's individual clinical and social situation and the resources of the institution in which care is being provided."

The clear intent is to use norms, criteria, and standards developed by physicians in the PSRO area to aid in selecting cases requiring in-depth review by peers. It is on this more detailed assessment that a peer physician can review a patient's medical and social situation and consider the judgment of the patient's attending physician. Only through such peer review—a process repeatedly supported by the AMA—will ultimate decisions regarding the medical necessity, appropriateness and quality of care be made.

OBJECTIVE OF THE PSRO PROGRAM

The question is raised implicitly and explicitly in the package material as to whether PSRO is primarily a cost control or a quality assurance program. The primary emphasis of the PSRO program is on assuring the quality of medical care. PSRO's are asked to determine for beneficiaries of Medicare, Medicaid and Maternal and Child Health Program if health care delivered in institutions is medically necessary—which is a quality as well as a cost issue—whether it is of a quality which meets physician developed norms, criteria and standards, and whether it is delivered in the setting most appropriate to the patient's needs. PSRO's have no authority to (1) review or set the level of physicians' or institutions' charges; (2) review or set patient eligibility parameters, or (3) review or set the benefits covered under Federally financed health care programs. The PSRO program will identify both overutilization and underutilization of health services. When instances of overutilization are identified, patients wil not be subjected to the hazards of unnecessary hospitalization or services and dollars will be saved. When patients are not receiving what local physicians agree are essential services for a particular problem, the use of these services will increase as will the attendant cost.

COST OF THE PSRO PROGRAM

In an issue closely related to the objective of the PSRO program, the AMA is concerned that the program will generate huge administrative costs and that the dollar savings will not justify these costs.

There is no question that the PSRO involves administrative costs. There have been expenditures for utilization review activities for a number of years. PSRO brings these activities together and adds important quality assurance components. Taken in proper perspective, the cost of this necessary quality assurance program represents a small proportion of the total cost of the health care pro-

grams which PSRO covers. The Administration's proposed $55 million PSRO fiscal year 1975 budget is about one-fourth of one percent of the total estimated cost of the Medicare and Medicaid programs for 1975.

As a result of having PSRO's, those health dollars spent will be spent better and patients whose health care is financed by the Federal Government will be getting better quality care. Taxpayers dollars will be spent more wisely and with ess waste of money and other resources. Physicians agree that their first responsibility is to their patients. While the cost of care is a legitimate consideration, the first consideration always must be the quality of care.

GOVERNMENT ENCROACHMENT IN MEDICAL PRACTICE

The issue is raised in the AMA material that PSRO will interfere with the physician's practice of medicine. PSRO's are composed exclusively of local, practicing physicians. Those physicians form, administer and operate the PSRO in their area, hiring and supervsing those non-physicians necessary to assist in the operation of the PSRO. The physicians develop, select and modify norms, criteria and standards of care. Only physicians can make final review determinations on care provided by physicians.

The Federal Government has no desire or authority to perform review of medical care. HEW agrees with physicians that local practitioners are those best qualified to review care provided by their peers.

TIME AND PAPERWORK REQUIRED BY PSRO

The AMA material states that the PSRO program will lead to "strangulation by paper", that "the data that physicians must prepare for PSRO . . . and acknowledge from it . . . will add new mountains to those which geology has created," and "that this paperwork will cut into the time that physicians give their patients."

The PSRO review system has been designed to minimize physician paperwork. Medical care review, as described in the PSRO Program Manual, does not a require a physician to do any additional routine paperwork. The physician's time will be concentrated on matters requiring professional medical judgment. Other health personnel can be used to do the preliminary screening and handle administrative detail. Paperwork will be kept to a minimum through greater uniformity and standardization in the collection and recording of medical care data. Performing review is on a voluntary basis, as is membership in a PSRO. No physician will be forced to engage in PSRO review activities.

Most physicians already spend time performing peer review and related activities in hospitals. When hospital review is performed satisfactorily, and meets PSRO objectives, the PSRO will not duplicate it. Thus, PSRO review, in most cases, will not require additional time and, therefore, will not decrease the amount of time physicians can spend with their patients.

CONFIDENTIALITY OF PATIENT RECORDS

The concern of the AMA relating to the need for maintaining the confidential nature of data and information used by PSRO's is shared by DHEW. The issue of confidentiality is a problem not only in our present Medicare and Medicaid programs, but also in existing private health insurance plans. Our common concern over confidentiality has precipitated several discussions between the AMA and DHEW personnel. A staff member of the Bureau of Quality Assurance participates as a member of the AMA Task Force on Data Collection, Processing and Storage. In addition, the chairman of this Task Force and the Director of the AMA Health Services Research Center attended a day-long working session with BQA personnel to address the problem of maintaining confidentiality in the PSRO program. These individuals will be involved on a continuing basis in the development of confidentiality safeguards.

That confidentiality was a concern of the Congress is shown by the legislation which contains a reference, Sec. 1155(a)(4) (P.L. 92-603) to the need to develop coding procedures which will "provide maximum confidentiality as to patient identity" and also contained strong prohibition against inappropriate disclosure of information (Sec. 1166). With the help of experts and affected organizations, DHEW currently is developing guidelines and regulations which address confidentiality in very specific terms. These guidelines will be made available to the PSRO's, to data processors who support PSRO's and other

involved groups. Their application will be mandatory for all the PSRO's and all groups which handle data for any PSRO.

The privacy of patients and physicians is a basic civil right and must be respected. Medical records contain a great deal of privileged information but the data collected for PSRO purposes will be limited to that required for review purposes. While the law requires the development of patient and physician profiles, the identity of these individuals is to be protected from disclosure not only to guarantee privacy but also to assure objectivity.

Confidentiality is essentially a problem which requires great sensitivity on the part of the individual user of the information and from all persons who handle the data. Awareness of the importance of protecting information from unauthorized disclosure must be a primary concern of all persons connected with PSRO operations. Maintaining confidentiality assumes that all personnel involved in the PSRO process are aware of and respect the right of privacy of *all* individuals.

A further concern is the need to provide for the security of the privileged information gathered for PSRO purposes. Security relates to guarding this information from theft or deliberate destruction. Unauthorized access to information must be prevented at all points where there is a potential threat. The PSRO legislation does not specifically address this subject but DHEW recognizes that complex data systems require that special attention be given to developing guidelines and regulations which will tightly control access to PSRO data.

PROCEDURES FOR GUARDING PRIVILEGED INFORMATION

The bases for the development of guidelines and regulations relating to privacy, confidentiality and security are the specific statutory requirements of the PSRO legislation and the Report of the Secretary's Advisory Committee on Automated Personal Data Systems entitled Records, Computers and the rights of Citizens. The Advisory Committee included data experts, physicians, lawyers and representatives of other knowledgeable and concerned groups.

The following aspects of privacy, confidentiality and security are being addressed in the development of the PSRO confidentiality policy:

1. Determination of the use of a personal identifier including designation of those documents, forms, and print-outs which will and will not require personal identification.
2. Control of the acquisition of data needed for PSRO purposes including those data acquired through the claims process and by the PSRO itself.
3. Procedures for the handling of data by PSRO personnel and by data processing personnel.
4. Procedures for training PSRO personnel including printed materials and on-site training sessions.
5. Procedures for maintaining physician security of both PSRO and data processing facilities.
6. Mechanisms for data verification by physician, patients, and the PSRO. authorized disclosure and to whom information may be disclosed.
7. Procedures for determining that unauthorized disclosure of information has occurred including specific interpretation of what constitutes authorized disclosure and to whom information may be disclosed.
8. Provisions for (a) purging of files that are inaccurate or (b) no longer necessary for PSRO purposes including definitive points in time when files must be purged and procedures for permitting verification of data maintained by PSRO's.
9. Procedures for maintaining records of access or use made of information in the PSRO review system.

Adequate safeguards against the unauthorized use of data are recognized as a vital component of the operations by PSRO's. Proper implementation and continued monitoring by HEW should alleviate the concerns about the potential threat to the privacy of individuals while at the same time permit the performance of effective peer review.

* * * * * * *

The Department of Health, Education, and Welfare desires to continue the dialogue with concerned physicians and physician groups, as well as the public, regarding all essential elements of the PSRO program. This dialogue is most productive when all concerned have available to them accurate information about the PSRO program as it develops. The Department hopes that the AMA, as well as all other groups representing and communicating with physicians and the public, will provide important, factual information to their constituencies.

Appendix G

Communications Received by Senator Dole Concerning PSRO

OVERLAND PARK, KANS., *May 4 1974.*

Hon. ROBERT DOLE,
U.S. Senator,
Senate Office Building,
Washington, D.C.

DEAR SENATOR DOLE: I would like to thank you for the opportunity to reply to your inquiry as to my feelings as a practicing physician regarding the PSRO legislation. I do hope that this reply will reach you in time for the hearings and may be of some value to you in your deliberations.

I am deeply concerned over the far-reaching implications of the PSRO and the effect that it will have upon the practice of medicine and the quality of medicine—particularly primary medical care.

As you know, the medical profession has for some fifteen years used peer review constantly and systematically in all the accredited hospitals of the United States since such review has been one of the requirements for hospital accreditation. I have not made a study of other professional groups, but to my knowledge, no other group has employed such a system of surveillance of the performance of its members. Thus, it seems difficult to understand that the medical profession should experience stringent government-enforced regulation in the name of better patient care. Contrary to what may be claimed, the peer reviews of which I speak have been effective and so one can only conclude that the additional concept of PSRO, as enacted by the Congress, is not one which has grown out of concern over patient care, but has been motivated entirely by budgetary and monetary considerations.

It might be claimed that it is not improper for the government to enact PSRO in as much as the government is financing more and more of the nation's medical bill if it were not for some very serious deleterious aspects of this control. I would like to indicate some of these which bear greatest concern. I think probably the most serious is the effect of stereotyping physicians and their mode of practice and thereby encouraging wholesale treatment with little or no thought given to the treatment of the individual and his own particular needs. If I may state this in the vernacular, it would be called "cookbook" medicine. If the excellence of the physician's management of a case is to be determined by a computer "criteria card" for a particular illness, rest assured that the physician eventually will find himself treating the criteria card and the computer primarily and the patient secondarily. This will be necessarily so, in as much as the physician's professional standing in the eyes of his peers and his government will be dictated by this criteria. In other words, the patient and his own particular problems must be made to conform to the regulations of the federal government. Probably equally important is the inherent discouragement of psysicians to think and to be able to treat patients as individuals. Not only will the physician find it unnecessary to think for himself, and individualize his treatment, he will find it actually professionally dangerous to do so since his handling of a particular case might be ideal for the patient but contrary to the established criteria card. Certainly this situation cannot be considered conducive to good patient care and it most certainly destroys the deep patient-physician relationship that I find my patients strongly desire even in 1974.

It has been stated that the PSRO concept need not be punitive, but without belaboring the point. I am certain that you will be able to see that there is every possibility and even likelihood for it to become so. Furthermore, it does not stretch ones imagination to envision the problems for the physicians that such information would present in the event of medical-legal situations. I am not concerned about the documentation of the physician's conduct of the case in this event, but the implication that a case was mis-managed if found to be contrary to the computer criteria card would render the defense of the physician essentially impossible.

In summary, I feel that the PSRO legislation is designed for monetary and budgetary reasons and has no relation to better patient care and that it is being imposed upon a professional group who already, for years, has done an out-

standing job in surveillance and control of its members' performance. I feel the PSRO will definitely structure medicine so tightly that individualization of patient care will be lost and that it will no longer be necessary for the physician to study his patient as an individual human being. I feel that there are deep medical-legal and professionally derogatory aspects which cannot be avoided in the PSRO system, and that these amount to gross discrimination against the medical profession. Lastly, I would point out that I believe some twenty-two state medical societies have indicated strong opposition. The Kansas State Medical Society will have its annual meeting this month, so we do not know what its official stand will be.

I realize that the PSRO became law January 1, 1974, but I do not feel that what has been said here is necessarily "after the fact" in as much as there is so much professional opposition expressed. Many physicians have views close to those indicated in this letter, and others are fundamentally in opposition to PSRO but take the position that "the government is going to do it to us anyway so even though it is a bad situation, we had best cooperation and get the best deal we can." This can hardly be considered as wholehearted and enthusiastic support. I have not heard a physician express pleasure and optimism concerning the PSRO, or that it will result in better patient care.

Thank you, Senator Dole, for your invitation to write you regarding this matter. Forgive me if my reply has been lengthy, but I feel that the PSRO represents a turning point in American medicine and that, if accomplished, the results will be greatly disappointing to those who have fostered the program and tragic to the American people and their medical needs.

Sincerely,

JOHN O. BAEKE, M.D.
MERRILL D. ATHON, M.D.
KALE C. GENTRY, M.D.

UNIVERSITY OF KANSAS MEDICAL CENTER,
DEPARTMENT OF FAMILY PRACTICE,
Kansas City, Kans., April 16, 1974.

Senator ROBERT DOLE,
U.S. Senate,
Washington, D.C.

DEAR BOB: I'm writing in response to your letter of April 5, 1974 concerning the hearings before the Senate Health Subcommittee on PRSO legislation.

Bob, I have mixed feelings about the proposed PSRO legislation. There is no doubt in my mind that the consumer of health services in America today expects and deserves a degree of professional accountability far beyond what they have received in the past. Many steps—particularly in the hospitals of our country—have already been taken in that direction over the past 10–15 years. We already have Utilization Review, the Joint Commission on Hospital Accreditation, Tissue Committees, Medicare and Medicaid audits, state licensure of hospitals and physicians, etc.—all of which are directed toward insuring the public of professional accountability. There is no doubt, Senator, that such steps have improved the quality of professional health services by physicians and hospitals. At the same time, it must be recognized that these same steps have created enormous burdens on physicians and hospitals in terms of paper work, additional personnel, expenditures of valuable time, and frustration. Nevertheless, I think most everybody accepts these steps and agrees that they have improved the quality and the accountability.

Now, we are faced with another proposal directed along these same lines. PSRO is well intended and would broaden the accountability into an area which, up until now, has been free of accountability—and that is the outpatient, private office practice of medicine. The overwhelming majority of health services in this country are still delivered outside of the hospital in the private, ambulatory sector.

Probably—we need some method of insuring accountability and quality control in these areas. I think the obvious concern, Senator, of most physicians is how to accomplish this with a minimum of red tape, costs, paper work, time consumption, and frustration. I think it is fair to say that the health care system can get so caught up with outside imposed legislation—designed with good intent—but so self-defeating with red tape, increased costs, etc. that it tends to destroy the idea that it set out to accomplish.

Bob, I guess, in summary, I can support the concept of PSRO—but only if I can be reassured that the legislation, guidelines, administrators, etc. recognize the need to implement PSRO with great care and to recognize that the good that is anticipated must be carefully weighed against the adverse effects. I guess I would urge you to either vote against PSRO legislation or to support it only if you have the guarantees as I have outlined above. With best personal regards, I remain

Very truly yours,

JACK D. WALKER, M.D.,
Chairman, Department of Family Practice.

LAWRENCE, KANS., *April 15, 1974.*

Hon. ROBERT DOLE,
U.S. Senate,
Washington, D.C.

DEAR BOB: Thank you for your letter concerning PSRO legislation. Enclosed is a clipping from one of our journals which, I believe, gives some of the views that we have on this new effort on the part of the liberals to control medicine and, of course, almost everything they can get their hands on.

Personally, I believe that PSRO would be a very good thing if taken care of by professionals that know what they are doing. Bureaucrats would only make a mess of it and, if the doctors try to regulate it, there is too much paranoid feeling among many of the medical men to make a go of it.

The people of the United States, except in very few instances, are getting excellent medical care and it can be improved maybe, but there is such a thing as making medical care worse by inflicting upon the doctors all the legislation that some people want.

Hoping this has given you some idea of my feelings.

Sincerely,

H. PENFIELD JONES, M.D.

RADIOLOGY & NUCLEAR MEDICINE,
TOPEKA, KANS., *April 15, 1974.*

Hon. ROBERT DOLE,
U.S. Senate,
New Senate Office Building,
Washington, D.C.

DEAR BOB: Thank you for your notification of the May 8 and 9 hearings to be held by the Subcommittee on Health of the Finance Committee of the Senate with regard to the status of implementation of PSRO legislation passed by the 92nd Congress. As Chairman of the Commission on Medical Services and Insurance of the American College of Radiology with responsibility for any direct ACR involvement with the PSRO program at the national level, my principal concern is not with the basic philosophic concept of peer review, but rather with the possible misuse of the tools provided to the bureaucracy in the legislation. We fear the diversion of effort away from a strengthened assurance of quality and toward cost containment for its own sake with the sacrifice of quality and professional prerogative.

The parties responsibe for federal management function in this vital area should be required to come to a common understanding that the emphasis in the Law on quality of care must be met by regulations which have the same emphasis. Officials vested with policy function in the BHI/SSA have been quite frank in their expression of intent to use PSRO primarily to control costs, while the OPSR and BQA which report to Dr. Edwards talk mostly about improving and sustaining the quality of medical care. These objectives are not necessarily incompatible, if one looks at cost containment from the standpoint of getting the largest bang for the buck, i.e., the most effective utilization of funds. However, past history demonstrates that bureaucrats tend to regard reduction of expenditure as a first objective, no matter what the result. It is very likely impossible to significantly reduce overall cost while sustaining quality and humanity in health care.

We also have a deep and abiding conviction that the National Professional Standards Review Council—now assigned a quasigovernmental review and

comment function, should be given substantially greater authority over the bureaucracy, so that an entrenched cadre does not become both policy maker and administrative executor.

It is important that the regulations which frame the operation of the PSRO program interfere to the smallest possible extent—preferably not at all—with the professional conduct and practice of the 8 or 9 out of 10 doctors who are engaged in conscientious, up-to-date medicine in and out of hospitals. If less than this is accomplished, the program has a real potential for becoming not only a meddlesome burden for physicians, but an expensive albatross around the neck of a health care system which is already buried by paper-shuffling and record-keeping.

The emphasis on local initiative and local determination in PSRO is laudable. There are, however, very few checks or balances against the virtually absolute power of the Secretary of HEW to render the system entirely centalized and federal in its operation, Senator Bennett—for whom I have the greatest respect—notwithstanding.

I recognize that the Senate Finance Committee—both its respected members and its professional staff—is reluctant to undertake any substantial changes in the Law prior to implementation. However, there are already evident some necessary corrections. The NPSRC may be an appropriate body to receive suggestions from the medical profession and other interested sectors, organize such comment, and present to your Subcommittee a coherent view. Not the least of the recommendations which need to be made is the already-mentioned strengthening of the policy-making role and arbitration power of the NPSRC, granting it a significant degree of autonomy and insulation from bureaucratic interference. It should also be able to relate directly to local and state organizations without going through the Secretary.

The recent action by Secretary Weinberger with regard to pre-admission certification of the necessity for hospital admission is an example of the kind of interference with professional judgment that worries us all. In the first place, the Secretary's directive on this subject imposed the necessity for review of every admission of a federal beneficiary before that patient could be hospitalized under he auspices of the Medicare program. The magnitude of the task alone staggers the mind. More distressing is the inherent assumption that the judgment of all physicians is so poor as to require such an enormous and practically fruitles undertaking. I use this only as an example of the kind of distorted and impractical rationalization by the bureaucracy which arouses both our fear and our anger.

As referral-based physicians whose primary obligation is to do well what other physicians request us to do for their patients, we radiologists are hard at work to define the concepts—and hopefully the methods—which will permit an assessment of the effectiveness with which we are able to perceive and respond to the medical needs of individual patients through the mediation of their personal (primary) physicians. We think it is essential that OPSR be directed legislatively to develop the guidelines for each area of medical service, e.g., hospital-based specialists in radiology, in close cooperation with bonafide representatives designed by the established organzations within that particular special field of medical endeavor. In effect, OPSR should be legislatively directed to write contracts which would embrace and recognize the abilities of an organization such as the American College of Radiology to develop methods for medical audit of radiological services—rather than going about the development of such guidelines within the bureaucracy and without any formal relationship with the specialty organizations of the medical profession.

Virtually all of the comments I have made reflect back upon our basic concern that the necessarily slow and patient process of development of guidelines and methods so essential to the operation of this enormous but fragile program will be pre-empted by a bureaucracy whose objectives may be in conflict with what our profession knows to be good medical practice and patient care. The Health Subcommittee of the Senate Finance Committee could make a major contribution at this very time by promulgating changes in the Law which obviate such an outcome by 1) placing a far greater degree of authority and responsibilitiy on the shoulders of the medical profession as it is represented (in part) by the NPSRC and 2) requiring a close relationship with professional organizations as indicated above.

In the end, the result should be a cooperative effort which supports and encourages good medical practice, not a rigid system which is arrogant, knit-picky, divisive, time-consuming, and top-heavy with bureaucratic encumbrance which demands a mountain of recorded justification for every professional act or dollar spent. It will require real statesmanship on the part of the legislative framers to make those adjustments in the PSRO legislation which are needed to prtvent PL 92-603 from becoming the instrument of transformation of the challenge of medical practice into trial and tribulation which can only be reflected in degration of the standard of medical care available to patients in Kansas and across the nation.

Thank you for the opportunity to place these comments before you.

Most cordially,

JOHN W. TRAVIS, M.D.,
Chairman, Commission on Medical Services and Insurance.

TOPEKA, KANS., *April 22, 1974.*

Hon. ROBERT DOLE,
Senate Office Building,
Washington, D.C.

DEAR SENATOR DOLE: Your letter of April 5, 1974, concerning the hearings on the implementation of PSRO has been received and I am glad that you are requesting grass roots opinion concerning the legislation.

First of all, let me state that I doubt if you will receive very much constructive information in your replies. The reason for this statement is the fact that the guide lines for in-hospital peer review have been received by only a very few physicians and only about ten days ago. Therefore, there has been inadequate time for study and forming an opinion. In addition to this, what the guidelines will be for practice outside of the hospital is fraught with conjecture, speculation and emotionalism. Too many physicians feel that full implementation of the law will introduce unwarranted restraints upon the physician, that it will destroy the proper patient physician relationship, and the confidentiality of patient records. A large number of physicians have the opinion that the primary purpose of PSRO legislation is only a method of economic control.

First, let me express some of my views on peer review. In the first place peer review should be for the purpose of quality control only. Quality assessment can only be made by physicians who are in the active practice of medicine. It can never be properly assessed by non-professional personnel or by physicians in administrative positions, far removed from the daily care of patients. Also it would be essential to define what is meant by "Quality". No two persons would arrive at the same definition. There would be environmental and geographical variations. Then there is the individual patient assessment of quality. I see many patients who have been seen by most competent physicians and who, according to their story have received excellent advice, but they are most critical of the physicians. This of course is the patient-physician relationship, which no type of involuntary regimentation will ever improve.

Now as to PSRO. Personally, I am not opposed to peer review as a mechanism of quality control. Neither am I opposed to utilization review as a mechanism of economic control. However, I believe the combination of the two approaches are incompatible and this will be particularly true when such review is extended to the practice of medicine in the offices of doctors, when the payor is the government or a commercial insurance carrier. How are you going to tell a patient that he doesn't need medical care, and when he is sure that he does? How are you going to deny payments for services so rendered to that patient? And if you do deny payments for such services, what are the long term results? Will the patient pay because it is denied by the third party payor, or is this to be written off as a business loss, therefore necessitating a rise in fees to all patients? In addition, PSRO legislation will by necessity create another bureau or council or what have you, for administrative control. Review committees, be they physicians or other professionals will need be paid for their services. There will be an increase in "paper work", (the bug-a-boo of all physicians) which will add to the costs of health care. In my opinion, the implementation of PSRO in its broadest sense will increase the cost of Health Care, not decrease it. It will cause physicians to practice defensive medicine, with far wider use of laboratory testing, both

clinical and X-ray. Uncontrolled malpractice insurance and the generosity of the courts in malpractice claims have done enough of this without the added impetus of the Federal Government. Basically, I believe the PSRO amendment should be repealed and that peer review should continue to be carried out on a voluntary basis by physicians themselves.

Too frequently the costs of Health Care in 1974 are compared with costs of medical care twenty-five years ago. However, such costs are not comparable. If we were to remove renal dialysis, kidney transplants, coronary by-pass operations, cardiac catheterizations and such procedures now done on a frequent basis, then a possible equitable comparison could be made.

Other areas of economic control could well reduce the inflationary spiral as far as health costs are concerned. For instance, the increase in the minimum wage on May 1, 1974, will increase the manpower costs in one local hospital by about $100,000.00 a year. It is estimated that the ripple effect of the new minimum wage will cost that hospital about $400,000, a year by January 1976. This will mean an increase in the daily room rate of perhaps five to six dollars a day. Can this result be attributed to anyone other than the Congress?

I do not believe that the Congress can properly assess the PSRO amendment until it properly assesses every other rule, regulation or law that is now in the statutes. Before any legislation is introduced or passed every phase of governmental intervention into the health delivery system should be studied. Overlapping programs from different departments should be consolidated into one department. The hospital provision under social security for those who can well afford paying for it themselves should be abolished. The Social Security Medical Insurance for those capable of carrying their own insurance should be abolished, (and I happen to be one who falls in that category). Catastrophic coverage and coverage for those who cannot afford it should be continued.

In summary, let me repeat (1) I favor repeal of the PSRO amendment. (2) I am in favor of voluntary peer review, but I oppose mandatory review. (3) I favor careful reassessment and evaluation of all laws concerned in the health care delivery system, retaining the good, culling out the undesirable, before any further legislation is introduced or considered.

Sincerely yours,

LUCIEN R. PYLE, M.D.

PAOLA, KANS., *April 15, 1974.*

Senator ROBERT DOLE,
New Senate Office Building,
Washington, D.C.

DEAR SENATOR DOLE: I appreciate the opportunity to answer your letter of April 5, 1974 concerning the PSRO implementation. I've had no experience with this at all as nothing has been done in the immediate area. My views about PSRO in general are as follows:

(1) I'm not opposed to PSRO in principle, I think it is possible we can improve medical care through it's implementation and do plan to participate.

(2) I'm concerned that in communities where there are a small number of doctors that their relationship with one another will deteriorate, therefore I feel that direct PSRO supervision in small areas where doctors must work closely together would be best done by a doctor from some distance who would not be involved in the immediate relationship.

(3) I am concerned that those wishing to control costs will exert pressure forcing practices which will lower quality.

(4) Who will determine the policies ultimately that we are to enforce? It would appear at this time that local doctors would set their own standards, but how long will that last? Somewhere, someone will look at a particular area, then another and conclude that they are not cutting costs enough. Eventually we'll all be following a uniform set of standards administered all over the country from Washington, it will only be a matter of time.

(5) All governmental regulations have a tendency to create an attitude in the doctor, whereby he feels more responsible to the government than to the patients.

Already the area of our greatest conflict with patients is in the field of Medicare payments for hospital stays. We are constantly trying to convince the relatives of patients, or the patients themselves that they must leave because medicare will no longer pay their bill, and they are insisting that the patient

requires further hospitalization and they cannot afford to pay it and the patient should be kept under medicare and in the hospital. The doctor continually takes the brunt of this matter and this probably creates more conflict and tension in my practice than any other single thing. It has not been adequately explained to the public exactly what medicare is supposed to do.

I can foresee that in other areas these types of policies will apply also. For instance, there is a policy in Medicare to cover only one Vitamin B–12 shot a month. This is fine if the patient has pernicious anemia, but if we are attempting to treat neuritis, it is not adequate in many cases. It is true that some doctors feel that B–12 will not help neuritis, nevertheless, there are many patients who feel that B–12 is the only source of relief which they have. They simply do not understand why the Medicare and doctor refuse more than one shot a month.

These are perhaps trivial examples, but they do represent the type of thing we get into. I realize it's difficult for the government to always explain every trivial detail of its policies to the entire public of the United States, however, that problem might be one good reason why the government should stay out of things rather than become involved.

Yours Sincerely,

R. E. BANKS, M.D.

COFFEYVILLE, KANS., *April 19, 1974.*

DEAR SENATOR DOLE: The following is a brief but hopefully informative letter as to the feelings of the Southeast Kansas Medical Society regarding PSRO. There is no question that medical societies need to regulate the quality of medicine to the infinitive degree. This our medical society has been doing in the past and will continue to do so in the future. No one recognizes better than our medical society that this needs to be strengthened and improved to insure quality in the practice of medicine whether on an out-patient or in-patient basis. The roll of the government in demanding such is appreciated.

We presently live in a land of democracy where we have a certain inherent right of self government. Our society strongly believes that government implications in PSRO impairs this inherent right and therefore we oppose the program because of the lack of clarity in the aim of the program and the recognition of the federal government wanting more control in another facet of a "free society."

Sincerely,

WILLIAM H. CAMPBELL, M.D.

ARKANSAS CITY, KANS., *May 3, 1974.*

BOB DOLE,
U.S. Senate,
Washington, D.C.

DEAR MR. DOLE: I have delayed purposely in answering and submitting an opinion, regarding the PSRO implementation to be discussed this month by the Health Subcommittee. This issue has been debated in our own County Medical Society by Representatives Roy and Skubitz, and among our members, informally and frequently. It is our opinion that despite its good intent, the PSRO will prove to be another forced intervention, which will not only fail to achieve its purpose, but actually cause further deterioration in the medical care.

Each added control, requires yet another control to gather in the loose ends and repair the problems caused by the last one.

If freedom is really better than the control system, why not demonstrate it by being for freedom and against further controls, as we are adding more and more of them in all phases of our life, yet our several conditions continue to worsen.

Your most sincerely,

GARLAND L. CAMPBELL, M.D.

WICHITA, KANS., *April 23, 1974.*

HON. ROBERT DOLE,
U.S. Senate,
Dirksen Senate Office Building,
Washington, D.C.

DEAR SENATOR DOLE: The following comments are in response to your letter of April 5 in regard to PSRO provision (Section 294F) of Public Law 92–603.

From my reading and discussion with other colleagues it seems that most practicing physicians in the United States favor the repeal of the PSRO program. Although the Senate held hearings on this law the House never did and therefore I feel that few members of the House understood the details of that provision of Public Law 92-603. If repeal cannot be accomplished many of the existing PSRO provisions should be amended. Principally those areas related to criteria and standards, how developed and applied, and the admission as evidence in civil cases. Other areas that should be amended include confidentiality of information, financial penalties, use of information gleaned from provider and patient profiles. Many of these provisions as currently written will create additional problems in relation to malpractice. It is suggested that the law be amended whereby the written records of the PSRO should not be subject to subpoena or used in discovery proceedings in civil actions, nor should any person involved in PSRO programs be subject to subpoena.

My profession believes that the primary purpose of peer review should be assessment and improvement of quality. It is our opinion that assessment and improvement of quality of health care be carried out at the local level by physicians and based on local standards and practice patterns.

The profession recognizes that it is appropriate that the government and the public should encourage and stimulate efforts regarding improvement in medical care delivery. In my opinion these objectives will not be accomplished through the PSRO program. If implemented in its present form it could erode patient physician relationships as well as the relationships between physicians and third parties.

The current law requires the PSRO to review medical services paid for by the federal government such as Medicare and Medicaid. If the PSRO is such a great program should it not equally apply to all care provided through federally sponsored programs such as Public Health Service, the Military Armed Services Medical Corp and the Veterans Administration?

PSRO will necessitate physicians spending more time in review, increase in paper work and therefore less time in patient care. Standardization of patient care according to norms and criteria could lead to cook-book type of medicine which will tend to decrease research, innovations and over-all quality.

It is recognized that the government bears responsibility to monitor funds it expends. It is my opinion that this can be accomplished through modification of the existing peer review program now in effect at the local level. This would eliminate the need to create another super-bureaucracy which could well cost more than it will save. It will create many additional problems and not accomplish its intended objectives.

Yours very truly,

RUTH PAGE, M.D.

MEDICAL SOCIETY OF SEDGWICK COUNTY,
Wichita, Kans., April 18, 1974.

Hon. ROBERT DOLE,
U.S. Senate,
Dirksen Senate Office Building,
Washington, D.C.

MY DEAR SENATOR DOLE: The following comments are in response to your letter of April 5th relative to the PSRO provision (Section 249-F) of Public Law 92-603.

The Society has reviewed in considerable detail the PSRO provisions and has canvassed the membership concerning their views on same. The majority of the local physicians favor the repeal of the PSRO provision as it is now written. It should be pointed out, however, that the profession supports the concept of peer review when its principle purpose is the assessment and improvement of the quality of medical care performed at the local level by local physicians in accordance with community standards and practice patterns.

The basis of our position for repeal is:

(1) It is the Society's opinion that the program in its present form is unworkable. Any nationwide review program should first be implemented on an experimental basis, coupled with thorough evaluation before nationwide implementation. For peer review to be successful, it is necessary to have

the support, assistance and cooperation of the practicing physicians. This is supported by the Arthur D. Little report, a HEW financed study on PSRO.

(2) It is the profession's view that the primary purpose of the PSRO program from the government's standpoint is to reduce health care costs and expenditures rather than assessment and improvement of quality. It is estimated that the startup and operating costs of each PSRO area (203) will be approximately $300,000. It is doubtful that health care costs or expenditures can be reduced by an equal amount through PSRO.

(3) If Congress truly feels that PSRO will accomplish its intended objectives, it is difficult to rationalize why PSRO is not being applied equally to all federally financed health programs, such as the Veterans Administration, the Public Health Service and the military hospitals. The profession totally opposes the immunity of these program areas to PSRO activity.

(4) It is the profession's opinion that the PSRO program ignores the intent of Congress, specifically Section 1801 of Public Law 89-97 which specifically states there shall be no interference in the practice of medicine.

(5) The profession is concerned that the confidentiality of patient records and information will be destroyed through PSRO rules and regulations.

(6) It also appears that information and data collected through the PSRO program, as well as those individuals involved in the PSRO activities, may be subpoened and used as evidence in civil actions. If such is true, this will only compound the current malpractice problems. Because of the inherent increase in paper work, standardization of practice, problems with third parties and governmental intermediaries, the program, if implemented in its present form, in all probability will tend to reduce the number of physicians willing to provide care to patients who are covered under governmental programs.

(7) Although the Senate did hold hearings on PSRO prior to its passage, similar hearings were not held by the House and it is doubtful whether the House members truly understood the details and ramifications of the PSRO provisions.

On the basis of the above reasons, the Board of Directors of the Medical Society of Sedgwick County favors the repeal of the PSRO Law. If repeal is not possible, then the law must be amended in the above mentioned areas whereby the private practice of medicine will not be unduly subjugated by governmental restrictions and/or third party intervention.

The Society appreciates this opportunity to present its view and is hopeful that your thoughtful consideration will be accorded same. If the Society can be of any further assistance to you, please do not hesitate to contact us.

Sincerely yours,

RALPH HALE, M.D., *President.*

LIBERAL, KANS., *April 22, 1974.*

BOB DOLE,
U.S. Senate,
Washington, D.C.

DEAR SENATOR DOLE: I thank you so much for your letter of April 5, 1974 in which you requested my opinion regarding PSRO. I think if PSRO is implemented it should certainly be done by physicians who are in the private practice of Medicine and not be some bureaucrat who is an employee of the federal government. The concept of PSRO does have some merit insofar as it will have beneficial effect on controlling the cost of government medical programs, however, I do not feel that cost is the only factor that should be taken into consideration in providing care for our patients. I do feel there may be some educational benefits which are derived secondarily through a program of this type.

Philosophically, I am opposed to this program which infringes on the private practice of medicine. However, if it is conducted under the direction of physicians in private practice, there may be some beneficial effects which are of a rather minor nature for the amount of funds which I suspect would necessarily have to be appropriated to carry this program out. Again, I thank you so much for your request for my opinion on this matter.

Warmest regards,

RAY E. ALLEN, M.D.

GARDEN MEDICAL SPECIALISTS,
Garden City, Kans., April 18, 1974.

Senator ROBERT DOLE,
U.S. Senate,
Washington, D.C.

DEAR SENATOR DOLE: This letter is in response to your inquiry of April 5, 1974.

I only wish that I had several weeks or even months of time to delve into this problem of a PSRO Legislation and its implementation. Needless to say, I am a very busy practitioner and do not have that time.

In our area, our local Kansas Medical Society Council District has had a committee of physicians authorized under the Kansas Foundation who have made several determinations in this area. These have been with Blue Shield, Medicare, Medicaid and Welfare cases. The physicians reluctantly serve on this committee because of their sparsity of time, but have served well in my opinion.

I think it is tragic that our legislature has deemed it necessary that physicians warrant this type of observation, and monitoring.

I certainly feel it would be unfair to have federally employed personnel performing this task. In a state such as ours, it is even unfair to some extent to having physicians from Topeka or Kansas City making judgment calls regarding how medicine is practiced in Garden City. If this program has to be implemented, I certainly favor the way we are implementing it here by using the Medical Society Counselor Districts as the basic unit.

I cannot complete this letter without commenting on the waste of time that this legislation imposes upon physicians. I wish you could see my desk and the absolutely unnecessary extensive documentation that I have do do to collect fees on any unusual case from Blue Shield, Welfare, Medicare and Medicaid. I would certainly be farther ahead to refuse to treat any patients under Medicare, Medicaid or Welfare. I estimate that the amount of unnecessary paperwork I do restricts me ⅛ to ½ my capabilities in taking care of sick patients. This excessive paperwork extends into all forms of 3rd party insurance coverage. If I could deal directly with patients in all circumstances, I am sure the patients would be happier; I am confident I would be happier, and I would have more time to take care of patients and would have more time to enjoy the good life that I frequently dream of having.

In summary, I am convinced that the United States has the best medical care available of any nation in the world. Bureaucraatic and socialistic restrictions on this system will only serve to slow this evolution toward excellence and in fact will cause many excellent practitioners to retire at an early age or get into some other form of livelihood I, for one, certainly can see myself giving up an active practice of clinical medicine if this oppression I feel at the present time gets any worse.

Thank you for your invitation to express my opinion. I hope you have the time to ponder them.

Respectfully,

RAMON W. SCHMIDT, M.D.

DODGE CITY MEDICAL CENTER,
Dodge City, Kans., April 17, 1974.

Senator BOB DOLE,
Dirksen Senate Office Building,
Washington, D.C.

DEAR SENATOR DOLE: I received a letter from you dated April 5, 1974, regarding PSRO legislation. I have two comments to submit to you, which I hope will be helpful. (1) There should be stringent guidelines built in so that there will not be bureaucratic harassment of physicians indulging in the Peer Review Program. (2) The peers reviewing the doctors should be doctors from the private practice community and not academicians or Fed-type non patient seeing doctors.

I think the physicians will cooperate with PSRO if the spirit of the Federal bureaucracy is one of true understanding and desire to practice the best medicine possible for the patient. I think that it will be severely resented and ultimately destroyed if there is the type of harassment that has been so characteristic of

the Medicare-Medicaid bureaucracy and I would be one of those if I see this occurring, to do everything possible to prevent any additional Federal involvement in physician-patient care.

Sincerely,

MORGAN U. STOCKWELL, M.D.

MEDICAL CENTER, P. A.,
Hutchinson, Kans., April 19, 1974.

Hon. BOB DOLE,
U.S. Senate,
Washington, D.C.

DEAR SENATOR DOLE: Thank you for the opportunity to voice a few comments in regard to PSRO legislation.

First, I have served for several years on peer review and utilization review committees. As you know, this type of hospital care review is not new and we have gained some experience with it. It has been my observation that a very large percentage of physicians are concerned and make every effort to maintain quality care and reduce utilization to a minimum, supervision by the committee not withstanding. Therefore, a great deal of time is wasted surveying what is already obvious by a profession whose time must be considered valuable. Possibly a print-out of all patients' hospital records who fall out of predicted norms would streamline this review.

Second, I can't possibly believe these review committees could include anyone other than physicians. It is difficult enough for me, a pediatrician, to critically examine a psychiatric case, let alone a layman.

I would also add a plea to leave PSRO in the hands of local professional people. If we must have controls to the spending of federal monies for health, let's not waste more on administration than you would save by the harassment of grass roots medicine. There are moments when I think the bureaucracy deserves to be given the privilege of manning the committees, making the reviews, and lastly but not least, telling the patients their final judgements.

Yours very truly,

ROBERT N. SHEARS, M.D.

NORTON, KANS., *April 15, 1974.*

Senator BOB DOLE,
U.S. Senate,
Washington, D.C.

DEAR SENATOR DOLE: It seems as though we doctors are faced by the situation to either "monitor ourselves by and within our own profession or be faced by having it done for us by 'outsiders'"! Frankly I do not want either!

PSRO will really do very little to improve or control the unethical, dishonest physician—and there are those, as in any profession.

It will be creating a super-structure of physicians faced by "paper work" that will lead to a "rubber stamp" approach. I would be very reluctant to serve on a PSRO review or governing body.

I would be even more reluctant to accept the judgement of a non-medical person serving in a PSRO capacity.

The final question and reason for objecting to the whole idea of PSRO is, "Why single out the medical profession?"

Let us also set up review standards and *arbitrarily* apply them to lawyers, and certainly there is no reason to overlook auto manufacturers, auto repairmen, and all of the hundreds of other persons involved in service type professions.

If our goals are to provide the consumer with higher quality of service for less cost (which is unquestionably admirable), then make it a constitutional question applicable to *all* citizens of this great land.

I do not believe that PSRO's are presently constitutional because they are discriminatory.

I plan to continue to try to give quality service at a reasonable fee but I do not plan to divert precious energy to pump life into the PSRO proposition.

Incidentally, if there is any way possible to call back the funds set-up for HMO's, please do so; that is the biggest "loser" of all time!

Sincerely yours,

ROBERT C. LONG, M.D.

AXTELL CLINIC,
Newton, Kans., April 14, 1974.

Hon. BOB DOLE,
U.S. Senate Building,
Washington, D.C.

DEAR SENATOR DOLE: You asked for comments regarding the implication of PSRO legislation. I do have a few. I should make it clear to start with I feel this legislation should be repealed. The improvement in care it would provide and/or the saving of money for the government would be negligible since people doing the on-going studies would necessarily have to be paid, records would have to be kept, etc. and this all costs money.

This would also be duplicating the present efforts of our utilization committees in each of our hospitals. This system already provides control on any mismanagement of medicare patients. I certainly feel that by and large almost all physicians are already doing the very best that they know how and another "big brother" watch dog would not produce any noticeable change in care or any vast saving of money.

The cost of medical care is already high enough, lets not add to it by increasing the costs of administration. If implementation indeed remains a fact, I feel that our present utilization review committees in our individual hospitals, through a coordinated state wide program, could handle the issue. Although I think that these committees, where they are not generally paid a fee for this time spent, would necessarily have to be paid something for their added efforts.

I hope this provides some information for you that will be of use.

Sincerely,

CHARLES A. ISAAC, M.D.

OBERLIN CLINIC, PA.,
Oberlin, Kans., April 19, 1974.

BOB DOLE,
U.S. Senate,
Washington, D.C.

DEAR MR. DOLE: Please accept my personal comments regarding the PSRO legislation. I am a family practioner in rural northwest Kansas. Two of us are in practice together and are the only physicians serving a community of 2500 with a trade and drawing area of about 7,000 people. Our closest specialist and referral city is one hundred miles away which has only partial specialist coverage. Some common specialties, if needed, are 280 miles distance from our town.

The three concerns I have about the PSRO legislation are as follows:

1. Is PSRO necessary and are necessary safeguards provided to prevent exploitation and repression of the minority medical profession by nonprofessionals?
2. Where will we get medical manpower to represent our interests in PSRO from physician-poor areas such as we serve in northwest Kansas?
3. Will PSRO compete and conflict with Utilization Review?

1. Is PSRO necessary? PSRO is an attempt to evaluate quality of medical care by the medical profession itself. It is supposed to provide objective data to support or deny that good quality medical care is being provided. It will say for A type disease, X type tests and procedures will be run and Z type treatment will be rendered. Even if a physician does not feel certain tests and procedures are necessary, he will be compelled to proceed with established procedure of PSRO thereby increasing the cost of medical care. PSRO in many cases will increase the cost of medical care to satisfy established criteria whether or not deemed necessary by the personal physician. I feel that in most cases the quality of care is already available for review through peer review and utilization review. I am fearful that PSRO is an organization wihch will ultimately be used to dictate to physicians how to practice medicine by nonprofessionals.

2. *Manpower.*—We take call and are at the hospital every other night and every other weekend which means we have sixteen evenings and two weekends a month not involved with direct medical care. Of this time, we spend several days on community functions or medical education leaving ten evenings a month and one weekend a month for family time which is still punctured with telephone calls. If I have to spend one day a week or one weekend a month, even though compensated for the time, it would be an excessive demand on my time.

I am already at a breaking point concerning time demands on my professional life and if more itme is required for paperwork without relief, I might have to leave the small community and seek employment in a less trying situation.

3. PSRO as a competing organization—As I understand the PSRO legislation it is designed primarily as a quality control mechanism. It will increase costs rather than decrease costs. Utilization Review, with which we already function, is an attempt at cost control. PSRO will say keep the patient in the hospital for testing and treatment and Utilization Review will say the patient has been in the hospital the standard time for the diagnosis which the patient is being treated and must be discharged. In a small community hospital many procedures ie. Barium x-ray studies, can only be done on certain days when a radiologist is available. The physician will be in a competing dilemma which program to satisfy—PSRO or Utilization Review. This conflict between the two programs will present many competing situations which will be impossible to satisfy both demands.

The three concerns I have about PSRO are my own personal opinions although many small town communities are in a worse manpower shortage than we are and the above concerns would be more magnified in these communities.

Thank you for hearing my viewpoint on the PSRO legislation.

Sincerely,

REN R. WHITAKER, M.D.,
President Northwest Kansas Medical Society.

Appendix H

Memorandum of Law Filed by the Association of American Physicians and Surgeons and the Memorandum in Support of Government's Motion for Summary Judgment Concerning Constitutionality of Professional Standards Review Legislation

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

JUDGE LYNCH

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, a not-for-profit corporation, for and on behalf of its members; and ROY R. GRINKER, SR., GEORGE E. SHAMBAUGH, JR., and EDWARD A. WOLPERT,

Plaintiffs,

vs.

CASPAR W. WEINBERGER, Secretary of the United States Department of Health, Education and Welfare, an Agency of the Federal Government,

Defendant.

73C 1052

COMPLAINT FOR DECLARATORY JUDGMENT AND INJUNCTIVE RELIEF

I. Jurisdiction

1. This is a civil action arising under the Constitution of the United States. The matter in controversy exceeds the value of $10,000, exclusive of interest and costs. This Court's jurisdiction is invoked pursuant to Section 1331 of Title 28 of the United States Code.

2. Plaintiffs seek (1) a declaratory judgment that Paragraph (b) of Section 249F of the "Social Security Amendments of 1972" (October 30, 1972, Pub. L. 92-603, Title II, §249F(b), 86 Stat. 1429) is unconstitutional on its face, and (2) permanent injunctive relief restraining the Defendant from implementing or enforcing

the provisions of said legislation. This Court is authorized to grant such relief in this action by Sections 2201 and 2202 of Title 28 of the United States Code.

3. Convocation of a three-judge court is required in this action by and pursuant to Sections 2282 and 2284 of Title 28 of the United States Code.

4. Plaintiffs expressly reserve the right to apply for preliminary injunctive relief in the future, pursuant to Section 2284 of Title 28, United States Code, as the conduct of the Defendant or change in circumstances may warrant.

II. Parties

1. Plaintiff Association of American Physicians and Surgeons is an Indiana not-for-profit corporation certified to do business in the State of Illinois. Plaintiff Association's national headquarters is located in the Northern District of Illinois. Plaintiff Association was organized for the purpose, inter alia, of improving the quality of medical care by: (a) protecting and improving the welfare and interests of its members in order that the entire medical profession may improve its service through the maintenance of high professional and ethical standards; and (b) protecting the right of the individual physician, as well as his patient, to freedom of action so that the traditional relation of physician and patient be maintained inviolate. Plaintiff Association's membership is composed

of medical practitioners variously licensed to practice medicine in all 50 states, the District of Columbia and Puerto Rico. Plaintiff Association brings this action to assert individual constitutional rights of its members affected in common by the matter in controversy.

2. Plaintiff Roy R. Grinker, Sr., is a citizen of the United States and a resident of the Northern District of Illinois. Plaintiff Grinker is licensed to practice medicine by the State of Illinois, and is certified by the American Board of Neurology and Psychiatry. He is Director of the Institute for Psychosomatic and Psychiatric Research and Training at Michael Reese Hospital and Medical Center, Chicago, Illinois, and is Chairman of that Hospital's Department of Psychiatry. He is a Professor of Psychiatry in the Pritzker School of Medicine, University of Chicago, Chicago, Illinois.

3. Plaintiff George E. Shambaugh, Jr. is a citizen of the United States and a resident of the Northern District of Illinois. Plaintiff Shambaugh is licensed to practice medicine by the State of Illinois and is certified by the American Board of Otolaryngology. He is Professor of Otolaryngology, Northwestern University Medical School, Chicago, Illinois, a member of the Attending Staff of Northwestern Memorial Hospital, Chicago, Illinois, and a member of the Consulting Staff of Henrotin Hospital, Chicago, Illinois.

4. Plaintiff Edward A. Wolpert is a citizen of the United States and a resident of the Northern District of Illinois and is

certified a Diplomate in Psychiatry by the American Board of Neurology and Psychiatry. He is the Director of Clinical Services at the Institute for Psychosomatic and Psychiatric Research and Training, Michael Reese Hospital and Medical Center, Chicago, Illinois, a Clinical Associate Professor of Psychiatry, Pritzker School of Medicine of the University of Chicago, Chicago, Illinois, and a Consultant to the Sonia Shankman Orthogenic School at the University of Chicago.

5. Plaintiffs Grinker, Shambaugh and Wolpert are not members of the Plaintiff Association.

6. Defendant Caspar W. Weinberger is Secretary of the United States Department of Health, Education and Welfare. He is named as the Defendant herein in his capacity as an officer of the United States.

III. Facts

1. Plaintiffs Grinker, Shambaugh, Wolpert, and the members of the Association of American Physicians and Surgeons (for brevity, hereinafter referred to collectively as "Plaintiff Physicians") are professionally competent medical practitioners of good moral character who have now, and will have in the future, patients who are recipients or beneficiaries under the Social Security Act. Each of the Plaintiffs makes his decisions concerning the diagnosis, treatment and care of

his patients solely in accordance with his best medical judgment of his patient's best interests as dictated by his training, experience and skills applied to the circumstances of each individual patient to the extent of his influence and control.

2. Paragraph (b) of Section 249F of the Social Security Amendments of 1972 (October 30, 1972, Pub. L. 92-603, Title II, 86 Stat. 1429) adds a new "Part B" to Title XI of the federal Social Security Act (Aug. 14, 1935, c. 531, Title XI, §§1101 et. seq. 49 Stat. 647, as amended; 42 U.S.C. §1301, et seq.). This "Part B", titled "Professional Standards Review", consists of twenty sections, numbered 1151 through 1170, inclusive. A true copy of the provisions of said Part B is attached to this Complaint as Exhibit A, and hereby incorporated herein.

3. The stated purpose of this legislation is to assure, through the application of "procedures of professional standards review" that services for which payment may be made under the Social Security Act will conform to certain pre-established federal "norms" of practice and that payment for such services will be made only if such services are deemed "medically necessary" by Defendant.

4. Defendant is required to establish, in each of several geographic regions to be designated by him throughout the United States, a "Professional Standards Review Organization" (hereinafter referred to as "PSRO"), which will be charged with regional implementation and enforcement of the scheme of regulation created by the

legislation in question in accordance with regulations promulgated by Defendant. [§1152]

5. Unless restrained from doing so by this Court, Defendant will initiate enforcement of said legislation against Plaintiffs at some time subsequent to the filing of this suit and prior to January 1, 1974.

6. The aforesaid PSRO's are to be private organizations (either pre-existing or specially-formed), designated by Defendant and operating under annual contracts with the Department of Health, Education and Welfare. A PSRO may consist of a group of physicians, or persons engaged in other governmental or non-governmental health care-related fields, such as insurance company employees. Such an organization will have jurisdiction over each of the Plaintiff Physicians and his patients, and the hospitals and similar institutions in which he treats his patients. If a particular PSRO does not enforce physician compliance with the norms of practice and the cost-control measures of the law to Defendant's satisfaction, he may cancel its contract, and award it to another organization [§§1152-1154].

7. Defendant has established a "National Professional Standards Review Council" as an agency of the Department of Health, Education and Welfare, which will develop, under Defendant's direction and control, the pre-set "norms" of diagnosis, treatment and care for

particular illnesses or health conditions to which Plaintiffs will be required to conform their practices, including norms governing the type of treatment Plaintiffs may prescribe for their patients, whether, when and where they may be hospitalized, and for how long. The function of the regional PSRO's under Part B will be to exercise surveillance over the medical judgments and activities of physicians, and the hospitals, clinics and other institutions in which they treat their patients, to insure that they conform to these norms set by the federal government.

8. Section 1167 of Part B purports to grant immunity from criminal or civil liability under any federal or state law to persons providing information to PSRO's or participating in their function, and to grant practitioners immunity from civil liability under federal and state law as a result of their compliance with or reliance on the norms of diagnosis, treatment and care applied by a PSRO.

9. Plaintiffs' ability to render, and their patients' ability to receive health care in accordance with the highest standards of medical practice will be seriously impaired if Plaintiffs are required to conform their medical judgments to a system of pre-set norms of diagnosis, treatment and care. Proper medical practice demands that, in diagnosing and treating a patient, a physician take into consideration a host of often-changing factors that are unique to each patient, and inherently incapable of reduction to "norms".

Superimposition of a system of norms of diagnosis and treatment upon the judgments of medical practitioners will have a chilling effect on the case-by-case practice of medicine and innovative progress in medical practice, to the ultimate detriment of Plaintiffs and their patients.

10. In certain categories of cases, Plaintiff Physicians will be required to obtain approval from a PSRO before they may hospitalize a patient, or enter upon a particular course of treatment, and the PSRO is empowered to deny approval if it deems the hospitalization or treatment medically unnecessary within the meaning of the law, or if it concludes that the particular physician seeking approval would not render services in conformity with the norms of the law [§1155]. Under these provisions, Plaintiffs' patients could be denied treatment Plaintiffs judge to be necessary, or they could be required to obtain such treatment from a physician other than the one of their choice.

11. Under this legislation, Plaintiffs will be required to supply data concerning each patient they treat to be used by a PSRO in maintaining "profiles" of the services Plaintiffs have ordered or rendered, which periodically will be reviewed to determine whether Plaintiffs are complying with the law. The PSRO's also will have authority to (a) make professional inquiries concerning Plaintiffs, either before or after they render services covered by the law,

(b) to examine Plaintiffs' patient records, and (c) to inspect facilities in which services or care are rendered [§1155].

12. Under Section 1160 of the law, Plaintiffs will have the burden of demonstrating by evidence in such form and fashion and at such times as a PSRO may require that they are complying with the norms of practice and cost control measures established by the law, and that they are assuring, to the extent of their influence and control, compliance with the law by their patients and the institutions in which they practice.

13. If Plaintiffs are required to supply information concerning their patients to PSRO's for use in creating physician and patient profiles, and maintain and disclose information necessary to convince a PSRO that they are complying with the law, Plaintiffs will no longer be able to afford their patients the privacy and confidentialit in their relationship that is necessary to foster the full and candid communication essential to diagnosis and treatment.

14. A PSRO will have the authority under the law to disapprove payments for services to Plaintiff Physicians, without prior notice or opportunity for hearing. A PSRO will also have the power to recommend the imposition of sanctions against Plaintiffs upon a finding of "unwillingness or lack of ability substantially to comply" with the law. Upon such a recommendation, the Defendant could, in addition to any other sanction provided by law, temporarily or

permanently exclude Plaintiffs from eligibility to provide services on a reimbursable basis under the Social Security Act, or require as a condition of continued eligibility that Plaintiffs pay the actua or estimated cost of the services found to be medically improper or unnecessary, up to the amount of $5,000 [§1160].

15. Under Section 1159 of the law, Plaintiffs and their patients would be entitled to seek review by Defendant of a PSRO's denial of payment only if the amount involved exceeded one hundred dollars, and would be entitled to seek judicial review of Defendant's denial of payment only when the amount involved exceeded one thousand dollars. PSRO's are thereby effectively empowered to disallow up to one hundred dollars in payment for services rendered by a physician to each patient he treats, as a matter of unreviewable discretion, and the Department of Health Education and Welfare is similarly effectively empowered to disallow such amounts up to one thousand dollars without its decision being subject to judicial review.

16. Plaintiffs will be deterred and hindered in advising and treating their patients as a direct consequence of the coercive effect of the provisions of this legislation. Plaintiffs will be exposed to irreconcilable conflicts between their professional obligations to their patients and their legal obligations under the law in instances where their best judgment concerning the needs o

their patients would not be acceptable to a PSRO upon prior or subsequent review. Such conflicts will have the further collateral effect of undermining the mutual trust and rapport between physicians and their patients that is essential to optimum treatment.

IV. Bases for Relief

1. Enforcement of the Federal Professional Standards Review law will deprive Plaintiffs of their right to practice their profession, in violation of the Fifth Amendment to the United States Constitution.

2. Enforcement of said law will deprive Plaintiffs of their right to administer medical care to their patients in accordance with the highest standards of medical practice and their best professional judgment, in violation of the Fifth Amendment to the United States Constitution.

3. Enforcement of said law will deprive Plaintiffs' patients of their right to receive medical care from physicians of their choice in accordance with the highest standards of medical practice and their physicians' best professional judgment, in violation of the Fifth Amendment to the United States Constitution.

4. Enforcement of said law will deprive Plaintiffs and their patients of the right to privacy in the physician-patient relationship guaranteed them by the First, Fourth, Fifth and Ninth Amendments

to the United States Constitution.

5. Said law, and in particular the provisions thereof requiring Plaintiffs to comply with governmentally-imposed norms of diagnosis, treatment and care, constitutes, on its face, an arbitrary, irrational and overbroad interference with fundamental rights of Plaintiffs and their patients, unjustified by any legitimate and compelling legislative interest, and prohibited by the Fifth Amendment to the United States Constitution.

6. Said law creates legal and factual presumptions, and imposes burdens of justification concerning Plaintiffs' conduct that are inconsistent with, and negate, the presumption of competence, good moral character, and regularity of conduct and motive created by Plaintiffs' licensure, in violation of rights guaranteed Plaintiffs by the Fifth Amendment to the United States Constitution.

7. Enforcement of said law will expose Plaintiffs to irreconcilable conflicts between their professional responsibilities to their patients and their duties under said law, in violation of rights guaranteed them by the Fifth Amendment to the United States Constitution.

8. The duties and obligations imposed upon Plaintiffs under penalty of sanctions by Section 1160 of said law are stated in such vague and uncertain terms that Plaintiffs must necessarily guess at their meaning, contrary to the due process of law guaranteed Plaintiff by the Fifth Amendment to the United States Constitution.

9. The procedures established by said law through which deprivations and sanctions can be imposed upon Plaintiffs and their patients, and by which federal health care recipients can be deprived of their right to treatment by the physician of their choice, are inconsistent with the due process of law required by the Fifth Amendment to the United States Constitution.

10. The duties of disclosure imposed upon Plaintiffs and their patients and the powers of investigation and inspection granted Defendant by said law expose Plaintiffs and their patients to unreasonable searches and seizures prohibited by the Fourth Amendment to the United States Constitution.

11. Said law, and in particular Section 1152 of said law, empowers private organizations that are inherently biased against Plaintiffs by their contractual relationship with Defendant and their economic self-interest, to exercise quasi-judicial authority over Plaintiffs in violation of rights guaranteed Plaintiffs by the Fifth Amendment to the United States Constitution.

12. It is beyond the constitutional legislative authority of Congress to grant the legal immunity against common law tort liability it has attempted to grant in Section 1167 of said law, and said Section therefore is void and of no effect, and its protection will not be available to Plaintiff Physicians.

13. The legal immunity against common law tort liability granted to medical practitioners, providers and others by

Section 1167 of said law violates rights of federal health care recipients guaranteed by the Fifth and Seventh Amendments to the United States Constitution, and therefore could not be relied upon by Plaintiffs as a defense if such an action were brought against them.

14. If the immunity provisions of Section 1167 of said law are unconstitutional, said law deprives Plaintiffs of the right, freedom and ability to order their conduct in accordance with common law standards of due care, and imposes duties and obligations upon them compliance with which may expose them to civil liability to their patients, all in violation of rights guaranteed them by the Fifth Amendment to the United States Constitution.

WHEREFORE, Plaintiffs pray that this Court:

A. Enter a declaratory judgment that Paragraph (b) of Section 249F of the Federal Social Security Amendments of 1972 (October 30, 1972, Pub. L. 92-603, Title II, §249F (b). 86 Stat. 1429) violates Article I, Section 8 of, and the First, Fourth, Fifth, Seventh and Ninth Amendments to, the Constitution of the United States and is therefore void and of no effect in all respects;

B. Issue its injunction immediately and permanently restraining the Defendant Caspar Weinberger, his successors in office, agents and employees from taking any further actions or doing any things to implement or enforce said Paragraph (b) of Section 249F of

the Social Security Amendments of 1972;

C. Allow Plaintiffs their costs herein and grant them such additional or alternative relief as the Court may deem just and appropriate.

R. R. McMahan

Harold L. Jacobson

Hugh C. Griffin

Lord, Bissell & Brook

Casimir R. Wachowski

Attorneys for Plaintiffs

LORD, BISSELL & BROOK
135 South LaSalle Street
Chicago, Illinois 60603
786-6200

EXHIBIT

PROFESSIONAL STANDARDS REVIEW

Sec. 249F. (a) The heading to title XI of the Social Security Act is amended by striking out

"TITLE XI—GENERAL PROVISIONS"

and inserting in lieu thereof

"TITLE XI—GENERAL PROVISIONS AND PROFESSIONAL STANDARDS REVIEW

"PART A—GENERAL PROVISIONS"

(b) Title XI of such Act[55] is further amended by adding the following:

"PART B—PROFESSIONAL STANDARDS REVIEW

"DECLARATION OF PURPOSE

"Sec. 1151. In order to promote the effective, efficient, and economical delivery of health care services of proper quality for which payment may be made (in whole or in part) under this Act and in recognition of the interests of patients, the public, practitioners, and providers in improved health care services, it is the purpose of this part to assure, through the application of suitable procedures of professional standards review, that the services for which payment may be made under the Social Security Act will conform to appropriate professional standards for the provision of health care and that payment for such services will be made—

"(1) only when, and to the extent, medically necessary, as determined in the exercise of reasonable limits of professional discretion; and

"(2) in the case of services provided by a hospital or other health care facility on an inpatient basis, only when and for such period as such services cannot, consistent with professionally recognized health care standards, effectively be provided on an outpatient basis or more economically in an inpatient health care facility of a different type, as determined in the exercise of reasonable limits of professional discretion.

"DESIGNATION OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"Sec. 1152. (a) The Secretary shall (1) not later than January 1, 1974, establish throughout the United States appropriate areas with respect to which Professional Standards Review Organizations may be designated, and (2) at the earliest practicable date after designation of an area enter into an agreement with a qualified organization whereby such an organization shall be conditionally designated as the Professional Standards Review Organization for such area. If, on the basis of its performance during such period of conditional designation, the Secretary determines that such organization is capable of fulfilling, in a satisfactory manner, the obligations and requirements for a Professional Standards Review Organization under this part, he shall enter into an agreement with such organization designating it as the Professional Standards Review Organization for such area.

"(b) For purposes of subsection (a), the term 'qualified organization' means—

"(1) when used in connection with any area—

"(A) an organization (i) which is a nonprofit professional association (or a component organization thereof), (ii) which is composed of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery

in such area, (iii) the membership of which includes a substantial proportion of all such physicians in such area, (iv) which is organized in a manner which makes available professional competence to review health care services of the types and kinds with respect to which Professional Standards Review Organizations have review responsibilities under this part, (v) the membership of which is voluntary and open to all doctors of medicine or osteopathy licensed to engage in the practice of medicine or surgery in such area without requirement of membership in or payment of dues to any organized medical society or association, and (vi) which does not restrict the eligibility of any member for service as an officer of the Professional Standards Review Organization or eligibility for and assignment to duties of such Professional Standards Review Organization, or, subject to subsection (c) (i),

"(B) such other public, nonprofit private, or other agency or organization, which the Secretary determines, in accordance with criteria prescribed by him in regulations, to be of professional competence and otherwise suitable; and

"(2) an organization which the Secretary, on the basis of his examination and evaluation of a formal plan submitted to him by the association, agency, or organization (as well as on the basis of other relevant data and information), finds to be willing to perform and capable of performing, in an effective, timely, and objective manner and at reasonable cost, the duties, functions, and activities of a Professional Standards Review Organization required by or pursuant to this part.

"(c) (1) The Secretary shall not enter into any agreement under this part under which there is designated as the Professional Standards Review Organization for any area any organization other than an organization referred to in subsection (b) (1) (A) prior to January 1, 1976, nor after such date, unless, in such area, there is no organization referred to in subsection (b) (1) (A) which meets the conditions specified in subsection (b) (2).

"(2) Whenever the Secretary shall have entered into an agreement under this part under which there is designated as the Professional Standards Review Organization for any area any organization other than an organization referred to in subsection (b) (1) (A), he shall not renew such agreements with such organization if he determines that—

"(A) there is in such area an organization referred to in subsection (b) (1) (A) which (i) has not been previously designated as a Professional Standards Review Organization, and (ii) is willing to enter into an agreement under this part under which such organization would be designated as the Professional Standards Review Organization for such area;

"(B) such organization meets the conditions specified in subsection (b) (2); and

"(C) the designation of such organization as the Professional Standards Review Organization for such area is anticipated to result in substantial improvement in the performance in such area of the duties and functions required of such organizations under this part.

"(d) Any such agreement under this part with an organization (other than an agreement established pursuant to section 1154) shall be for a term of 12 months; except that, prior to the expiration of such term such agreement may be terminated—

"(1) by the organization at such time and upon such notice to the Secretary as may be prescribed in regulations (except that notice of more than 3 months may not be required); or

"(2) by the Secretary at such time and upon such reasonable notice to the organization as may be prescribed in regulations, but only after the Secretary has determined (after providing such organization with an opportunity for a formal hearing on the matter) that such organization is not substantially complying with or effectively carrying out the provisions of such agreement.

"(e) In order to avoid duplication of functions and unnecessary review and control activities, the Secretary is authorized to waive any or all of the review, certification, or similar activities otherwise required under or pursuant to any provision of this Act (other than this part) where he finds, on the basis of substantial evidence of the effective performance of review and control activities by Professional Standards Review Organizations, that the review, certification, and similar activities otherwise so required are not needed for the provision of adequate review and control.

"(f) (1) In the case of agreements entered into prior to January 1, 1976, under this part under which any organization is designated as the Professional Standards Review Organization for any area, the Secretary shall, prior to entering into any such agreement with any organization for any area, inform (under regulations of the Secretary) the doctors of medicine or osteopathy who are in active practice in such area of the Secretary's intention to enter into such an agreement with such organization.

"(2) If, within a reasonable period of time following the serving of such notice, more than 10 per centum of such doctors object to the Secretary's entering into such an agreement with such organization on the ground that such organization is not representative of doctors in such area, the Secretary shall conduct a poll of such doctors to determine whether or not such organization is representative of such doctors in such area. If more than 50 per centum of the doctors responding to such poll indicate that such organization is not representative of such doctors in such area the Secretary shall not enter into such an agreement with such organization.

"REVIEW PENDING DESIGNATION OF PROFESSIONAL STANDARDS REVIEW ORGANIZATION

"Sec. 1153. Pending the assumption by a Professional Standards Review Organization for any area, of full review responsibility, and pending a demonstration of capacity for improved review effort with respect to matters involving the provision of health care services in such area for which payment (in whole or in part) may be made, under this Act, any review with respect to such services which has not been designated by the Secretary as the full responsibility of such organization, shall be reviewed in the manner otherwise provided for under law.

"TRIAL PERIOD FOR PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"Sec. 1154. (a) The Secretary shall initially designate an organization as a Professional Standards Review Organization for any area on a conditional basis with a view to determining the capacity of such organization to perform the duties and functions imposed under this part on Professional Standards Review Organizations. Such designation may not be made prior to receipt from such organization and approval by the Secretary of a formal plan for the orderly assumption and implementation of the responsibilities of the Professional Standards Review Organization under this part.

"(b) During any such trial period (which may not exceed 24 months), the Secretary may require a Professional Standards Review Organization to perform only such of the duties and functions required under this part of Professional Standards Review Organization as he determines such organization to be capable of performing. The number and type of such duties shall, during the trial period, be progressively increased as the organization becomes capable of added responsibility, so that, by the end of such period, such organization shall be considered a qualified organization only if the Secretary finds that it is substantially carrying out in a satisfactory manner, the activities and functions required of Professional Standards Review Organizations under this part with respect to the review of health care services provided or ordered by physicians and other practitioners and institutional and other health care facilities, agencies, and organizations. Any of such duties and functions not performed by such organization during such period shall be performed in the manner and to the extent otherwise provided for under law.

"(c) Any agreement under which any organization is conditionally designated as the Professional Standards Review Organization for any area may be terminated by such organization upon 90 days notice to the Secretary or by the Secretary upon 90 days notice to such organization.

"DUTIES AND FUNCTIONS OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"Sec. 1155. (a) (1) Notwithstanding any other provision of law, but consistent with the provisions of this part, it shall (subject to the provisions of subsection (g)), be the duty and function of each Professional Standards Review Organization for any area to assume, at the earliest date practicable, responsibility for the review of the professional activities in such area of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under this Act for the purpose of determining whether—

"(A) such services and items are or were medically necessary;

"(B) the quality of such services meets professionally recognized standards of health care; and

"(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type. . . .

"(2) Each Professional Standards Review Organization shall have the authority to determine, in advance, in the case of—

"(A) any elective admission to a hospital, or other health care facility, or

"(B) any other health care service which will consist of extended or costly courses of treatment,

whether such service, if provided, or if provided by a particular health care practitioner or by a particular hospital or other health care facility, organization, or agency, would meet the criteria specified in clauses (A) and (C) of paragraph (1).

"(3) Each Professional Standards Review Organization shall, in accordance with regulations of the Secretary, determine and publish, from time to time, the types and kinds of cases (whether by type of health care or diagnosis involved, or whether in terms of other relevant criteria relating to the provision of health care services) with respect to which such organization will, in order most effectively to carry out the purposes of this part, exercise the authority conferred upon it under paragraph (2).

"(4) Each Professional Standards Review Organization shall be responsible for the arranging for the maintenance of and the regular review of profiles of care and services received and provided with respect to patients, utilizing to the greatest extent practicable in such patient profiles, methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation consistent with the purposes of this part. Profiles shall also be regularly reviewed on an ongoing basis with respect to each health care practitioner and provider to determine whether the care and services ordered or rendered are consistent with the criteria specified in clauses (A), (B), and (C) of paragraph (1).

"(5) Physicians assigned responsibility for the review of hospital care may be only those having active hospital staff privileges in at least one of the participating hospitals in the area served by the Professional Standards Review Organization and (except as may be otherwise provided under subsection (e) (1) of this section) such physicians ordinarily should not be responsible for, but may participate in the review of care and services provided in any hospital in which such physicians have active staff privileges.

"(6) No physician shall be permitted to review—

"(A) health care services provided to a patient if he was directly or indirectly involved in providing such services, or

"(B) health care services provided in or by an institution, organization, or agency, if he or any member of his family has, directly or indirectly, any financial interest in such institution, organization, or agency.

For purposes of this paragraph, a physician's family includes only his spouse (other than a spouse who is legally separated from him under a decree of divorce or separate maintenance), children (including legally adopted children), grandchildren, parents, and grandparents.

"(b) To the extent necessary or appropriate for the proper performance of its duties and functions, the Professional Standards Review Organization serving any area is authorized in accordance with regulations prescribed by the Secretary to—

"(1) make arrangements to utilize the services of persons who are practitioners of or specialists in the various areas of medicine (including dentistry), or other types of health care, which persons shall, to the maximum extent practicable, be individuals engaged in the practice of their profession within the area served by such organization;

"(2) undertake such professional inquiry either before or after, or both before and after, the provision of services with respect to which such organization has a responsibility for review under subsection (a) (1);

"(3) examine the pertinent records of any practitioner or provider of health care services providing services with respect to which such organization has a responsibility for review under subsection (a) (1); and

"(4) inspect the facilities in which care is rendered or services provided (which are located in such area) of any practitioner or provider.

"(c) No Professional Standards Review Organization shall utilize the services of any individual who is not a duly licensed doctor of medicine or osteopathy to make final determinations in accordance with its duties and functions under this part with respect to the professional conduct of any other duly licensed doctor of medicine or osteopathy, or any act performed by any duly licensed doctor of medicine or osteopathy in the exercise of his profession.

"(d) In order to familiarize physicians with the review functions and activities of Professional Standards Review Organizations and to promote acceptance of such functions and activities by physicians, patients, and other persons, each Professional Standards Review Organization, in carrying out its review responsibilities, shall (to the maximum extent consistent with the effective and timely performance of its duties and functions)—

"(1) encourage all physicians practicing their profession in the area served by such Organization to participate as reviewers in the review activities of such Organizations;

"(2) provide rotating physician membership of review committees on an extensive and continuing basis;

"(3) assure that membership on review committees have the broadest representation feasible in terms of the various types of practice in which physicians engage in the area served by such Organization; and

"(4) utilize, whenever appropriate, medical periodicals and similar publications to publicize the functions and activities of Professional Standards Review Organizations.

"(e) (1) Each Professional Standards Review Organization shall utilize the services of, and accept the findings of, the review committees of a hospital or other operating health care facility or organization located in the area served by such organization, but only when and only to the extent and only for such time that such committees in such hospital or other operating health care facility or organization have demonstrated to the satisfaction of such organization their capacity effectively and in timely fashion to review activities in such hospital or other operating health care facility or organization (including the medical necessity of admissions, types and extent of services ordered, and lengths of stay) so as to aid in accomplishing the purposes and responsibilities described in subsection (a) (1), except where the Secretary disapproves, for good cause, such acceptance.

"(2) The Secretary may prescribe regulations to carry out the provisions of this subsection.

"(f) (1) An agreement entered into under this part between the Secretary and any organization under which such organization is designated as the Professional Standards Review Organization for any area shall provide that such organization will—

"(A) perform such duties and functions and assume such responsibilities and comply with such other requirements as may be required by this part or under regulations of the Secretary promulgated to carry out the provisions of this part; and

"(B) collect such data relevant to its functions and such information and keep and maintain such records in such form as the Secretary may require to carry out the purposes of this part and to permit access to and use of any such records as the Secretary may require for such purposes.

"(2) Any such agreement with an organization under this part shall provide that the Secretary make payments to such organization equal to the amount of expenses reasonably and necessarily incurred, as determined by the Secretary, by such organization in carrying out or preparing to carry out the duties and functions required by such agreement.

"(g) Notwithstanding any other provision of this part, the responsibility, for review of health care services of any Professional Standards Review Organization shall be the review of health care services provided by or in institutions, unless such Organization shall have made a request to the Secretary that it be charged with the duty and function of reviewing other health care services and the Secretary shall have approved such request.

"NORMS OF HEALTH CARE SERVICES FOR VARIOUS ILLNESSES OR HEALTH CONDITIONS

"SEC. 1156. (a) Each Professional Standards Review Organization shall apply professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice in its regions (including typical lengths-of-stay for institutional care by age and diagnosis) as principal points of evaluation and review. The National Professional Standards Review Council and the Secretary shall provide such technical assistance to the organization as will be helpful in utilizing and applying such norms of care, diagnosis, and treatment. Where the actual norms of care, diagnosis, and treatment in a Professional Standards Review Organization area are significantly different from professionally developed regional norms of care, diagnosis, and treatment, approved for comparable conditions, the Professional Standards Review Organization concerned shall be so informed, and in the event that appropriate consultation and discussion indicate reasonable basis for usage of other norms in the area concerned, the Professional Standards Review Organization may apply such norms in such area as are approved by the National Professional Standards Review Council.

"(b) Such norms with respect to treatment for particular illnesses or health conditions shall include (in accordance with regulations of the Secretary)—

"(1) the types and extent of the health care services which, taking into account differing, but acceptable, modes of treatment and methods of organizing and delivering care are considered within the range of appropriate diagnosis and treatment of such illness or health condition, consistent with professionally recognized and accepted patterns of care;

"(2) the type of health care facility which is considered, consistent with such standards, to be the type in which health care services which are medically appropriate for such illness or condition can most economically be provided.

"(c) (1) The National Professional Standards Review Council shall provide for the preparation and distribution, to each Professional Standards Review Organization and to each other agency or person performing review functions with respect to the provision of health care services under this Act, of appropriate materials indicating the regional norms to be utilized pursuant to this part. Such data concerning norms shall be reviewed and revised from time to time. The approval of the National Professional Standards Review Council of norms of care, diagnosis, and treatment shall be based on its analysis of appropriate and adequate data.

"(2) Each review organization, agency, or person referred to in paragraph (1) shall utilize the norms developed under this section as a principal point of evaluation and review for determining, with respect to any health care services which have been or are proposed to be provided, whether such care and services are consistent with the criteria specified in section 1155(a) (1).

"(d) (1) Each Professional Standards Review Organization shall—

"(A) in accordance with regulations of the Secretary, specify the appropriate points in time after the admission of a patient for inpatient care in a health care institution, at which the physician attending such patient shall execute a certification stating that further inpatient care in such institution will be medically necessary effectively to meet the health care needs of such patient; and

"(B) require that there be included in any such certification with respect to any patient such information as may be necessary to enable such organization properly to evaluate the medical necessity of the further institutional health care recommended by the physician executing such certification.

"(2) The points in time at which any such certification will be required (usually, not later than the 50th percentile of lengths-of-stay for patients in similar age groups with similar diagnoses) shall be consistent with and based on professionally developed norms of care and treatment and data developed with respect to length of stay in health care institutions of patients having various illnesses, injuries, or health conditions, and requiring various types of health care services or procedures.

"SUBMISSION OF REPORTS BY PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"Sec. 1157. If, in discharging its duties and functions under this part, any Professional Standards Review Organization determines that any health care practitioner or any hospital, or other health care facility, agency, or organization has violated any of the obligations imposed by section 1160, such organization shall report the matter to the Statewide Professional Standards Review Council for the State in which such organization is located together with the recommendations of such Organization as to the action which should be taken with respect to the matter. Any Statewide Professional Standards Review Council receiving any such report and recommendation shall review the same and promptly transmit such report and recommendation to the Secretary together with any additional comments or recommendations thereon as it deems appropriate. The Secretary may utilize a Professional Standards Review Organization, in lieu of a program review team as specified in sections 1862 and 1866, for purposes of subparagraph (C) of section 1862(d)(1) and subparagraph (F) of section 1866(b)(2).

"REQUIREMENT OF REVIEW APPROVAL AS CONDITION OF PAYMENT OF CLAIMS

"Sec. 1158. (a) Except as provided for in section 1159, no Federal funds appropriated under any title of this Act (other than title V) for the provision of health care services or items shall be used (directly or indirectly) for the payment, under such title or any program established pursuant thereto, of any claim for the provision of such services or items, unless the Secretary, pursuant to regulation determines that the claimant is without fault if—

"(1) the provision of such services or items is subject to review under this part by any Professional Standards Review Organization, or other agency; and

"(2) such organization or other agency has, in the proper exercise of its duties and functions under or consistent with the purposes of this part, disapproved of the services or items giving rise to such claim, and has notified the practitioner or provider who provided or proposed to provide such services or items and the individual who would receive or was proposed to receive such services or items of its disapproval of the provision of such services or items.

"(b) Whenever any Professional Standards Review Organization, in the discharge of its duties and functions as specified by or pursuant to this part, disapproves of any health care services or items furnished or to be furnished by any practitioner or provider, such organization shall, after notifying the practitioner, provider, or other organization or agency of its disapproval in accordance with subsection (a), promptly notify the agency or organization having responsibility for acting upon claims for payment for or on account of such services or items.

"HEARINGS AND REVIEW BY SECRETARY

"Sec. 1159. (a) Any beneficiary or recipient who is entitled to benefits under this Act (other than title V) or a provider or practitioner who is dissatisfied with a determination with respect to a claim made by a Professional Standards Review Organization in carrying out its responsibilities for the review of professional activities in accordance with paragraphs (1) and (2) of section 1155(a) shall, after being notified of such determination, be entitled to a reconsideration thereof by the Professional Standards Review Organization and, where the Professional Standards Review Organization reaffirms such determination in a State which has established a Statewide Professional Standards Review Council, and where the matter in controversy is $100 or more, such determination shall be reviewed by professional members of such Council and, if the Council so determined, revised.

"(b) Where the determination of the Statewide Professional Standards Review Council is adverse to the beneficiary or recipient (or, in the absence of such Council in a State and where the matter in controversy is $100 or more), such beneficiary or recipient shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 205(b), and, where the amount in controversy is $1,000 or more, to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g). The Secretary will render a decision only after appropriate professional consultation on the matter.

"(c) Any review or appeals provided under this section shall be in lieu of any review, hearing, or appeal under this Act with respect to the same issue.

"OBLIGATIONS OF HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES; SANCTIONS AND PENALTIES; HEARINGS AND REVIEW

"Sec. 1160. (a) (1) It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this Act, to assure that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this Act—

"(A) will be provided only when, and to the extent, medically necessary; and

"(B) will be of a quality which meets professionally recognized standards of health care; and

"(C) will be supported by evidence of such medical necessity and quality, in such form and fashion and at such time as may reasonably be required by the Professional Standards Review Organization in the exercise of its duties and responsibilities;

and it shall be the obligation of any health care practitioner in ordering, authorizing, directing, or arranging for the provision by any other person (including a hospital or other health care facility, organization, or agency), of health care services for any patient of such practitioner, to exercise his professional responsibility with a view to assuring (to the extent of his influence or control over such patient, such person, or the provision of such services) that such services or items will be provided—

"(D) only when, and to the extent, medically necessary; and

"(E) will be of a quality which meets professionally recognized standards of health care.

"(2) Each health care practitioner, and each hospital or other provider of health care services, shall have an obligation, within reasonable limits of professional discretion, not to take any action, in the exercise of his profession (in the case of any health care practitioner), or in the conduct of its business (in the case of any hospital or other such provider), which would authorize any individual to be admitted as an inpatient in or to continue as an inpatient in any hospital or other health care facility unless—

"(A) inpatient care is determined by such practitioner and by such hospital or other provider, consistent with professionally recognized health care standards, to be medically necessary for the proper care of such individual; and

"(B) (i) the inpatient care required by such individual cannot, consistent with such standards, be provided more economically in a health care facility of a different type; or

"(ii) (in the case of a patient who requires care which can, consistent with such standards, be provided more economically in a health care facility of a different type) there is, in the area in which such individual is located, no such facility or no such

facility which is available to provide care to such individual at the time when care is needed by him.

"(b) (1) If after reasonable notice and opportunity for discussion with the practitioner or provider concerned, any Professional Standards Review Organization submits a report and recommendations to the Secretary pursuant to section 1157 (which report and recommendations shall be submitted through the Statewide Professional Standards Review Council, if such Council has been established, which shall promptly transmit such report and recommendations together with any additional comments and recommendations thereon as it deems appropriate) and if the Secretary determines that such practitioner or provider, in providing health care services over which such organization has review responsibility and for which payment (in whole or in part) may be made under this Act has—

"(A) by failing, in a substantial number of cases, substantially to comply with any obligation imposed on him under subsection (a), or

"(B) by grossly and flagrantly violating any such obligation in one or more instances,

demonstrated an unwillingness or a lack of ability substantially to comply with such obligations, he (in addition to any other sanction provided under law) may exclude (permanently for such period as the Secretary may prescribe) such practitioner or provider from eligibility to provide such services on a reimbursable basis.

"(2) A determination made by the Secretary under this subsection shall be effective at such time and upon such reasonable notice to the public and to the person furnishing the services involved as may be specified in regulations. Such determination shall be effective with respect to services furnished to an individual on or after the effective date of such determination (except that in the case of institutional health care services such determination shall be effective in the manner provided in title XVIII with respect to terminations of provider agreements), and shall remain in effect until the Secretary finds and gives reasonable notice to the public that the basis for such determination has been removed and that there is reasonable assurance that it will not recur.

"(3) In lieu of the sanction authorized by paragraph (1), the Secretary may require that (as a condition to the continued eligibility of such practitioner or provider to provide such health care services on a reimbursable basis) such practitioner or provider pay to the United States, in case such acts or conduct involved the provision or ordering by such practitioner or provider of health care services which were medically improper or unnecessary, an amount not in excess of the actual or estimated cost of the medically improper or unnecessary services so provided, or (if less) $5,000. Such amount may be deducted from any sums owing by the United States (or any instrumentality thereof) to the person from whom such amount is claimed.

"(4) Any person furnishing services described in paragraph (1) who is dissatisfied with a determination made by the Secretary under this subsection shall be entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g).

"(c) It shall be the duty of each Professional Standards Review Organization and each Statewide Professional Standards Review Council to use such authority or influence it may possess as a professional organization, and to enlist the support of any other professional or governmental organization having influence or authority over health care practitioners and any other person (including a hospital or other health care facility, organization, or agency) providing health care services in the area served by such review organization, in assuring that each practitioner or provider (referred to in subsection (a)) providing health care services in such area shall comply with all obligations imposed on him under subsection (a).

"NOTICE TO PRACTITIONER OR PROVIDER

"Sec. 1161. Whenever any Professional Standards Review Organization takes any action or makes any determination—

"(a) which denies any request, by a health care practitioner or other provider of health care services, for approval of a health care service or item proposed to be ordered or provided by such practitioner or provider; or

"(b) that any such practitioner or provider has violated any obligation imposed on such practitioner or provider under section 1160,

such organization shall, immediately after taking such action or making such determination, give notice to such practitioner or provider of such determination and the basis therefor, and shall provide him with appropriate opportunity for discussion and review of the matter.

"STATEWIDE PROFESSIONAL STANDARDS REVIEW COUNCILS; ADVISORY GROUPS TO SUCH COUNCILS

"Sec. 1162. (a) In any State in which there are located three or more Professional Standards Review Organizations, the Secretary shall establish a Statewide Professional Standards Review Council.

"(b) The membership of any such Council for any State shall be appointed by the Secretary and shall consist of—

"(1) one representative from and designated by each Professional Standards Review Organization in the State;

"(2) four physicians, two of whom may be designated by the State medical society and two of whom may be designated by the State hospital association of such State to serve as members on such Council; and

"(3) four persons knowledgeable in health care from such State whom the Secretary shall have selected as representatives

of the public in such State (at least two of whom shall have been recommended for membership on the Council by the Governor of such State).

"(c) It shall be the duty and function of the Statewide Professional Standards Review Council for any State, in accordance with regulations of the Secretary, (1) to coordinate the activities of, and disseminate information and data among the various Professional Standards Review Organizations within such State including assisting the Secretary in development of uniform data gathering procedures and operating procedures applicable to the several areas in a State (including, where appropriate, common data processing operations serving several or all areas) to assure efficient operation and objective evaluation of comparative performance of the several areas and, (2) to assist the Secretary in evaluating the performance of each Professional Standards Review Organization, and (3) where the Secretary finds it necessary to replace a Professional Standards Review Organization, to assist him in developing and arranging for a qualified replacement Professional Standards Review Organization.

"(d) The Secretary is authorized to enter into an agreement with any such Council under which the Secretary shall make payments to such Council equal to the amount of expenses reasonably and necessarily incurred, as determined by the Secretary, by such Council in carrying out the duties and functions provided in this section.

"(e) (1) The Statewide Professional Standards Review Council for any State (or in a State which does not have such Council, the Professional Standards Review Organizations in such State which have agreements with the Secretary) shall be advised and assisted in carrying out its functions by an advisory group (of not less than seven nor more than eleven members) which shall be made up of representatives of health care practitioners (other than physicians) and hospitals and other health care facilities which provide within the State health care services for which payment (in whole or in part) may be made under any program established by or pursuant to this Act.

"(2) The Secretary shall by regulations provide the manner in which members of such advisory group shall be selected by the Statewide Professional Standards Review Council (or Professional Standards Review Organizations in States without such Councils).

"(3) The expenses reasonably and necessarily incurred, as determined by the Secretary, by such group in carrying out its duties and functions under this subsection shall be considered to be expenses necessarily incurred by the Statewide Professional Standards Review Council served by such group.

"NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

"Sec. 1163. (a) (1) There shall be established a National Professional Standards Review Council (hereinafter in this section referred to as the 'Council') which shall consist of eleven physicians, not otherwise in the employ of the United States, appointed by the

Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service.

"(2) Members of the Council shall be appointed for a term of three years and shall be eligible for reappointment.

"(3) The Secretary shall from time to time designate one of the members of the Council to serve as Chairman thereof.

"(b) Members of the Council shall consist of physicians of recognized standing and distinction in the appraisal of medical practice. A majority of such members shall be physicians who have been recommended by the Secretary to serve on the Council by national organizations recognized by the Secretary as representing practicing physicians. The membership of the Council shall include physicians who have been recommended for membership on the Council by consumer groups and other health care interests.

"(c) The Council is authorized to utilize, and the Secretary shall make available, or arrange for, such technical and professional consultative assistance as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Council such secretarial, clerical and other assistance and such pertinent data prepared by, for, or otherwise available to, the Department of Health, Education, and Welfare as the Council may require to carry out its functions.

"(d) Members of the Council, while serving on business of the Council, shall be entitled to receive compensation at a rate fixed by the Secretary (but not in excess of the daily rate paid under GS–18 of the General Schedule under section 5332 of title 5, United States Code), including travel time; and while so serving away from their homes or regular places of business, they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in Government service employed intermittently.

"(e) It shall be the duty of the Council to—

"(1) advise the Secretary in the administration of this part;

"(2) provide for the development and distribution, among Statewide Professional Standards Review Councils and Professional Standards Review Organizations of information and data which will assist such review councils and organizations in carrying out their duties and functions;

"(3) review the operations of Statewide Professional Standards Review Councils and Professional Standards Review Organizations with a view to determining the effectiveness and comparative performance of such review councils and organizations in carrying out the purposes of this part; and

"(4) make or arrange for the making of studies and investigations with a view to developing and recommending to the Secretary and to the Congress measures designed more effectively to accomplish the purposes and objectives of this part.

"(f) The National Professional Standards Review Council shall from time to time, but not less often than annually, submit to the

Secretary and to the Congress a report on its activities and shall include in such report the findings of its studies and investigations together with any recommendations it may have with respect to the more effective accomplishment of the purposes and objectives of this part. Such report shall also contain comparative data indicating the results of review activities, conducted pursuant to this part, in each State and in each of the various areas thereof.

"APPLICATION OF THIS PART TO CERTAIN STATE PROGRAMS RECEIVING FEDERAL FINANCIAL ASSISTANCE

"Sec. 1164. (a) In addition to the requirements imposed by law as a condition of approval of a State plan approved under any title of this Act under which health care services are paid for in whole or part, with Federal funds, there is hereby imposed the requirement that provisions of this part shall apply to the operation of such plan or program.

"(b) The requirement imposed by subsection (a) with respect to such State plans approved under this Act shall apply—

"(1) in the case of any such plan where legislative action by the State legislature is not necessary to meet such requirement, on and after January 1, 1974; and

"(2) in the case of any such plan where legislative action by the State legislature is necessary to meet such requirement, whichever of the following is earlier—

"(A) on and after July 1, 1974, or

"(B) on and after the first day of the calendar month which first commences more than ninety days after the close of the first regular session of the legislature of such State which begins after December 31, 1973.

"CORRELATION OF FUNCTIONS BETWEEN PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS AND ADMINISTRATIVE INSTRUMENTALITIES

"Sec. 1165. The Secretary shall by regulations provide for such correlation of activities, such interchange of data and information, and such other cooperation consistent with economical, efficient, coordinated, and comprehensive implementation of this part (including, but not limited to, usage of existing mechanical and other data-gathering capacity) between and among—

"(a) (1) agencies and organizations which are parties to agreements entered into pursuant to section 1816, (2) carriers which are parties to contracts entered into pursuant to section 1842, and (3) any other public or private agency (other than a Professional Standards Review Organization) having review or control functions, or proved relevant data-gathering procedures and experience, and

"(b) Professional Standards Review Organizations, as may be necessary or appropriate for the effective administration of title XVIII, or State plans approved under this Act.

"PROHIBITION AGAINST DISCLOSURE OF INFORMATION

"Sec. 1166. (a) Any data or information acquired by any Professional Standards Review Organization, in the exercise of its duties and functions, shall be held in confidence and shall not be disclosed to any person except (1) to the extent that may be necessary to carry out the purposes of this part or (2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care.

"(b) It shall be unlawful for any person to disclose any such information other than for such purposes, and any person violating the provisions of this section shall, upon conviction, be fined not more than $1,000, and imprisoned for not more than six months, or both, together with the costs of prosecution.

"LIMITATION ON LIABILITY FOR PERSONS PROVIDING INFORMATION, AND FOR MEMBERS AND EMPLOYEES OF PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS, AND FOR HEALTH CARE PRACTITIONERS AND PROVIDERS

"Sec. 1167. (a) Notwithstanding any other provision of law, no person providing information to any Professional Standards Review Organization shall be held, by reason of having provided such information, to have violated any criminal law, or to be civilly liable under any law, of the United States or of any State (or political subdivision thereof) unless—

"(1) such information is unrelated to the performance of the duties and functions of such Organization, or

"(2) such information is false and the person providing such information knew, or had reason to believe, that such information was false.

"(b) (1) No individual who, as a member or employee of any Professional Standards Review Organization or who furnishes professional counsel or services to such organization, shall be held by reason of the performance by him of any duty, function, or activity authorized or required of Professional Standards Review Organizations under this part, to have violated any criminal law, or to be civilly liable under any law, of the United States or of any State (or political subdivision thereof) provided he has exercised due care.

"(2) The provisions of paragraph (1) shall not apply with respect to any action taken by any individual if such individual, in taking such action, was motivated by malice toward any person affected by such action.

"(c) No doctor of medicine or osteopathy and no provider (including directors, trustees, employees, or officials thereof) of health care services shall be civilly liable to any person under any law of the United States or of any State (or political subdivision thereof) on account of any action taken by him in compliance with or reliance upon professionally developed norms of care and treatment applied by a Professional Standards Review Organization (which has been designated in accordance with section 1152(b) (1) (A)) operating

in the area where such doctor of medicine or osteopathy or provider took such action but only if—

"(1) he takes such action (in the case of a health care practitioner) in the exercise of his profession as a doctor of medicine or osteopathy (or in the case of a provider of health care services) in the exercise of his functions as a provider of health care services, and

"(2) he exercised due care in all professional conduct taken or directed by him and reasonably related to, and resulting from, the actions taken in compliance with or reliance upon such professionally accepted norms of care and treatment.

"AUTHORIZATION FOR USE OF CERTAIN FUNDS TO ADMINISTER THE PROVISIONS OF THIS PART

"Sec. 1168. Expenses incurred in the administration of this part shall be payable from—

"(a) funds in the Federal Hospital Insurance Trust Fund;

"(b) funds in the Federal Supplementary Medical Insurance Trust Fund; and

"(c) funds appropriated to carry out the health care provisions of the several titles of this Act;

in such amounts from each of the sources of funds (referred to in subsections (a), (b), and (c)) as the Secretary shall deem to be fair and equitable after taking into consideration the costs attributable to the administration of this part with respect to each of such plans and programs.

"TECHNICAL ASSISTANCE TO ORGANIZATIONS DESIRING TO BE DESIGNATED AS PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

"Sec. 1169. The Secretary is authorized to provide all necessary technical and other assistance (including the preparation of prototype plans of organization and operation) to organizations described in section 1152(b) (1) which—

"(a) express a desire to be designated as a Professional Standards Review Organization; and

"(b) the Secretary determines have a potential for meeting the requirements of a Professional Standards Review Organization;

to assist such organizations in developing a proper plan to be submitted to the Secretary and otherwise in preparing to meet the requirements of this part for designation as a Professional Standards Review Organization.

"EXEMPTIONS OF CHRISTIAN SCIENCE SANATORIUMS

"Sec. 1170. The provisions of this part shall not apply with respect to a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts."

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, etc., et al.,

Plaintiffs,

v.

CASPAR W. WEINBERGER, Secretary of the United States Department of Health, Education & Welfare, an Agency of the Federal Government,

Defendant.

No. 73 C 1653

MEMORANDUM IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

CONTENTS

STATEMENT OF FACTS

I.

Background

Until recently in our country's history, the federal government had not acted in any substantial manner as a third-party payer of medical and hospital bills. With the enactment into law of the medicare and medicaid programs,[1] however, the federal government became the largest health insurer in the United States.[2]

Congress was aware, of course, at the time of the enactment of these social programs that tremendous costs would be incurred; however, recent statements by Congressional committees disclose that the costs actually incurred by medicare and medicaid are far greater than the costs originally anticipated. As the United States Senate Committee on Finance noted:

> According to recent estimates the costs of the medicare hospital insurance program will overrun the estimates made in 1967, by some $240 billion over a 25-year period. The monthly premium costs for part B of medicare -- doctors' bills -- rose from a total of $6 monthly per person on July 1, 1966, to $11.60 per person on July 1, 1972. Medicaid costs are also rising at precipitous rates.[3]

The Senate Committee on Finance felt that the rapidly increasing costs of medicare and medicaid were attributable to two factors: (1) an increase in the unit costs of medical services and (2) an increase in the number of

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1/ Pub. L. 89-97, 79 Stat. 286, July 30, 1965. The medicare program is now set forth in subchapter XVIII to the Social Security Act, 42 U.S.C. §§1395-1395pp; the medicaid program is set forth in subchapter XIX to the Social Security Act, 42 U.S.C. §§1396-1396i.

2/ 118 Cong. Rec. S16111 (daily ed. Sept. 27, 1972) (remarks of Senator Bennett).

3/ Sen. R. No. 92-1230, 92d Cong., 2d Sess. 254 (1972) (hereinafter referred to as "Sen. R. No. 92-1230").

services provided to beneficiaries. With regard to the latter factor, the Committee stated:

> . . . The Committee on Finance has, for several years, focused its attention on methods of assuring proper utilization of these services. That utilization controls are particularly important was extensively revealed in hearings conducted by the subcommittee on medicare and medicaid. Witnesses testified that a significant proportion of the health services provided under medicare and medicaid are probably not medically necessary. In view of the per diem costs of hospital and nursing facility care, and the costs of medical and surgical procedures, the economic impact of this overutilization becomes extremely significant. Aside from the economic impact the committee is most concerned about the effect of overutilization on the health of the aged and the poor. Unnecessary hospitalization and unnecessary surgery are not consistent with proper health care. 4/

Since the inception of the medicare and medicaid programs, Congress has grappled with the problem of insuring proper utilization of medical services for beneficiaries. 5/ Because the legislation challenged in the instant suit is Congress' latest attempt to solve this problem, it would

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4/ Sen. R. No. 92-1230 at 254.

5/ In 1965, the Senate Committee on Finance stated with regard to the pending medicare and medicaid legislation:

> The committee is particularly concerned that the utilization and review function is carried out in a manner which protects the patients while at the same time making certain that they remain in the hospital only so long as is necessary, and that every effort be made to move them from the hospital to other facilities which can provide less expensive, but equal, care to meet their current medical needs.

Sen. R. No. 404, 89th Cong., 1st Sess. 47 (1965).

appear helpful to an understanding of the challenged legislation to examine both the methods of utilization review presently in operation and the criticisms of such methods.

II.

Present Utilization Review Methods

Subchapter XVIII of the Social Security Act ["medicare"], 42 U.S.C. §§1395-1395pp, is divided into three parts: Part A, 42 U.S.C. §§1395c-1395i-2, deals with hospital insurance benefits for the aged; Part B, 42 U.S.C. §§1395j-1395w, deals with supplementary medical insurance benefits for the aged; and Part C, 42 U.S.C. §§1395x-1395pp, deals with miscellaneous provisions relative to the entire medicare program. The entire medicaid program is set forth in subchapter XIX of the Social Security Act, 42 U.S.C. §§1396-1396i.

At the present time, the utilization review procedures for benefits provided by Part A of medicare are different from the utilization review procedures for benefits provided by Part B. Similarly, the utilization review procedures for benefits provided by medicaid are different from those used for medicare. For purposes of clarity, therefore, the utilization review procedures for each group of services will be examined separately.

A.

Utilization Review Procedures For Benefits Provided By Part A Of Medicare

Part A of medicare is designed to provide "basic protection against the costs of hospital and related post-hospital services" for eligible individuals aged 65 or older, 42 U.S.C. §1395c. Hospitals and extended care facilities which receive reimbursement for treatment of eligible

individuals under Part A of medicare are required by 42 U.S.C. §§1395x(e)(6) and 1395x(j)(8) to have a utilization review plan which meets the requirements of 42 U.S.C. §1395x(k). Section 1395x(k)(2) provides for a review of hospital services by either (1) "a staff committee of the institution composed of two or more physicians, with or without participation of other professional personnel," or (2) a group outside the institution which is similarly composed and (a) established by a local medical society and some or all of the hospitals and extended care facilities in the locality or (b) established in such other manner as may be approved by the Secretary of Health, Education and Welfare. The review committee must examine on a sample or other basis:

> . . . admissions to the institution, the duration of the stays therein, and the professional services (including drugs and biologicals) furnished (A) with respect to the medical necessity of the services, and (B) for the purpose of promoting the most efficient use of available health facilities and services . . . . 42 U.S.C. §1395x(k)(1).

Pursuant to 42 U.S.C. §1395hh, the Secretary of Health, Education and Welfare (hereinafter referred to as the "Secretary") has promulgated regulations setting forth the utilization review requirements of Section 1395x(k) in greater detail. One such regulation requires that a hospital's review plan:

> should have as its over-all objective the maintenance of high quality patient care, and an increase in effective utilization of hospital services to be achieved through an educational approach involving study of patterns of care, and the encouragement of appropriate utilization. 20 C.F.R. §405.1035(b)(2).

Other applicable regulations provide, inter alia, that a hospital's utilization review plan be in writing, 20 C.F.R. §405.1035(d); that the review committee be broadly representative of the hospital's medical staff, 20 C.F.R. §405.1035(e)(2)(iii); and that records be kept of the activities of the committee, 20 C.F.R. §405.1035(h).

Regulations also provide for termination of inpatient hospital benefits where a utilization review committee makes a finding that inpatient services are no longer medically necessary, 20 C.F.R. §405.162. A similar provision covers post-hospital care, 20 C.F.R. §405.166. Review is mandatory in "long-stay" (over 20 days) inpatient cases and failure to make such a review requires termination of benefits, 20 C.F.R. §405.163. A similar regulation covers "long-stay" outpatient cases, 20 C.F.R. §405.167. Notice and hearing in case of termination of benefits are also provided for by regulation, 20 C.F.R. §405.617.

If a hospital or extended care facility wishes to be reimbursed through a public agency or private organization for treatment of eligible individuals under Part A of medicare, the Secretary is authorized to enter into an agreement with such agency or organization providing for:

> . . . the determination by such agency or organization . . . of the amount of the payments required pursuant to this part to be made to such providers, and for the making of such payments by such agency or organization to such providers. 42 U.S.C. §1395h(a).

Section 1395h(b) further provides:

> The Secretary shall not enter into an agreement with any agency or organization under this section unless

> . . . he finds . . . (1) that such agency or organization is willing and able to assist the providers to which payments are made through it under this part in the application of safeguards against unnecessary utilization of services furnished by them to individuals entitled to hospital insurance benefits under section 426 of this title, and the agreement provides for such assistance, and (2) such agency or organization agrees to furnish to the Secretary such of the information acquired by it in carrying out its agreement under this section as the Secretary may find necessary in performing his functions under this part.

Regulations issued relative to 42 U.S.C. §1395h provide that the Secretary may enter into an agreement authorized by Section 1395h with an agency or organization if the Secretary finds that:

> Where the proposed agreement is to provide that the nominated agency or organization is to assist providers in the application of safeguards against unnecessary utilization of services under Subpart A of this part, such agency or organization is willing and able to provide such assistance . . . . 20 C.F.R. §405.660(b).[6/]

B.

Utilization Review Procedures For Benefits Provided By Part B Of Medicare

Part B of medicare establishes "a voluntary insurance program to provide medical insurance benefits" for eligible individuals aged 65 or

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6/ It has been noted:

> Most non-profit community hospitals as well as some other types of hospitals, (a total of 6876 out of 7906 hospitals) nominated the Blue Cross Association as intermediary through their membership in the American Hospital Association. Additionally somewhat more than half of the extended care facilities also selected Blue Cross as their fiscal intermediary. The balance of the extended care facilities selected various commercial insurance companies as fiscal intermediaries. In addition, certain facilities, primarily government hospitals have elected to deal directly with the Government.

Staff of Senate Comm. on Finance, 91st Cong., 2d Sess., Medicare and Medicaid -- Problems, Issues, and Alternatives 113 (Comm. Print 1970) (Hereinafter referred to as "Staff Report").

older; the program is financed by premium payments from enrollees together with federal funds, 42 U.S.C. §1395j.

Pursuant to 42 U.S.C. §1395u, the Secretary is authorized to contract with carriers [7] in order to have such carriers disburse the benefits provided by Part B. Section 1395u(a)(2)(B) provides that the carriers operating under such a contract may be authorized by the Secretary to:

> . . . assist providers of services and other persons who furnish services for which payment may be made under this part in the development of procedures relating to utilization practices, make studies of the effectiveness of such procedures and methods for their improvement, assist in the application of safeguards against unnecessary utilization of services furnished by providers of services and other persons to individuals entitled to benefits under this part, and provide procedures for and assist in arranging, where necessary, the establishment of groups outside hospitals (meeting the requirements of section 1395(k)(2) of this title) to make reviews of utilization . . . . 42 U.S.C. §1395u(a)(2)(B).[8]

7/ "Carrier" is defined as:

> . . . a voluntary association, corporation, partnership, or other nongovernmental organization which is lawfully engaged in providing, paying for, or reimbursing the cost of, health services under group insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar group arrangements, in consideration of premiums or other periodic charges payable to the carrier, including a health benefits plan duly sponsored or underwritten by an employee organization. . . . 42 U.S.C. §1395u(f)(1).

8/ The authorization set forth in Section 1395u has been restated by regulation, 20 C.F.R. §405.677(d).

A regulation promulgated in furtherance of the legislative purpose behind 42 U.S.C. §1395u provides:

> A carrier which has entered into a contract with the Secretary shall:
>
> * * *
>
> (c) Institute utilization safeguards which include methods for professionally assuring that payments made under part B title XVIII are for covered services which are medically necessary. If, after appropriate consultation, the carrier concludes that a service or services for which a claim has been made were not medically necessary or that the claim as presented is improper in reflecting the amount and character of services rendered, the carrier is responsible for taking appropriate action with respect to adjustment or rejection of the claim.
>
> (d) Establish methods and procedures for identifying utilization patterns which deviate from medically established norms, and bring such patterns of utilization to the attention of appropriate professional groups.
>
> * * *
>
> (f) Maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under paragraph (c) of this section and otherwise to carry out the purposes of the supplementary medical insurance benefits plan. 20 C.F.R. §405.678.

C.

Utilization Review Procedures For Benefits Provided By Medicaid

Medicaid authorizes a yearly appropriated sum to be made available to states in order to enable the states to furnish medical and rehabilitative

services to families with dependent children and to aged, blind or disabled individuals with insufficient income, 42 U.S.C. §1396. In order to be eligible for medicaid assistance, a state must designate or establish a single state agency to administer the medicaid plan or to supervise the administration of the plan, 42 U.S.C. §1396a(a)(5).

Section 1902(a)(30) of the Social Security Act, 42 U.S.C. §1396a(a)(30), provides that an eligible state plan must:

> . . . provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments (including payments for any drugs provided under the plan) are not in excess of reasonable charges consistent with efficiency, economy, and quality of care.

The necessary utilization review procedures for state programs receiving medicaid funds are described in 45 C.F.R. §250.20. The regulation provides that the utilization review committee of a hospital established under Part A of medicare may be delegated to act as the review committee for medicaid. If the review is not delegated to this committee, the medical assistance unit of the single state agency must perform and/or monitor utilization reviews. The regulation provides:

> Review of professional services through existing peer review mechanism is encouraged to the fullest extent possible. 45 C.F.R. §250.20(a)(1)(ii).

The regulation further provides that the medical assistance unit of the single state agency is responsible for all utilization review plans and activities under the medicaid program.

III.

Criticism Of Present Utilization Review Procedures

Criticism of the present utilization review procedures varies with the type of procedure concerned; for purposes of clarity, therefore, the criticisms of each review procedure will be discussed separately.

A.

Criticism Of Utilization Review Procedures Under Part A Of Medicare

When the issue of utilization review under Part A of medicare was before the staff of the Senate Committee on Finance in 1970, the staff noted:

> . . . Based on a sample of hospitals taken in the middle of 1968, the Social Security Administration found:
>
> 1. 10 percent of the hospitals not conducting a review of extended stay cases.
>
> 2. 47 percent of hospitals were not reviewing any admissions (a basic statutory requirement).
>
> 3. 42 percent of hospitals did not even maintain an abstract of the medical record or other summary form which could provide a basis for evaluating utilization by diagnosis or other common factor.
>
> In one State, the health agency conducted a detailed program review in November 1968. Their findings were that half of the hospitals and all of the extended care facilities failed to perform any sample reviews of cases which were not in the long-stay category (a statutory requirement).9/

A number of reasons have been proffered for the ineffectiveness of Part A's utilization review procedures. As stated by one Senator:

> Review solely within the hospital is generally inadequate. This sort of review has largely been a failure in the past, as hospital utilization review committees appear reluctant either

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9/ Staff Report at 107.

> to antagonize fellow staff members (who often refer and consult with each other) or to reduce the hospital's bed census. Secondly, institutional utilization review committees are usually too small to make efficient use of computor profiles, and other aids to the review process. Thirdly, and perhaps most important, only one aspect of medical care is reviewed. Hospital utilization review committees, which may meet as infrequently as once a month, do not provide a logical nor comprehensive focus for the continuing review of total patient care -- physicians' office services, skilled nursing home care, drugs, physical therapy, and so forth.[10]

The deficiencies with the present method of institutional utilization review have also been noted by the Senate Finance Committee:

> The detailed information which the committee has collected and developed as well as internal reports of the Social Security Administration indicate clearly that utilization review activities have, generally speaking, been of a token nature and ineffective as a curb to unnecessary use of institutional care and services. Utilization review in medicare can be characterized as more form than substance. The present situation has been aptly described by a State medical society in these words:
>
> > Where hospital beds are in short supply, utilization review is fully effective. Where there is no pressure on the hospital beds, utilization review is less intense and often token.[11]

Review by fiscal intermediaries[12] has also been found to be ineffective. The Senate Finance Committee noted:

> Available data indicate that in many cases intermediaries have not been performing these functions satisfactorily despite the fact that the Secretary may not, under the law, make agreements with an intermediary who is unwilling, or unable, to assist providers of services with utilization review functions.[13]

10/ 116 Cong. Rec. 32845 (1970) (Remarks of Senator Bennett).

11/ Sen. R. No. 92-1230 at 255-56.

12/ See footnote 6, supra, and accompanying text.

13/ Sen. R. No. 92-1230 at 256.

A number of reasons have been suggested for the ineffectiveness of intermediary utilization review:

> For example, one intermediary reported that it was somewhat hesitant to require the hospitals for which it acts as intermediary to do a more effective job of utilization review or to take other steps to control costs, fearing that some of the providers would choose another less critical and more accommodating organization as intermediary. Thus, the intermediary nominating provision, originally intended to furnish assurance to hospitals that they would be dealing with a familiar organization under the new program, may lead to situations which subvert cost control aspects of the program. While there have not been widespread changes in intermediary assignments, the mere threat of change operates in a negative way to dampen positive administration.
>
> Moreover, under this provision it is possible for intermediaries to offer themselves to an institution with the understanding, implicit or explicit, that in return for its nomination the intermediary will give preferential treatment to the institution. We have learned of situations in Florida, Connecticut and in Pennsylvania where the intermediary also began underwriting the casualty and other insurance needs of institutions. Thus, the relationship can be profitable to both the intermediary (despite the fact that it receives no more than costs for its medicare services) and the institution -- to the possible detriment of the program and probably to the beneficiaries as well.[14]

B. —

Criticism Of Utilization Review Procedures Under Part B Of Medicare

The basic criticism of utilization review under Part B of medicare arises out of the fact that the responsibility for such review is largely in the hands of non-medical personnel employed by various carriers.[15] The Senate Committee on Finance has stated:

14/ Staff Report at 114.

15/ See footnote 7, supra, and accompanying text.

> Apart from the problems experienced in connection with their determinations of 'reasonable' charges, the performance of the carriers responsible for payment for physicians' services under medicare has also varied widely in terms of evaluating the medical necessity and appropriateness of such services. Moreover, ever since medicare began, physicians have expressed resentment that their medical determinations are challenged by insurance company personnel.[16]

During hearings on medicare and medicaid, members of the medical profession indicated displeasure at having non-medical personnel reviewing the medical decisions of doctors. One officer of a medical society stated:

> I think what we are saying is that if there are professionals, both on the private and public level, there would be no problem in the peer review mechanism. The great fear that patients and physicians would have is that there would be any system instituted whereby nonphysician personnel would attempt to evaluate professional activity. Clearly it would not be a very proper situation.
>
> Unfortunately and very regrettably in some sections of the country where there are carriers, insurance carriers, who have not put forth the kind of effort necessary to get effective cooperation from the profession, there are nonprofessionals attempting to evaluate medical problems.[17]

Thus, while the criticism of utilization review procedures under Part A of medicare is based largely on the ineffectiveness of institutional review, the criticism of the utilization review procedures under Part B is based largely upon (1) the varying performance records of the different carriers and (2) the fact that non-medical personnel are supervising and often overruling the medical decisions of professional doctors.

16/ Sen. R. No. 92-1230 at 256.

17/ Hearings on Medicare and Medicaid Before a Subcomm. of the Senate Comm. on Finance, 91st Cong., 2d Sess. 651 (1970) (Comment of Dr. Andrew L. Thomas, Secretary, House of Delegates, National Medical Association).

C.

Criticism Of Utilization Review Procedures Under Medicaid

Because the single state agency responsible for monitoring each state's utilization review programs under medicaid is allowed to designate the utilization review committees set up under Part A of medicare as its utilization review mechanism,[18] it necessarily follows that the criticisms of the institutional review procedures of Part A of medicare apply with equal force to institutional review procedures of medicaid.

In addition, there is evidence that state agencies are not well suited to review the medical opinions of doctors. A representative of the New York Department of Health has stated:

> I would say that generally health departments are not particularly enthusiastic about this kind of activity. They have not been trained historically and by activity to be the kind of monitors that are needed.[19]

IV.

The Utilization Review Procedures Established By The Challenged Legislation

Section 249F of Title II of the 1972 amendments to the Social Security Act,[20] codified at 42 U.S.C. §§1320c-1320c-19, added a new Part B to Title XI of the Social Security Act. This new Part, entitled "Professional

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18/ See page 9, supra.

19/ Hearings on Medicare and Medicaid Before a Subcomm. of the Senate Comm. on Finance, 91st Cong., 2d Sess. 520 (1970) (Comment of Dr. Lowell E. Bellin, First Deputy Commissioner, Department of Health, New York, N.Y.).

20/ Act of Oct. 30, 1972, Title II, §249F, 86 Stat. 1429-45.

Standards Review," is the legislation challenged in the instant suit.

The purpose behind the new legislation is to insure that payment for services performed under medicare and medicaid will be made:

> (1) only when, and to the extent, medically necessary, as determined in the exercise of reasonable limits of professional discretion; and
>
> (2) in the case of services provided by a hospital or other health care facility on an inpatient basis, only when and for such period as such services cannot, consistent with professionally recognized health care standards, effectively be provided on an outpatient basis or more economically in an inpatient health care facility of a different type, as determined in the exercise of reasonable limits of professional discretion. 42 U.S.C. §1320c.

The challenged legislation establishes a number of new organizations and creates certain new limitations of liability. For purposes of clarity, therefore, this discussion of the legislation will be broken down into various topics.

A.

Professional Standards Review Organizations

The legislation provides that the Secretary shall, not later than January 1, 1974, establish throughout the United States "appropriate areas" with respect to which "Professional Standards Review Organizations" (hereinafter referred to as "PSRO's") may be designated. At the earliest practicable date after the designation of an appropriate area, the Secretary must enter into an agreement with a "qualified organization" whereby such organization is designated as a PSRO for such area. 42 U.S.C. §1320c-1(a).[21/]

21/ The organization is first conditionally designated the PSRO; if the performance of the organization is satisfactory, the conditional status ceases, 42 U.S.C. §1320c-1(a). The limitations of a conditional status are set forth in 42 U.S.C. §1320c-3. The agreement between the organizatic and the Secretary is for a 12 month period although either party may terminate it earlier under certain prescribed conditions. 42 U.S.C. §1320c-1(d).

A "qualified organization" is defined by the legislation as a nonprofit professional association composed of licensed doctors practicing in the appropriate area, the membership of which includes a substantial proportion of all such doctors in the area.[22] The organization must be organized "in a manner which makes available professional competence to review health care services of the types and kinds with respect to which [PSRO's] have review responsibilities," and have membership voluntary and open to all doctors in the area without requiring membership in or payment of dues to any organized medical society; further, the organization cannot prevent any of its members from serving on or working with a PSRO, 42 U.S.C. §1320c-1(b)(1)(A). In addition, the Secretary must find that the organization is willing and able to perform the functions of a PSRO before it can be designated as such. 42 U.S.C. §1320c-1(b)(2).[23]

22/ Until January 1, 1976, the Secretary must notify the practicing physicians in the area of his intention to enter into an agreement designating an organization as a PSRO. Following such notice, at the request of ten percent or more of the practicing physicians in the area, the Secretary is required to poll the practicing physicians in the area to determine whether or not the organization substantially represents them. If more than 50 percent of the practicing physicians in the area responding to the poll indicate that the organization does not substantially represent them, the organization cannot be designated a PSRO. 42 U.S.C. §1320c-1(f).

23/ There is another legislative definition of "qualified organization":

> [S]uch other public, nonprofit private, or other agency or organization, which the Secretary determines, in accordance with criteria prescribed by him in regulations, to be of professional competence and otherwise suitable . . . . 42 U.S.C. §1320c-1(b)(1)(B).

In regard to this type of organization, the Senate Committee on Finance stated:

> Physician organizations or groupings would be completely free to undertake or to decline

B.

Duties and Responsibilities of PSRO's

Each PSRO is required to assume, at the earliest date practicable:

> . . . responsibility for the review of the professional activities in such area of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under this chapter for the purpose of determining whether ---
>
> (A) such services and items are or were medically necessary;
>
> (B) the quality of such services meets professionally recognized standards of health care; and

---

> assumption of the responsibilities of organizing a PSRO. If they decline, the Secretary would be empowered to seek alternative applicants from among other medical organizations, State and local health departments, medical schools, and failing all else, carriers and intermediaries or other health insurers. In no case, however, could any organization be designated as a PSRO which did not have professional medical competence. And, in no case could any final adverse determinations by a PSRO with respect to the conduct or provision of care by a physician be made by anyone except another qualified physician.

Sen. R. No. 92-1230 at 259-60. The Secretary cannot enter into an agreement with a section 1320c-1(b)(1)(B) organization until January 1, 1976, nor after such date, unless there is no organization described by section 1320c-1(b)(1)(A) in the appropriate area. 42 U.S.C. §1320c-1(c)(1). If the Secretary has an agreement with a section 1320c-1(b)(1)(B) organization, he cannot renew it if he determines (1) that there is a section 1320c-1(b)(1)(A) organization in the area ready and able to assume the functions of a PSRO and (2) that the selection of the section 1320c-1(b)(1)(A) organization would result in substantial improvement of the PSRO functions in the area. 42 U.S.C. §1320c-1(c)(2).

> (C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type. 42 U.S.C. §1320c-4(a)(1).[24]

The challenged legislation places an obligation upon practitioners and providers of health care services to assure that services provided under medicare or medicaid are medically necessary and of professional quality; further, practitioners and providers are obligated to support such assurances with such evidence as may reasonably be required by a PSRO. 42 U.S.C. §1320c-9(a)(1). The legislation also requires practitioners and providers not to take any action which would authorize any individual to be admitted as an inpatient unless inpatient treatment was medically necessary. 42 U.S.C. §1320c-9(a)(2).

If a PSRO, acting pursuant to 42 U.S.C. §1320c-6, reports to the Secretary that a particular practitioner or provider of services has (1) failed, in a substantial number of cases, to comply with any of the above-cited obligations or (2) grossly and flagrantly violated any such obligation in one or more instances and recommends sanctions against such practitioner or provider, and the Secretary agrees with the report and recommendation of the PSRO, practitioner or provider may be excluded from

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24/ Pending the assumption by a PSRO of full review responsibility, the utilization review procedures discussed previously remain in effect. 42 U.S.C. §1320c-2. Once a PSRO begins to assume its review responsibilities, however, the Secretary can waive any or all of the present review procedures. 42 U.S.C. §1320c-1(e).

participation in the medicare and medicaid programs. 42 U.S.C. §1320c-9(b)(1).[25] The legislation provides for notice and hearing of such determinations. 42 U.S.C. §1320c-9(b)(4).

Each PSRO will have the authority to determine, in advance, whether (1) any elective admission to a hospital or other health care facility, or (2) any other health care service which will consist of extended or costly courses of treatment, is medically necessary or could be provided for in a more economical manner. 42 U.S.C. §1320c-4(a)(2). If a PSRO determines that services provided or about to be provided are not medically necessary or could be performed in a more economical manner, no federal funds may be used as payment for such services. 42 U.S.C. §1320c-7. However, a PSRO cannot have any person other than a licensed physician make a final determination as to the professional conduct of any other physician. 42 U.S.C. §1320c-4(c).[26]

Each PSRO is required to determine and publish the types and kinds of cases with respect to which it will exercise the authority conferred upon it under section 1320c-4(a)(2). 42 U.S.C. §1320c-4(a)(3). Also, each PSRO is responsible for maintaining a regular review of profiles of care and services provided to patients, utilizing to the greatest extent

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25/ An alternative sanction is to require the errant practitioner or provider to pay to the United States an amount not in excess of the actual or estimated cost of the medically improper or unnecessary services so provided or (if less) $5,000. 42 U.S.C. §1320c-9(b)(3).

26/ The legislation provides for a hearing and review by the Secretary of all PSRO determinations denying payment for services where the amount in controversy is $100 or more. If the amount in controversy is $1,000 or more, the aggrieved party is entitled to judicial review of an adverse determination by the Secretary. 42 U.S.C. §1320c-8.

possible, "methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation consistent with the purposes of this part." Profiles are also to be maintained on each health care practitioner and provider of services to determine whether the services ordered or rendered are consistent with the criteria set forth in section 1320c-4(a)(1). 42 U.S.C. §1320c-4(a)(4).[27]

Each PSRO has the power to (1) make arrangements to utilize the services of practitioners or specialists; (2) undertake professional inquiry of services it has a responsibility to review; (3) examine records of any doctor pertinent to the providing of services under medicare or medicaid; and (4) inspect the facilities in which care is rendered or services performed under medicare or medicaid. 42 U.S.C. §1320c-4(b).[28] However, the utilization review of a PSRO is limited to health care services provided by or in institutions, unless the PSRO requests to be charged with the duty and function of reviewing other health care services and the Secretary approves of such request. 42 U.S.C. §1320c-4(g).

The challenged legislation also provides that a PSRO must give notice to any practitioner or provider of any determination (1) denying any request

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27/A PSRO may utilize the services of a hospital or health care facility review committee (see pages 3-5, supra) if the PSRO is satisfied as to the effectiveness of such review committee. 42 U.S.C. §1320c-4(e).

28/Physicians assigned the review of hospital care must have active staff privileges in at least one hospital within the designated area. 42 U.S.C. §1320c-4(a)(5). However, a physician cannot review services provided by an institution in which he has a financial interest. 42 U.S.C. §1320c-4(a)(6).

for approval of health care service or (2) that such practitioner or provider has violated any obligation imposed upon him by the legislation. 42 U.S.C. §1320c-10.

C.

Norms Of Health Care Services

Each PSRO is required to apply professionally developed norms of care, diagnosis, and treatment based upon typical practice in its area as principal points of evaluation and review. 42 U.S.C. §1320c-5(a). Such norms are to include (1) the types and extent of health care services considered within the range of appropriate diagnosis and treatment for a particular illness or condition and (2) the most economical type of health care facility considered medically appropriate for a particular illness or condition. 42 U.S.C. §1320c-5(b).

Consistent with the development of norms, each PSRO is required to specify the appropriate time after the admission of a patient for inpatient treatment when the attending physician must certify that further inpatient treatment is necessary. Such certification must be accompanied by information sufficient to enable a reviewing PSRO to evaluate such medical necessity. 42 U.S.C. §1320c-5(d).

D.

Statewide Professional Standards Review Council

The challenged legislation provides that in any State in which there are located three or more PSRO's, the Secretary shall establish a Statewide Professional Standards Review Council (hereinafter referred to

as "Council"). 42 U.S.C. §1320c-11(a). The membership of a Council shall be appointed by the Secretary and shall consist of (1) one representative from each PSRO in the State, (2) four physicians, two of whom may be designated by the State medical society and two of whom may be designated by the State hospital association, and (3) four persons knowledgeable in health care who are selected as representatives of the public in such State (at least two of whom shall be recommended by the Governor of the State). 42 U.S.C. §1320c-11(b).

It is the duty of each Council to (1) coordinate the activities of, and disseminate information among, the PSRO's within the State; (2) assist the Secretary in evaluating the performance of each PSRO; and (3) assist the Secretary in developing and arranging a qualified replacement PSRO if the Secretary deems such replacement necessary. 42 U.S.C. §1320c-11(c).

E.

National Professional Standards Review Council

The challenged legislation establishes a National Professional Standards Review Council (hereinafter referred to as "National Council"). The National Council consists of 11 physicians of recognized standing and distinction, not otherwise employed by the federal government, appointed by the Secretary. 42 U.S.C. §§1320c-12(a) and 1320c-12(b).

The National Council's duties are (1) to advise the Secretary in the administration of the challenged legislation, (2) to provide information and data to PSRO's and Councils which will assist such organizations in the performance of their duties, (3) to review the operations of PSRO's and Councils, and (4) to make or arrange for the making of studies and

investigations with a view to developing and recommending to the Secretary and Congress measures to help accomplish more effectively the purposes of the challenged legislation. 42 U.S.C. §1320c-12(e).

F.

Limitations of Liability

The challenged legislation provides that no person furnishing information to any PSRO shall be criminally or civilly liable by reason of the furnishing of such information unless (1) such information is unrelated to the performance of the duties and functions of such PSRO, or (2) such information is false and the person providing such information knew, or had reason to believe, that such information was false. 42 U.S.C. §1320c-16(a).

The legislation further provides that no person, employed by or serving upon a PSRO, shall be criminally or civilly liable for any act performed by him in the performance of such duties provided he has exercised due care. This limitation does not lie, however, if such act was motivated by malice toward any person affected by such action. 42 U.S.C. §1320c-16(b).

Finally, the legislation establishes the following limitation of liability:

> No doctor of medicine or osteopathy and no provider (including directors, trustees, employees, or officials thereof) of health care services shall be civilly liable to any person under any law of the United States or of any State (or political subdivision thereof) on account of any action taken by him in compliance with or reliance upon professionally developed norms of care and treatment applied by a Professional Standards Review Organization . . . operating in the area where such doctor of medicine or osteopathy or provider took such action but only if --

(1) he takes such action (in the case of a health care practitioner) in the exercise of his profession as a doctor of medicine or osteopathy (or in the case of a provider of health care services) in the exercise of his functions as a provider of health care services, and

(2) he exercised due care in all professional conduct taken or directed by him and reasonably related to, and resulting from, the actions taken in compliance with or reliance upon such professionally accepted norms of care and treatment. 42 U.S.C. §1320c-16(c).

V.

The Instant Litigation

On June 26, 1973, the instant lawsuit was filed. Plaintiffs are the Association of American Physicians and Surgeons (hereinafter referred to as "Association"), a not-for-profit corporation whose membership is composed of medical practitioners; and three medical practitioners who are not members of the Association. The defendant is the Secretary of Health, Education and Welfare.

Plaintiffs seek (1) a declaratory judgment that the challenged legislation "is unconstitutional on its face" and (2) a permanent injunction restraining the defendant from implementing or enforcing the legislation.

Plaintiffs have alleged that enforcement of the challenged legislation will violate plaintiffs' constitutional rights in 14 different ways. Stripped of their considerable surplusage, these 14 allegations may fairly be grouped in the following contentions:

1. Enforcement of the challenged legislation will deprive plaintiffs of their right to practice their

profession in violation of the fifth amendment to the United States Constitution.[29]

2. Enforcement of the challenged legislation will interfere with the relationship between plaintiffs and their patients in violation of the fifth amendment.[30]

3. Enforcement of the challenged legislation will invade the privacy of plaintiffs and their patients in violation of the first, fourth, fifth and ninth amendments.[31]

4. The challenged legislation is vague and uncertain in violation of the fifth amendment.[32]

5. The challenged legislation imposes limitations of liability which Congress has no power to impose and the imposition of duties upon plaintiffs without valid limitations of liability violates the fifth amendment.[33]

6. The legislation creates presumptions inconsistent with the presumption of competence, good moral character, and regularity of conduct and motive created by plaintiffs' licensure in violation of the fifth amendment.[34]

7. The legislation empowers biased private organizations to exercise quasi-judicial authority over plaintiffs in violation of the fifth amendment.[35]

Each of these contentions will be discussed separately. In addition,

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29/ Complaint, part IV, ¶1

30/ Complaint, part IV, ¶¶2, 3, 5, 7, and 9

31/ Complaint, part IV, ¶¶4 and 10

32/ Complaint, part IV, ¶8

33/ Complaint, part IV, ¶¶12, 13 and 14

34/ Complaint, part IV, ¶6

35/ Complaint, part IV, ¶11

the issues of plaintiffs' standing to maintain the instant suit, this court's jurisdiction over the subject matter, and the reasonableness of the challenged legislation will be discussed.

ARGUMENT

I.

THE CHALLENGED LEGISLATION DOES NOT DEPRIVE PLAINTIFFS OF THEIR RIGHT TO PRACTICE THEIR PROFESSION

Plaintiffs allege:

> A PSRO will have the authority under the law to disapprove payments for services to Plaintiff Physicians, without prior notice or opportunity for hearing. A PSRO will also have the power to recommend the imposition of sanctions against Plaintiffs upon a finding of 'unwillingness or lack of ability substantially to comply' with the law. Upon such a recommendation, the Defendant could, in addition to any other sanction provided by law, temporarily or permanently exclude Plaintiffs from eligibility to provide services on a reimbursable basis under the Social Security Act, or require as a condition of continued eligibility that Plaintiffs pay the actual or estimated cost of the services found to be medically improper or unnecessary, up to the amount of $5,000 . . . .[36]

Although the complaint in the instant case suffers from an acute lack of specificity, it would appear that this allegation is basis for plaintiffs' contention that enforcement of the challenged legislation would interfere with their right to practice their profession in violation of the fifth amendment to the United States Constitution.

The first part of the allegation asserts that PSRO's may disapprove of payments for services "without prior notice or opportunity for hearing." The utter lack of merit of this assertion can be shown by merely reading the legislation. Title 42, United States Code, Section 1320c-10 provides:

36/ Complaint, part III, ¶14.

> Whenever any Professional Standards Review Organization takes any action or makes any determination --
>
> (a) which denies any request, by a health care practitioner or other provider of health care services, for approval of a health care service or item proposed to be ordered or provided by such practitioner or provider; or
>
> (b) that any such practitioner or provider has violated any obligation imposed on such practitioner or provider under section 1320c-9 of this title,
>
> such organization shall, immediately after taking such action or making such determination, give notice to such practitioner or provider of such determination and the basis therefor, and shall provide him with appropriate opportunity for discussion and review of the matter.

Title 42, United States Code, Section 1320c-8 provides that "a provider or practitioner who is dissatisfied with a determination made by a [PSRO]" may demand a hearing before the Secretary if the amount in controversy exceeds $100. If the amount in controversy exceeds $1,000, the practitioner or provider is entitled to judicial review of an adverse decision by the Secretary.

The second part of the allegation asserts that the challenged legislation would interfere with plaintiffs' right to practice their profession; however, the allegation clearly shows that the most severe sanction that could be imposed upon practitioners or providers by a PSRO (with the approval of the Secretary) is disqualification from the medicare and medicaid programs.[37/] Thus, plaintiffs must contend that their right to

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37/ See pages 18 - 19, supra.

receive reimbursement under these social programs is tantamount to their right to practice their profession. Such a contention cannot stand.

Under the challenged legislation, plaintiffs would be able to take any action they wish to take regarding their profession. They may treat any patient they wish to treat; they may use any method of treatment they wish to use. The Senate Committee on Finance has stated:

> PSRO disapproval of the medical necessity for continued hospital care beyond the norm for that diagnosis will not mean that the physician must discharge his patient. The physician's authority to decide the date of discharge as well as whether his patient should be admitted in the first place cannot be and are not taken from him by the PSRO. The review responsibility of the PSRO is to determine whether the care should be paid for by medicare and medicaid. By making this determination in advance, the patient, the institution, and the physician will all be forewarned of the desirability of making alternative plans for providing care or financing the care being contemplated.38/

Plaintiffs also allege:

> In certain categories of cases, Plaintiff Physicians will be required to obtain approval from a PSRO before they may hospitalize a patient, or enter upon a particular course of treatment, and the PSRO is empowered to deny approval if it deems the hospitalization or treatment medically unnecessary within the meaning of the law, or if it concludes that the particular physician seeking approval would not render services in conformity with the norms of the law. . . .39/

This allegation simply is not true. The challenged legislation in no way interferes with plaintiffs' right to treat beneficiaries of medicare or medicaid except insofar as reimbursement under these programs is sought. As one Senator noted:

38/ Sen. R. No. 92-1230 at 263-64.

39/ Complaint, part III, ¶10.

> The physician's privilege of admitting patients to a hospital is absolutely not affected by this amendment. His admission privileges will continue to be governed solely by the limitation presently imposed upon him by the organized medical staff of his hospital. The amendment simply provides that a proposed hospital admission, if disapproved by the [PSRO] in advance will not be payable under Medicare or Medicaid. Thus, the doctor can still admit his patient -- but he, the patient and the hospital would have to look beyond Medicaid for payment. This is similar to the present practice of Blue Cross - Blue Shield and private health insurance with one important improvement. Instead of care being provided and then having payment denied, with the Bennett Amendment, everyone will know where they stand in advance rather than after the fact.40/

Plaintiffs are perfectly willing to accept their fees under the medicare and medicaid programs; they are apparently unwilling, however, to accept any regulation over the payment of such fees. In Wickard v. Filburn, 311 U.S. 111, 131 (1942), the Court stated:

> It is hardly lack of due process for the Government to regulate that which it subsidizes.

In the instant case, it is hardly lack of due process for the Government to insure that the sums it pays out under the medicare and medicaid programs are used only for services which are medically necessary and delivered in the most economical manner possible.

II.

THE CHALLENGED LEGISLATION DOES NOT INTERFERE WITH THE RELATIONSHIP BETWEEN PLAINTIFFS AND THEIR PATIENTS IN VIOLATION OF THE FIFTH AMENDMENT

Plaintiffs allege:

> Plaintiffs' ability to render, and their patients' ability to receive health care in accordance with the

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40/ 116 Cong. Rec. 32845 (1970) (Statement of Senator Bennett).

> highest standards of medical practice will be seriously impaired if Plaintiffs are required to conform their medical judgments to a system of pre-set norms of diagnosis, treatment and care. Proper medical practice demands that, in diagnosing and treating a patient, a physician take into consideration a host of often-changing factors that are unique to each patient, and inherently incapable of reduction to 'norms'. Superimposition of a system of norms of diagnosis and treatment upon the judgments of medical practitioners will have a chilling effect on the case-by-case practice of medicine and innovative progress in medical practice, to the ultimate detriment of Plaintiffs and their patients.

This allegation appears to be the basis for plaintiffs' assertion that the challenged legislation unconstitutionally interferes with the relationship between plaintiffs and their patients. It is obvious, however, there are at least two things seriously wrong with this allegation.

First of all, the norms which plaintiffs assert will have a "chilling effect" on the doctor-patient relationship have yet to be established. Thus, because it is impossible to determine what effect a particular norm might have prior to its creation, it would appear plaintiffs have not presented the court with an actual case or controversy. As the Court stated in United Public Workers v. Mitchell, 330 U.S. 75, 89-90 (1947):

> The power of courts, and ultimately of this Court, to pass upon the constitutionality of acts of Congress arises only when the interests of litigants require the use of this judicial authority for their protection against actual interference. A hypothetical threat is not enough.

It is clear that the threat posed by the proposed norms will remain hypothetical until such time as the norms are actually established and

enforced. 41/

Secondly, there is absolutely no authority for plaintiffs' assertion that the relationship between a doctor and his patient is within the definition of "life, liberty, or property" as protected by the Due Process Clause of the fifth amendment. It is already well settled that a beneficiary's right to receive Social Security benefits is not within that definition. Richardson v. Belcher, 404 U.S. 78, 80 (1971). It would appear obvious, therefore, that a relationship created to pass those benefits from the beneficiaries of the Social Security Act to the plaintiffs is not entitled to any greater protection or stature.

III.

THE CHALLENGED LEGISLATION DOES NOT INVADE THE PRIVACY OF PLAINTIFFS AND THEIR PATIENTS IN VIOLATION OF THE FIRST, FOURTH, FIFTH, AND NINTH AMENDMENTS

Plaintiffs allege:

> If Plaintiffs are required to supply information concerning their patients to PSRO's for use in creating physician and patient profiles, and maintain and disclose information necessary to convince a PSRO that they are

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41/ If the norms are established in conformity with Congress' intent, as they must be, it appears that the "chilling effect," which plaintiffs indicate the norms will engender will never occur. The Senate Committee on Finance has noted:

> Neither should the use of norms as check-points, nor any other activity of the PSRO, be used to stifle innovative medical practice or procedures. The intent is not conformism in medical practice -- the objective is reasonableness.

Sen. R. No. 92-1230 at 263.

> complying with the law, Plaintiffs will no longer be able to afford their patients the privacy and confidentiality in their relationship that is necessary to foster the full and candid communication essential to diagnosis and treatment.[42]

This allegation is obviously the basis for plaintiffs' assertion that the challenged legislation violates the privacy of plaintiffs and their patients in violation of first, fourth, fifth, and ninth amendments.

In Felber v. Foote, 321 F. Supp. 85 (D. Conn. 1970) (three judge district court), a physician challenged the constitutionality of a Connecticut statute requiring him to report the names of "drug-dependent" patients to the Connecticut State Commissioner of Health. The physician argued that the statute invaded his right of privacy and required him to violate "unspecified professional standards of conduct or ethics."

In finding the statute constitutional, the court stated:

> Plaintiff further makes the unwarranted assumption that the special nature of the doctor-patient relationship affords him a constitutionally protected right to privacy in his conduct of the relationship. There is no 'general constitutional right to privacy.' . . . Id. at 88.

After discussing the cases cited by the physician in support of his argument, the court held:

> In short, the right to privacy asserted by the plaintiff is not supported by the Constitution or any federal law. Id. at 89.

The Connecticut statute provided that the physician's report was inadmissible in criminal prosecutions. The protection awarded the information required by the challenged legislation is much greater.

42/ Complaint, part III, ¶13.

Title 42, United States Code, Section 1320c-15, provides:

> (a) Any data or information acquired by any Professional Standards Review Organization, in the exercise of its duties and functions, shall be held in confidence and shall not be disclosed to any person except (1) to the extent that may be necessary to carry out the purposes of this part or (2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care.
>
> (b) It shall be unlawful for any person to disclose any such information other than for such purposes, and any person violating the provisions of this section shall, upon conviction, be fined not more than $1,000 and imprisoned for not more than six months, or both, together with the costs of prosecution.

It is submitted that the decision in Felber v. Foote, supra, is dispositive of plaintiffs' assertion that the challenged legislation invades their right to privacy.

IV.

THE CHALLENGED LEGISLATION IS NOT VAGUE AND UNCERTAIN IN VIOLATION OF THE FIFTH AMENDMENT

Plaintiffs allege that the duties and obligations imposed upon them by 42 U.S.C. §1320c-9 are stated in such vague and uncertain terms "that Plaintiffs must necessarily guess at their meaning" contrary to the fifth amendment.[43/]

In United States v. Petrillo, 332 U.S. 1, 7-8 (1947), the Court stated:

> . . . the Constitution does not require impossible standards. The language here challenged conveys sufficiently definite warning as to the proscribed conduct when measured by common understanding and practices. The Constitution requires no more.

43/ Complaint, part IV, ¶8.

Physician Plaintiffs, all highly qualified members of the medical profession, 44/ claim that they must guess at the meaning of the phrases "medically necessary," "quality which meets professionally recognized standards of health care," "professionally recognized health care standards," and so forth.

In determining whether the language of a statute is unconstitutionally vague, the test to be applied is whether men of common intelligence must necessarily guess at its meaning. Hosack v. Smiley, 276 F. Supp. 876, 878 (D. Colo. 1967), aff'd., 390 U.S. 744 (1968). Since the challenged legislation imposes its duties only upon practitioners and providers of service, the test must be rephrased to include only members of the medical profession of common intelligence. Accordingly, in order to hold the challenged legislation unconstitutionally vague, this Court must hold that members of the medical profession of common intelligence must guess at the meaning of the phrases "medically necessary," "professionally recognized health care standards," "proper care" and so forth. Not only would such a holding have a frightening effect on the recipients of medical care, but it also would be totally unjustified by common experience. Congress has done the best it can with the language of the challenged legislation; to require, as plaintiffs seem to argue, that Congress must specify in its legislation when a kidney must be removed or how long a gall bladder case should be hospitalized would be to impose a higher standard of legislative specificity than that demanded by the Constitution.

44/ Complaint, part II, ¶¶2, 3, and 4.

V.

THE CHALLENGED LEGISLATION DOES NOT VIOLATE THE FIFTH AMENDMENT BY IMPOSING LIMITATIONS OF LIABILITY WHICH CONGRESS HAS NO POWER TO IMPOSE AND IMPOSING DUTIES UPON PLAINTIFFS WITHOUT VALID LIMITATIONS OF LIABILITY

Plaintiffs allege (1) that Congress has no power to grant legal immunity against common law tort liability,[45] and (2) if the immunity provisions of the challenged legislation[46] are enforceable, the challenged legislation imposes duties and obligations on plaintiffs which may unconstitutionally expose them to civil liability.[47]

It is readily apparent that this case is not in a proper posture to adjudicate the constitutionality of the limitations of liability. As plaintiffs impliedly admit, the only persons having the right to challenge the constitutionality of the statutory limitations of liability are the beneficiaries of medicare and medicaid.[48] Accordingly, plaintiffs have

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45/ Complaint, part IV, ¶¶12 and 13.

46/ See pages 23-24, supra. Apparently, plaintiffs are only challenging the limitations of liability set forth in 42 U.S.C. §1320c-16(c).

47/ Complaint, part IV, ¶14.

48/ Plaintiffs allege:

> The legal immunity against common law tort liability granted to medical practitioners, providers and others by Section 1167 of said law [42 U.S.C. §1320c-16] violates rights of federal health care recipients guaranteed by the Fifth and Seventh Amendments to the United States Constitution . . . .

Complaint, part IV, ¶13.

not presented this issue in the form of an actual case or controversy. Golden v. Zwickler, 394 U.S. 103 (1969).[49/]

It is also readily apparent that Congress does have the power to impose such limitations of liability. In Silver v. Silver, 280 U.S. 117, 122 (1929), the Court stated:

> . . . the Constitution does not forbid the creation of new rights, or the abolition of old ones recognized by the common law, to attain a permissible legislative object.

There are numerous cases upholding Congressional limitations of liability. See, e.g., Carr v. United States, 422 F.2d 1007 (4th Cir. 1970) (abolition of common law right of action against fellow employee held constitutional); Stumo v. United Air Lines, 382 F.2d 780 (7th Cir. 1967) (abolition of right to jury trial for wrongful discharge from employment held constitutional).

Despite the fact that the limitations of liability established by the challenged legislation are obviously constitutional, this court is nevertheless requested by the movant to defer a ruling on this issue until an actual case or controversy exists regarding the constitutionality of such limitations.

49/ In Flast v. Cohen, 392 U.S. 83, 99-100 (1968), the Court stated:

> . . . when standing is placed in issue in a case, the question is whether the person whose standing is challenged is a proper party to request an adjudication of a particular issue and not whether the issue itself is justiciable.

VI.

THE CHALLENGED LEGISLATION DOES NOT VIOLATE THE FIFTH AMENDMENT BY CREATING PRESUMPTIONS INCONSISTENT WITH THE PRESUMPTIONS OF COMPETENCE, GOOD MORAL CHARACTER, AND REGULARITY OF CONDUCT AND MOTIVE CREATED BY PLAINTIFFS' LICENSURE

Plaintiffs allege:

> Under Section 1160 of the law [42 U.S.C. §1320c-9], Plaintiffs will have the burden of demonstrating by evidence in such form and fashion and at such times as a PSRO may require that they are complying with the norms of practice and cost control measures established by the law, and that they are assuring, to the extent of their influence and control, compliance with the law by their patients and the institutions in which they practice.50/

This allegation is apparently the basis for plaintiffs' assertion that the challenged legislation violates the fifth amendment by creating presumptions inconsistent with the presumptions of competence, good moral character, and regularity of conduct and motive created by plaintiffs' licensure. This assertion is frivolous.

Stripped of its verbiage, plaintiffs' contention is that the federal government is constitutionally prohibited from requiring evidence of performance of services from those persons to whom the government pays money for such services. As Chief Justice White once noted: "To state the proposition is to refute it."51/

In Perkins v. Lukens Steel Co., 310 U.S. 113, (1940), governmental contractors challenged the enforcement of a federal statute requiring the

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50/ Complaint, part III, ¶12.

51/ The Employers' Liability Cases, 207 U.S. 463, 502 (1908).

contractors to pay wages at least as high as the prevailing minimum wages in the locality. In refusing to enjoin enforcement of the act, the Court stated:

> Like private individuals and businesses, the Government enjoys the unrestricted power to produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases. Acting through its agents as it must of necessity, the Government may for the purpose of keeping its own house in order lay down guide posts by which its agents are to proceed in the procurement of supplies, and which create duties to the Government alone. Id. at 127.

Since it is firmly established that the Government may fix the terms and conditions upon which it may purchase supplies, it necessarily follows that Congress has the power to fix the terms and conditions upon which it may procure the services of professional personnel. Congress has created such terms and conditions in the challenged legislation; they should remain undisturbed by the judiciary.

VII.

THE CHALLENGED LEGISLATION DOES NOT VIOLATE THE FIFTH AMENDMENT BY EMPOWERING QUASI-JUDICIAL AUTHORITY OVER PLAINTIFFS TO BIASED PRIVATE ORGANIZATIONS

Plaintiffs allege:

> Said law, and in particular Section 1152 of said law [42 U.S.C. §1320c-1], empowers private organizations that are inherently biased against Plaintiffs by their contractual relationship with Defendant and their economic self-interest, to exercise quasi-judicial authority over Plaintiffs . . . .[52/]

52/ Complaint, part IV, ¶11.

Plaintiffs apparently are asserting that they are being deprived of "life, liberty, or property" by a partial tribunal in violation of the fifth amendment. This assertion is incorrect for several reasons.

First of all, the PSRO's are incapable of depriving plaintiffs of their "property" as protected by the fifth amendment. As noted previously,[53] the right to receive reimbursement under the medicare and medicaid program is not protected by the fifth amendment.

Secondly, no inference of partiality can be drawn solely from the fact that PSRO's are private organizations. Courts have long recognized that federal agencies can contract with private organizations in order to have such organizations perform governmental functions. See, e.g., State of Texas v. National Bank of Commerce of San Antonio, 290 F.2d 229 (5th Cir.), cert. denied, 368 U.S. 832 (1961). The only issue which may be raised by plaintiffs is whether the administrative scheme allows for a hearing on the private organization's determinations. Coral Gables Convalescent Home, Inc. v. Richardson, 340 F. Supp. 646 (S.D. Fla. 1972). It is obvious the challenged legislation meets the requirements of procedural due process.[54]

Plaintiffs have presented no basis, other than a bald allegation, for their assertion that PSRO's will be biased against them. The assertion is remarkable in that one major factor behind the enactment of the challenged legislation was to eliminate the bias of profit-motivated fiscal

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53/ See pages 28-32, supra.

54/ See pages 27-28, supra.

intermediaries which the non-profit PSRO's are eventually to replace.[55]

VIII.

THIS COURT LACKS JURISDICTION OVER
THE SUBJECT MATTER OF THE INSTANT SUIT

Plaintiffs allege this court has jurisdiction over the subject matter of the instant suit pursuant to 28 U.S.C. §1331. That section provides:

> (a) The district courts shall have original jurisdiction of all civil actions wherein the matter in controversy exceeds the sum or value of $10,000, exclusive of interests and costs, and arises under the Constitution, laws, or treaties of the United States.

Although plaintiffs have alleged that the matter in controversy exceeds $10,000, exclusive of interest and costs,[56] they have failed to make any factual assertions of financial detriment.

In suits brought for injunctive relief, the amount in controversy is the value of the right to be protected or the extent of the injury to be prevented. Goldsmith v. Sutherland, 426 F.2d 1395, 1398 (4th Cir.), cert. denied, 400 U.S. 960 (1970). Since plaintiffs have failed to show injury to any legally enforceable right, it is urged that the amount in controversy is not in excess of $10,000. Accordingly, this court lacks jurisdiction over the subject matter.

IX.

THE CHALLENGED LEGISLATION IS A VALID
EXERCISE OF CONGRESSIONAL POWER

A rather lengthy statement of facts has been set forth herein in order to show the court the congressional purposes behind the challenged

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55/ See page 12, supra.

56/ Complaint, part I, ¶1.

legislation. A summary of the statement is as follows.

The costs of medicare and medicaid were found by congressional committees to be increasing at a frightening pace. The increase in the costs of these social programs was found to be attributable in a large part to the overutilization of medical services. Prior legislative attempts to prevent overutilization were found by Congress to be ineffective for a number of reasons set forth herein. In the challenged legislation, Congress sought to remedy the defects of the prior systems. Where single institution review committees were found to be ineffective, Congress formed review organizations covering many institutions. Where profit-motivated fiscal intermediaries suffered from a conflict of interest by having utilization review duties placed upon them, Congress formed non-profit review organizations which would suffer no such conflict. Where doctors complained of having their medical decisions reviewed by non-medical personnel, Congress insured that all medical decisions would be reviewed only by professional medical personnel.

The challenged legislation was the product of considerable give and take within Congress' chambers. Many persons and organizations, including the plaintiff organization, 57/ testified or otherwise made their views known to Congress.

Defendant does not at this time urge upon this Court that the challenged legislation is a wise law or an efficient law; the sole issue before this Court is whether the challenged legislation is a valid law. It is respectfully submitted that it is.

57/ Hearings on H.R. 1 Before the Senate Comm. on Finance, 92d Cong., 1st and 2d Sess. 3330-94 (1971-72) (Statement of Dr. Rafael Solari, Vice-Chairman of the California Chapter of the Association of American Physicians and Surgeons).

CONCLUSION

It is respectfully urged that defendant's motion for summary judgment be granted for the reasons stated herein.

Respectfully submitted,

JAMES R. THOMPSON
United States Attorney

CERTIFICATE OF SERVICE

It is hereby certified that service of the Memorandum In Support Of Defendant's Motion For Summary Judgment has been made on opposing counsel by hand delivery on this 11th day of December, 1973, to the following individuals:

R. R. McMahan, Esq.
Harold L. Jacobson, Esq.
Hugh C. Griffin, Esq.
Lord, Bissell and Brook
135 South LaSalle Street
Chicago, Illinois 60603

PAUL F. STACK
Assistant United States Attorney

SUBSCRIBED and SWORN TO
before me this _____ day
of December, 1973.

NOTARY PUBLIC

[HEARING INSERT]

Memorandum of Law Filed by the Association of American Physicians and Surgeons

(Note: This memorandum of law was inadvertently omitted from Appendix H of the Committee on Finance printed hearings entitled "Implementation of PSRO Legislation". Please insert these pages following page 947.)

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, a not-for-profit corporation, for and on behalf of its members; and ROY R. GRINKER, SR., GEORGE E. SHAMBAUGH, JR., AND EDWARD A. WOLPERT,	)	
Plaintiffs,	)	
vs.	)	No. 73 C 1653
CASPAR W. WEINBERGER, Secretary of the United States Department of Health, Education and Welfare, an Agency of the Federal Government,	)	
Defendant.	)	

PLAINTIFFS' MEMORANDUM OF LAW
IN OPPOSITION TO DEFENDANT'S
MOTION FOR SUMMARY JUDGMENT

This is an action to enjoin the defendant Secretary of Health, Education and Welfare from implementing or enforcing the Federal "Professional Standards Review" law (42 U.S.C. §§1320c through 1320c--19) on the ground that it violates rights guaranteed the plaintiff physicians and their patients by the Constitution of the United States.

In lieu of answering the allegations of plaintiffs' complaint, the defendant has filed a naked motion for summary judgment, unsupported by evidentiary matter going outside the complaint -- such as depositions or affidavits. A motion for summary judgment made solely on the pleadings is functionally the same as a motion to dismiss for failure to state a claim upon which relief could be granted and is to be so viewed by the Court. Schwartz v. Compagnie General Transatlantique, 405 F.2d 270, 273 (2d Cir. 1968); 6 Moore's Federal Practice ¶56.02[3]. Consequently, for the purposes of the instant motion, the well-pleaded material allegations of plaintiffs' complaint are to be taken as admitted, and defendant's motion is not to be granted unless it appears to a certainty that plaintiffs are entitled to no relief under any state of facts which could be proved in support of their claims. 2A Moore's Federal Practice ¶12.08.

Statement of the Case

The legislation plaintiffs challenge as unconstitutional was enacted by Congress in 1972 as part of extensive amendments to the Social Security Act. ("Social Security Amendments of 1972", October 30, 1972, Pub. L. 920603, Title II, §249F(b), 86 Stat. 1429). As the legislative history set out in defendant's memorandum indicates, the overwhelmingly predominant purpose of this legislation was to curb the soaring cost of providing health care under the federal medicare and medicaid programs. While the statute expresses a concern that health care services be of "proper quality", it appears that Congress' intention in this regard focused upon unnecessary medical treatment and overutilization of health care services as inconsistent with the health of patients. (See defendant's Memorandum p. 2). Defendant

does not suggest that Congress intended to improve health care by expanding the services available under the medicare and medicaid programs. The extended discussion of efforts to control the costs of federal health care programs to which defendant devotes the first 26 pages of his memorandum leaves no doubt that the legislation in question was designed to limit the demand made upon the resources of such programs by circumscribing the health care services provided by physicians to patients who are eligible under them.

To that end, Congress has created an elaborate and novel scheme of prior restraints on physicians' diagnosis, treatment and care of patients who are potential medicare-medicaid beneficiaries. Under the law in question, a group of eleven physicians chosen by defendant [§1320c--12(a)] will formulate "norms" of diagnosis, treatment and care for particular illnesses or health conditions governing the types and extent of the health care services that are considered within the range of "appropriate" diagnosis and treatment of such illness or health condition, and the type of health care facility in which such treatment can be most economically provided [§1320c--5(b), (c)].

The defendant is to divide the nation into geographical territories and designate for each a "Professional Standards Review Organization" (hereinafter referred to as "PSRO") to exercise surveillance over the activities of physicians and institutions providing health care services under

the Social Security Act [§§1320c--1, 1320c--4]. The PSRO's are to employ the above-described norms of diagnosis, treatment and care as a "principal point of evaluation and review" in determining whether

> (A) such services and items are or were medically necessary;
>
> (B) the quality of such services meets professionally recognized standards of health care; and
>
> (C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type.
>
> [§1320c--4(a)(1)]

A PSRO also is authorized to determine in advance, on a case-to-case basis, whether any elective admission to a hospital, or any other health care service which will consist of extended or costly courses of treatment, would meet the criteria quoted above, if rendered by a particular physician or institution [§1320c--4(a)(2)].

In addition, the PSRO's are charged with specifying, in accordance with defendant's regulations, ". . . the appropriate points in time after the admission of a patient for inpatient care in a health care institution, at which the physician attending such patient shall execute a certification stating that further inpatient care in such institution will be medically necessary effectively to meet the health care need of such patient." Such

certifications must include such information as may be necessary to enable a PSRO to evaluate the necessity for the further institutional care recommended by the physicians [§1320c--5(d)].

Finally, the PSRO's will maintain and regularly review

> . . . profiles of care and services received and provided with respect to patients, utilizing to the greatest extent practicable in such patient profiles, methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation consistent with the purposes of this part. Profiles shall also be regularly reviewed on an ongoing basis with respect to each health care practitioner and provider to determine whether the care and services ordered or rendered are consistent with the criteria specified in clauses (A), (B), and (C) of paragraph (1) [of §1320c--4(a), quoted above].

This legislation also imposes extensive obligations on physicians to comply with these norms of diagnosis, treatment and care. Section 1320c--9(a) of the law provides that it shall be the obligation of a physician to assure that services or items he orders or provides for beneficiaries and recipients under the Social Security Act are medically necessary and of professional quality, and are to be "supported by evidence of such medical necessity and quality in such form and fashion and at such time as may reasonably be required by the Professional Standards Review Organization in the exercise of its duties and responsibilities . . ."

Physicians also are charged in this Section with a broad responsibility for governing the conduct of others:

> . . . it shall be the obligation of any health care practitioner in ordering, authorizing, directing, or arranging for the provision by any other person (including a hospital or other health care facility, organization, or agency), of health care services for any patient of such practitioner, to exercise his professional responsibility with a view to assuring (to the extent of his influence or control over such patient, such person, or the provision of such services) that such services or items will be provided--
>
> (D) only when, and to the extent, medically necessary; and
>
> (E) will be of a quality which meets professionally recognized standards of health care.

Special responsibilities are placed upon physicians where judgments concerning inpatient care are concerned:

> Each health care practitioner . . . shall have an obligation, within reasonable limits of professional discretion, not to take any action, in the exercise of his profession . . . which would authorize any individual to be admitted as an inpatient in or to continue as an inpatient in any hospital or other health care facility unless--
>
> (A) inpatient care is determined by such practitioner and by such hospital or other provider, consistent with professionally recognized health care standards, to be medically necessary for the proper care of such individual; and
>
> (B) (i) the inpatient care required by such individual cannot, consistent with such standards, be provided more economically in a health care facility of a different type;
>
> . . . .
>
> [§1320c--9(a)(2)]

The PSRO's will be responsible for policing physician compliance with these obligations. If the defendant finds, upon a charge made by a

PSRO, that a physician has ". . . demonstrated an unwillingness or a lack of ability substantially to comply with such obligation . . .", he may, in addition to any other sanction provided under law ". . . exclude (permanently or for such period as the Secretary may prescribe) such practitioner . . . from eligibility to provide such services on a reimbursable basis." An "unwillingness" or "lack of ability" to comply with these obligations is to be inferred from failure in a substantial number of cases, substantially to comply with an obligation imposed by the law, or from gross and flagrant violation of any such obligation in one or more instances [§1320c--9(b)(1)(A) and (B)]. In lieu of the sanction described above, the defendant

> . . . may require that (as a condition to the continued eligibility of such practitioner or provider to provide such health care services on a reimbursable basis) such practitioner or provider pay to the United States, in case such acts or conduct involved the provision or ordering by such practitioner or provider of health care services which were medically improper or unnecessary, an amount not in excess of the actual or estimated cost of the medically improper or unnecessary services so provided, or (if less) $5,000.00.
>
> [§1320c--9(b)(3)]

The Professional Standards Review law represents a radical departure from previous medical utilization review philosophy and mechanisms. It marks the initial entry of the federal authority into the control of the substantive aspects of medical practice through the imposition of

prior restraints upon physicians' professional medical judgments and practices in treating patients eligible for Social Security benefits.

It is important to understand the distinction between the historical function of "peer review" within the medical profession and the cost-control objectives sought to be achieved through the PSRO arrangement created by the legislation in question. See Decker & Bonner (eds.), PSRO: Organization for Regional Peer Review, 119 (Ballinger Publishing Co., 1973):[1]

> Appropriate use of hospital and medical resources and facilities has always been of concern to conscientious and thoughtful physicians and hospital administrators. The medical audit has always pointed out excessive use of drugs, unnecessary hospital stays, and other wasteful practices. The medical audit did not have its origin, however, in attention to the conservation of resources but rather it sprang from one of the most basic drives in medicine, the drive to provide the best care. Leadership in developing a methodical approach to monitoring the quality of care and maintaining the highest standards came not only from the American College of Surgeons and the American College of Physicians but also from hospitals and particularly from their medical staffs. Hospitals in 1949 spurred the establishment of the Professional Activity Study and then went on with the American College of Surgeons to develop the Medical Audit Program.
>
> The medical audit movement had barely achieved a good foothold when third parties began to demand tighter control over the use of hospital resources. Hospitals were asked and even ordered to establish utilization committees, not primarily to improve the quality of care, but to reduce the amount of care.

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[1] This study was prepared by Arthur D. Little, Inc., pursuant to a contract with the Community Health Service, Health Services and Mental Health Administration, of the U.S. Department of Health, Education and Welfare. (Hereinafter cited as "Decker & Bonner")

Elsewhere in this study the authors have concluded that the objectives of the PSRO approach to regulation and control of medical practice requires a departure from traditional peer review concepts:

> Consultation and teaching or supervisory rounds are the oldest and simplest form of peer review. Such one-to-one review is generally concurrent, has a formative role in patient care, and depends upon the application of implicit criteria by a recognized expert. Within hospitals, the responsibility for peer review has been delegated to the medical staff, a particular service, its chief, or a designated committee. Collectivity has enlarged the scope of review and introduced retrospective methods geared to prospective educational solutions. Nevertheless, until recently, hospital peer review has also depended upon the application of implicit criteria by recognized experts.
>
> The demands of large-scale medical care appraisal, however, and the parallel shortage of physicians for evaluation activities, generate new requirements for regional peer review.
>
> (1) To process the volume of work, automated screening and professional review only of exceptions become necessary.
> (2) To permit automation, and insure uniformity, it becomes necessary to define explicit criteria and select appropriate cases for study.
> (3) To make large-scale regional review worthwhile, it becomes necessary to develop appropriate and effective educational or fiscal outputs which demonstrably modify future physican behavior. [Emphasis added]
>
> [Decker & Bonner 14]

The study subsequently notes that "education" of physicians may not be enough:

> In many cases the educational solution will not be found in further training or motivation for the physician, but in recognizing systematic constraints on the physician's performance and in making appropriate system modifications to eliminate them.

* * *

> The non-educational outputs of peer review include a variety of financial controls over the reimbursement process and a variety of sanctions which regulate physician activities. Financial controls include approval (or disapproval) of payment through retrospective claims review, and prospective or continuing authorization for payment through pre-certification. Sanctions may be applied at the level of licensure, hospital privileges, or the continued ability to participate in a specific reimbursement program.
>
> [Decker & Bonner 19-20]

The panel of experts conducting the Decker & Bonner study recognized that the PSRO program would result in substantial changes in traditional medical practice:

> Legal constraints, public demands, and professional attitudes make it impossible to justify two standards of medical care in our contemporary society. The consulting panel understood P.L. 92-603 to mandate professional review only for the beneficiaries of the Social Security Act. More importantly, the panel appreciated that this restriction, except in terms of dollar support for the activity, is literally impossible.
>
> The norms of care and most of the forms of professional audit developed for federal beneficiaries under PSRO, will ultimately be applied to all private medical services. In addition to their inherent resistance to separating "federal care" from "medical care," as evidenced by the common extension of utilization review to private hospital care, physicians are aware of the public and legal pressures to extend PSRO norms and reviews to the entire private health delivery system.
>
> [Decker & Bonner 11]

The plaintiffs in this case are physicians who are subject to the legal burdens and obligations described above. In their Complaint they have alleged themselves to be professionally competent medical practitioners of good moral character who have patients who are Social Security recipients or beneficiaries, and that in administering to these patients each makes his decisions concerning diagnosis, treatment and care solely in accordance with his best medical judgment of the patient's best interests -- as his training, experience and skills dictate in the circumstances of each case. Plaintiffs allege that subjecting their professional judgments and conduct to prior restraints on the basis of any system of pre-set norms of diagnosis, treatment and care will seriously impair their ability to render, and their patients' ability to receive health care in accordance with the highest standards of medical practice. (Complaint, Part III, ¶¶1. 9)

Plaintiffs also allege that under this law their patients could be denied treatment Plaintiffs judge necessary, or be required to obtain such treatment from a physician other than the one of their choice. They allege that the obligations imposed upon them to maintain and disclose information concerning their patients will interfere with the privacy and confidentiality of their relationship with patients which is necessary to foster the full and candid communication between physician and patient essential to diagnosis and treatment. They allege that they will be deterred and hindered in advising and treating their patients by the chilling effect of the law's coercive

sanctions and the irreconcilable conflicts between the professional obligations and legal duties that will be engendered by the law. (Complaint, Part III, ¶¶10, 13, 16)

Defendant has not controverted these allegations by answer or evidentiary matter filed in connection with his motion for summary judgment. Therefore, the sole question raised by defendant's motion is whether, taking these allegations as true, the rights and relationships described above are constitutionally protected. If they are, then Plaintiffs have stated a claim upon which relief could be granted following proof of these allegations at trial.

ARGUMENT

I. A physician's right to practice his profession, and the physician-patient relationship itself, involve constitutionally protected interests of both patients and physicians. Therefore, Plaintiffs' claim that the PSRO law constitutes an arbitrary, irrational and overbroad invasion of those interests is a claim upon which relief could be granted.

The principal argument advanced by defendant in support of dismissal of this action is that Social Security health care benefits are a form of federal gratuity or public largesse in which beneficiaries have no constitutionally protected interests -- and that, consequently, congressional regulation of such expenditures is immune to challenge in a suit such as this. Thus, in the first point of his memorandum defendant characterizes the statute in question as only affecting a physician's economic interest in receiving fees under federal health care programs,[2] which interest, he contends, Congress may regulate in any way it sees fit, citing as his sole authority for that proposition

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[2] Defendant's memorandum misrepresents the role of a physician treating a patient eligible for federal health care benefits as being that of an agent of the federal government whose services are "procured" in the same way that the government purchases supplies (see Memorandum pp. 30, 39). The defendant does not "purchase" physicians' professional services under medicare and medicaid as though the physician were a federal employee or contractor. Benefits are payable to, or on the behalf of persons eligible under the Social Security Act. (42 U.S.C.§§ 1395d, 1395k). These provisions do not in themselves create any sort of contractual relationship between a physician and the government, or bring to bear upon him any of the regulatory power the government might have incident to a true contractual arrangement.

an aphoristic dictum from Wickard v. Filburn, 317 U.S. 111 (1942) to the effect that it is not a lack of due process "for the Government to regulate that which it subsidizes."

In a similar vein, defendant contends in the second point of his memorandum that the physician-patient relationship involved here is merely a relationship created to pass benefits from the beneficiaries to the plaintiffs and is not constitutionally protected, because a beneficiary has no protected interest in receiving them. As authority for the latter proposition, he cites only Richardson v. Belcher, 404 U.S. 78 (1971), which, as plaintiffs will show, holds precisely to the contrary. In his third point of argument the defendant also denies that constitutionally protected rights of privacy are implicated in the physician-patient relationship, citing as his sole authority the case of Felber v. Foote, 321 F. Supp. 85 (D.C. Conn. 1970), which is no longer good law, as plaintiffs will demonstrate below.

In essence, the defendant Secretary is saying to millions of elderly and indigent Americans, and the physicians who care for their health, that if they do not want to accept federal health care reimbursement under any regulatory conditions Congress deems necessary, they are free to pay for such health care themselves. That, of course, is not a realistic alternative for most of them, and fortunately the Constitution and Courts of the United States forbid the defendant to present them with such a dilemma.

The Supreme Court has said in Richardson v. Belcher, 404 U.S. 78, 81 (1971):

> To characterize an Act of Congress as conferring a "public benefit" does not, of course, immunize it from scrutiny under the Fifth Amendment. We have held that "[t]he interest of a covered employee under the [Social Security] Act is of sufficient substance to fall within the protection from arbitrary governmental action afforded by the Due Process Clause" . . . .[citing Fleming v. Nestor, 363 U.S. 603, 611].

The Court very recently has declared certain cost-control and fraud prevention provisions of the federal Food Stamp Act of 1963 constitutionally invalid on the grounds of arbitrariness and overbreadth, without finding an invasion of a constitutional right or fundamental interest. U.S. Dept. of Agriculture v. Murry, 413 U.S. 508 (1973); U.S. Dept. of Agriculture v. Moreno, 413 U.S. 528 (1973).

Where, as plaintiffs will show to be the case here, legislative regulation of public benefits and governmental "privileges" is challenged as interfering with constitutional rights -- or interests that are considered "fundamental", even though they are not expressly mentioned in the Constitution such legislation is subject to an even stricter judicial scrutiny. See Memorial Hospital v. Maricopa County, ... U.S. . . . ., 42 U.S.L. Wk. 4277, 4281 (Feb. 26, 1974) (involving state medical benefits); Lefkowitz v. Turley, ... U.S. . . . . 38 L. Ed. 2d 274, 284 (1973); Shapiro v. Thompson, 394 U.S. 618,

631 (1969); Sherbert v. Verner, 374 U.S. 398, 407 (1963); Reed v. Gardner, 261 F.Supp. 87, 91 (C.D. Calif. 1966) (involving medicare benefits); City of Carmel-By-The-Sea v. Young, 466 P.2d 225, 229 (Calif. 1970). See also the dissenting opinion of Marshall, J., in California v. LaRue, 409 U.S. 109, 137 (1972).

Courts traditionally have employed a "balancing" test to determine the constitutionality of social and economic legislation -- weighing the private interests invaded against the public interests to be served by the invading enactment. If the private interests invaded are considered to be of a high order of value, the standards by which the legislation will be measured will be more stringent. The Supreme Court has said repeatedly that "Where certain 'fundamental rights' are involved, . . . regulation limiting those rights may be justified only by a 'compelling state interest' . . . and . . . legislative enactments must be narrowly drawn to express only the legitimate state interests at stake." Roe v. Wade, 410 U.S. 113, 155 (1973).

A. The principles of trust, confidentiality and ethical obligation that historically have characterized the physician-patient relationship embody a variety of rights of a fundamental nature.

The physician has a right to practice his profession free of arbitrary government interference:

Dent v. West Virginia, 129 U.S. 114, 121-122 (1889):

> It is undoubtedly the right of every citizen of the United States to follow any lawful calling, business, or profession he may choose, subject only to such restrictions as are imposed upon all persons of like age, sex and condition. This right may in many respects be considered as a distinguishing feature of our republican institutions. Here all vocations are open to every one on like conditions. All may be pursued as sources of livelihood, some requiring years of study and great learning for their successful prosecution. The interest, or, as it is sometimes termed, the estate acquired in them, that is, the right to continue their prosecution, is often of great value to the possessors, and cannot be arbitrarily taken from them, any more than their real or personal property can be thus taken.

Meyer v. Nebraska, 262 U.S. 390, 399 (1923):

> While this Court has not attempted to define with exactness the liberty thus guaranteed by the Due Process Clause of the Fourteenth Amendment, the term has received much consideration and some of the included things have been definitely stated. Without doubt, it denotes not merely freedom from bodily restraint but also the right of the individual to contract, to engage in any of the common occupations of life, . . . and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men.

Barsky v. Board of Regents, 347 U.S. 442, 459 (1954) (Black, J. dissenting):

> I have no doubt that New York has broad power to regulate the practice of medicine. But the right to practice is . . . a very precious part of the liberty of an individual physician or surgeon. It may mean more than any property. Such a right is protected from arbitrary infringement by our Constition . . .

The rights and interests of a patient in his relationship with his doctor were examined at length in the case of Hammonds v. Aetna Casualty & Surety Co., 243 F. Supp. 793, 801 (N.D. Ohio 1965):

> When a patient seeks out a doctor and retains him, he must admit him to the most private part of the material domain of man. Nothing material is more important or more intimate to man that the health of his mind and body. Since the layman is unfamiliar with the road to recovery, he cannot sift the circumstances of his life and habits to determine what is information pertinent to his health. As a consequence, he must disclose all information in his consultations with his doctor -- even that which is embarrassing, disgraceful or incriminating. To promote full disclosure, the medical profession extends the promise of secrecy referred to above. The candor which this promise elicits is necessary to the effective pursuit of health; there can be no reticence, no reservation, no reluctance when patients discuss their problems with their doctors. But the disclosure is certainly intended to be private. If a doctor should reveal any of these confidences, he surely effects an invasion of the privacy of his patient. We are of the opinion that the preservation of the patient's privacy is no mere ethical duty upon the part of the doctor; there is a legal duty as well. The unauthorized revelation of medical secrets, or any confidential communication given in the course of treatment, is tortious conduct which may be the basis for an action in damages.

The recent case of Doe v. Bolton, 410 U.S. 179 (1973), reveals the constitutional dimensions of this relationship in an especially pertinent context. In that case, doctors argued that the Georgia abortion statute impermissibly restricted the physician's right to practice his profession and deprived him of due process of law because it subjected a doctor's individual medical judgment to committee approval and to confirming consultations. The Supreme Court agreed:

> Viewing the Georgia statute as a whole, we see no constitutionally justifiable pertinence in the structure for the advance approval by the abortion committee. With regard to the protection of potential life, the medical judgment is already completed prior to the Committee stage,

> and review by a committee once removed from diagnosis is basically redundant. We are not cited to any other surgical procedure made subject to committee approval as a matter of state criminal law. The woman's right to receive medical care in accordance with her licensed physician's best judgment and the physician's right to administer it are substantially limited by this statutorily imposed overview.[410 U.S. at 197]

Justice Douglas examined patients' rights at greater length in his concurring opinions:

> The right of privacy has no more conspicuous place than in the physician-patient relationship, unless it be in the priest-penitent relation.
>
> It is one thing for a patient to agree that her physician may consult with another physician about her case. It is quite a different matter for the State compulsorily to impose on that physician-patient relationship another layer, or as in this case, still a third layer of physicians. The right of privacy -- the right to care for one's health and person and to seek out a physician of one's own choice protected by the Fourteenth Amendment -- becomes only a matter of theory not a reality, when a multiple physician approval system is mandated by the State. [410 U.S. at 219]

The rationale of the Supreme Court's holding in Doe v. Bolton, was anticipated by a Kansas federal court in Poe v. Menshini, 339 F. Supp. 986, 995 (D.C. Kan. 1972):

> With respect to the three-physician requirement, plaintiffs further contend it infringes upon the fundamental right of physicians to administer necessary health care to their patients. They assert that the First, Ninth and Fourteenth Amendments protect the right of physicians as well as every other citizen to pursue his chosen profession free from unnecessary interference from the state. Undoubtedly, physicians should be free to practice their profession and to exercise their professional discretion

> subject only to such regulations as are necessary for the protection of legitimate public interests. It is undeniable in this case that the disputed provision infringes upon this right. In fact, the provision seeks to subordinate the attending physician's judgment to that of two other physicians without any showing that it effectively advances a legitimate state interest. Rather, its only effect is to classify abortions apart from other medical procedures and to curtail the availability of abortions in derogation of a woman's fundamental right to procure an abortion, and of the physician's right to administer to his patients in accordance with his best judgment.

Two rulings made in litigation currently pending in the Second Circuit are especially pertinent to defendant's motion for summary judgment and his citation of Felber v. Foote, supra, in support thereof. In Roe v. Ingraham, 480 F. 2d 102 (2d Cir. 1973) the plaintiffs attacked the constitutionality of the patient disclosure requirements of the New York Controlled Substances Act on the ground that it constituted an impermissible invasion of patients' constitutional right to privacy with respect to the status of their health and the medical treatment they are receiving, and impaired physicians' constitutional right to make their decisions solely on the basis of medical considerations. The Court of Appeals held that this claim raised a constitutional question of sufficient substantiality to warrant convening a three-judge court. 480 F. 2d at 106-108. On remand, the claim survived the more rigorous test of a motion to dismiss. 364 F. Supp. 536, 542-43, 546 (S. D. N. Y. 1973).

B. The claims made in this suit are justiciable, and Plaintiffs have standing to raise them.

At page 31 of his memorandum defendant asserts that plaintiffs' objection to the system of pre-set norms of diagnosis, treatment and care that is to be created by mandate of the legislation in question is hypothetical and nonjusticiable because ". . . it is impossible to determine what effect a particular norm might have prior to its creation . . . ." Defendant blithely disregards the fact that plaintiffs' complaint asks for a declaration that the PSRO statute is unconstitutional on its face, and alleges that the host of unique and often changing factors that must be taken into consideration in diagnosing and treating an individual patient in accordance with the highest standards of medical practice are inherently incapable of reduction to "norms". They allege that conforming their professional judgments to a pre-set system would deprive their patients of the best medical care they are capable of rendering. (See Complaint Part I, ¶2; Part III, ¶9).

The Random House Dictionary of the English Language describes a "norm" as a "standard, model, or pattern"; a "general level or average". According to the study of PSRO implementation cited earlier in this memorandum [3]

> Norms generally specify quantitative levels of performance. They are usually developed empirically, by measuring performance in a stated sample, but may

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[3] Decker & Bonner 15.

> be modified by deliberative judgment. Norms, commonly in use, deal with length of stay, frequency of visits, charges, and mortality rates. Selected norms may be optional, average, or minimal or may describe the frequency distribution of a given event in a defined sample. Norms have been developed for both the processes and the outcomes of medical care.

Under any system of pre-set norms of medical diagnosis, treatment and care the government might create, there will be patients who do not fit the mold, are not average, and their physicians will have to depart from the norms in treating them -- if they are courageous enough to run the risk of economic sanctions and professional stigmatization in the event that those in charge of enforcing compliance with the norms disagree with the departure.

A system of pre-set norms will be imposed upon plaintiffs' professional practice by this law -- that is a certainty, not a hypothetical possibility. Plaintiffs' objection to such a system is no less justiciable now than if it were made after specific norms have been promulgated. Plaintiffs and their patients need not wait until that threat of injury becomes a reality. See YWCA of Princeton v. Kugler, 342 F. Supp. 1048, 1055 (D.C. N.J. 1972); Doe v. Dunbar, 320 F. Supp. 1297, 1301 (D.C. Colo. 1970); Reed v. Gardner, 261 F. Supp. 87, 92 (C.D. Calif. 1966). There is also no question that plaintiffs have standing to represent the interests of their patients threatened by the statute in question. See Doe v. Bolton, 410 U.S. 179 (1973);

Griswold v. Connecticut, 381 U.S. 479, 481 (1965); Roe v. Ingraham, 364 F. Supp. 536, 540 fn. 6 (S.D. N.Y. 1973); YWCA of Princeton v. Kugler, supra; Doe v. Dunbar, supra.

C. The legislation in question is unconstitutionally overbroad.

The Professional Standards Review Act constitutes an arbitrary, irrational and overbroad interference with the constitutionally protected rights of physicians and patients described above.

The primary purpose of the Act is to control the rapidly rising costs of governmental health care delivery systems. It represents partial abandonment of attempts to control the costs of health care delivery systems through output controls such as spot reviews, in favor of a system of prior restraint, or input controls, in the form of pre-set norms of practice and screening devices enforced by sanctions. Implicit in this legislative judgment that prior restraints on a physician's medical judgment concerning matters of care, diagnosis and treatment are necessary, is the assumption that, where federally-financed health care is involved, self-regulation based upon moral, ethical and professional considerations no longer is functioning, and cannot be corrected by the usual legal sanctions for unprofessional conduct.

Legislative action taken upon such a premise is per se arbitrary and irrational. Since the 19th Century the legal balance between a physician's

right to practice his profession and the government's right to regulate his conduct has been struck upon the principle that the public's interest in health care is best secured, not by legislating standards of diagnosis and treatment to which practitioners must adhere, but by limiting access to practice to persons who, because of their technical skills, will be capable of accurate medical judgments, and who, because of their moral character, will in fact make such judgments solely according to the best interests of their patients. Restrictive licensing of physicians has been justified by this principle. See Dent v. West Virginia, 129 U.S. 114 (1889); Hawker v. New York, 170 U.S. 189, 194, 198-99 (1898). In the Dent case the Court said:

> Few professions require more careful preparation by one who seeks to enter it than that of medicine. It has to deal with all those subtle and mysterious influences upon which health and life depend, and requires not only a knowledge of the properties of vegetable and mineral substances, but of the human body in all its complicated parts, and their relation to each other, as well as their influence upon the mind. The physician must be able to detect readily the presence of disease, and prescribe appropriate remedies for its removal. Every one may have occasion to consult him, but comparatively few can judge of the qualifications of learning and skill which he possesses. Reliance must be placed upon the assurance given by his license, issued by an authority competent to judge in that respect, that he possesses the requisite qualifications. Due consideration, therefore, for the protection of society may well induce the State to exclude from practice those who have not such a license, or who are found upon examination not to be fully qualified.
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> [129 U.S. at 122-123]

Governmental inquiry into a physician's character, associations, and beliefs, otherwise highly questionable, also has been justified by this principle: Barsky v. Board of Regents, 347 U.S. 442 (1954); cf. Konigsberg v. State Bar of California, 366 U.S. 36 (1961); In re Anastaplo, 366 U.S. 82 (1961). And competitive business practices among practitioners are restricted in the service of this principle: Semler v. Oregon State Bd. of Dental Examiners, 294 U.S. 608, 611 (1935); United States v. Oregon State Medical Society, 343 U.S. 326, 336 (1952).

A license to practice medicine carries with it presumptions of competence and regularity of motive and conduct that are not lightly overcome by governmental regulation predicated upon contrary presumptions. The most recent authority for this proposition is the Supreme Court's decision in Doe v. Bolton, 410 U.S. 179 (1973). In declaring unconstitutional the Georgia abortion statute's requirement that abortion decisions be confirmed by two other physicians, the Court said:

> If a physician is licensed by the State, he is recognized by the State as capable of exercising acceptable clinical judgment. If he fails in this, professional censure or deprivation of his license are available remedies. Required acquiescence by co-practitioners has no rational connection with a patient's needs and unduly infringes on the physician's right to practice. The attending physician will know when a consultation is advisable -- the doubtful situation, the need for assurance when the medical decision is a delicate one, and the like. Physicians have followed this routine historically and know its usefulness and benefit for all concerned. It is still true today that "[r]eliance must be placed upon the assurance given by his

> license, issued by an authority competent to judge in that respect, that he [the physician] possesses the requisite qualifications." Dent v. West Virginia, 129 U.S. 114, 122-123, 9 S.Ct. 231, 233, 32 L.Ed. [410 U.S. at 199].

Concurring in that decision, Justice Douglas added:

> The State licenses a physician. If he is derelict or faithless, the procedures available to punish him or to deprive him of his license are well known. He is entitled to procedural due process before professional disciplinary sanction may be imposed. [410 U.S. at 219].

In United States v. Vuitch, 402 U.S. 62 (1971) a physician challenged the constitutionality of the District of Columbia abortion law, alleging that it placed on physicians the burden of proving that abortions they prescribed were necessary for the preservation of the life or health of the patient. Invoking the presumption discussed above, the Court saved the constitutionality of the statute by construing it as not placing such a burden of proof on doctors:

> Placing such a burden of proof on a doctor would be peculiarly inconsistent with society's notions of the responsibilities of the medical profession. Generally, doctors are encouraged by society's expectations, by the strictures of malpractice law and by their own professional standards to give their patients such treatment as is necessary to preserve their health. We are unable to believe that Congress intended that a physician be required to prove his innocence. [402 U.S. at 70-71].

Contrary to this presumption, the legislation in question here shifts the burden of proving the regularity of his professional conduct to the doctor by, inter alia, requiring that he maintain records that will

satisfy the PSRO, should it decide to make inquiry. The particular vice of such a shift in the burden of proof is that it has a chilling effect upon the doctor's freedom to make professional judgments solely according to the circumstances of an individual patient's case, and requires him to practice defensive medicine. The Supreme Court has noted in a different context that:

> The man who knows that he must bring forth proof and persuade another of the lawfulness of his conduct necessarily must steer far wider of the unlawful zone than if the State must bear these burdens. This is especially to be feared when the complexity of the proofs and the generality of the standards applied . . . provide but shifting sands on which the litigant must maintain his position . . . . "It is apparant that a constitutional prohibition cannot be transgressed indirectly by the creation of a statutory presumption any more than it can be violated by direct enactment. The power to create presumptions is not a means of escape from constitutional restrictions." Bailey v. Alabama, 219 U.S. 219, 239.
>
> [Speiser v. Randall, 357 U.S. 513, 526 (1958)]

The results reached by the courts in the cases discussed above strongly suggest that the legal protection afforded by these presumptions is an intrinsic part of a physician's constitutionally protected right to practice his profession. Evidence of conduct inconsistent with these presumptions does not justify violation of them on a profession-wide basis.

The Supreme Court has held in a variety of contexts that the state's interest in cost control and the prevention of fraud, abuse, and overuse of public spending programs does not justify an overbroad and undiscriminating

interference with the private rights and interests of those who are beneficiaries or recipients under them. In Memorial Hospital v. Maricopa County, ... U.S. ...., 42 U.S.L.Wk. 4277 (Feb. 26, 1974) the Court struck down an Arizona statute requiring one-year's residence in a county as a condition to receiving free medical care, saying:

> The County thus attempts to sustain the requirement as a necessary means to insure the fiscal integrity of its free medical care program by discouraging an influx of indigents, particularly those entering the county for the sole purpose of obtaining the benefits of its hospital facilities.
>
> First, a State may not protect the public fisc by drawing invidious distinction between classes of its citizens, [citing Shapiro v. Thompson, 394 U.S. 618, 633 (1969)] so appellees must do more than show that denying free medical care to new residents saves money. The conservation of the taxpayers' purse is simply not a sufficient state interest to sustain a durational residency requirement which, in effect, severely penalizes exercise of the right to freely migrate and settle in another state.
>
> ****
>
> [T]o the extent the purpose is to deter only those indigents who take up residence in the county solely to utilize its new and modern public facilities, the requirement at issue is clearly over-inclusive. The challenged durational residence requirement treats every indigent, in his first year of residence, as if he came to the jurisdiction solely to obtain free medical care.
>
> [42 U.S.L.Wk. at 4281-82]

In U.S. Dept. of Agriculture v. Moreno, 413 U.S. 528 (1973) the Court struck down a federal statutory provision limiting eligibility for federal food stamps to households consisting only of related individuals, saying:

> [T]he Government maintains that the challenged classification should . . . be upheld as rationally related to the clearly legitimate governmental interest in minimizing fraud in the administration of the food stamp program.
>
> ****
>
> But even if we were to accept as rational the Government's wholly unsubstantiated assumptions concerning the differences between "related" and "unrelated" households, we still could not agree with the Government's conclusion that the denial of essential federal food assistance to all otherwise eligible households containing unrelated members constitutes a rational effort to deal with these concerns.
>
> [413 U.S. at 535-36]

See also: U.S. Dept. of Agriculture v. Murry, 413 U.S. 507, 513 (1973); Sherbert v. Verner, 374 U.S. 398, 407 (1963); Word v. Poelker, . . . F.2d . . . . (8th Cir. Feb. 20, 1974), 42 U.S.L.Wk. 2448-49 (March 5, 1974) (holding an ordinance regulating abortion clinics unconstitutional as an overbroad interference with fundamental rights of physicians and patients).

Defendant contends that plaintiffs' allegations of unconstitutional overbreadth should be dismissed for failure to state a claim upon which relief could be granted because

> Since it is firmly established that the Government may fix the terms and conditions upon which it may purchase supplies, it necessarily follows that Congress has the power to fix the terms and conditions upon which it may procure the service of professional personnel.
>
> [Defendant's Memorandum p. 39]

The sole authority Defendant cites for his analogy of physicians to paper clips is Perkins v. Lukens Steel Co., 310 U.S. 113 (1940), which held that Congress had the power to include a minimum wage requirement in public

contracts because the Government enjoys the unrestricted power to produce its own supplies, to determine those with whom it will deal, and to fix the terms and conditions upon which it will make needed purchases.

As plaintiffs have pointed out earlier in this memorandum (see Footnote 2, supra) physicians become neither federal employees nor public contractors simply by virtue of treating a patient who is eligible for federal health care benefits, and even if they were such, their participation in the programs could not be made contingent upon the surrender of their constitutional rights. See Lefkowitz v. Turley, . . . U.S. . . . ., 38 L.Ed.2d 274, 285 (1973).

II. Plaintiffs' allegations that the disclosure and inspection requirements of the PSRO law constitute an overbroad interference with the right to privacy in the physician-patient relationship, and the right to be free from unreasonable searches and seizures state a claim upon which relief can be granted.

Under the legislation in question, physicians will be required to disclose extensive data concerning each patient they treat, which will be used to maintain "profiles" of the "care and services received and provided with respect to patients" (emphasis added). These profiles are to be "regularly reviewed" by the PSRO's on an "ongoing basis" with respect to each physician in order to determine whether the care and services ordered or rendered by the physician are consistent with requirements of the law. [§1320c--4(a)(4)]. The law, in addition, empowers the PSRO's to examine

the "pertinent" records of a physician and inspect the facilities in which he renders care, to the extent "necessary or appropriate" for the proper performance of its duties [§1320c--4(b)], and requires physicians to maintain and produce evidence -- in such form and fashion and at such time as a PSRO may reasonably require in the performance of its duties -- that he is treating his patients and conducting his practice in conformity with the requirements of the statute. [§1320c--9(a)]. Thus, the law not only requires disclosure of patient data and authorizes inspections in connection with a particular physician's treatment of a particular patient in a particular case, it requires continuing disclosures and inspections as a matter of general surveillance of physicians and their patients.

Plaintiffs allege that the disclosures of confidential information required by this law will substantially hinder them in their treatment of their patients, and that this violation of the privacy of the physician-patient relationship is not constitutionally justifiable.

The right of plaintiffs and their patients to be free of unwarranted or overbroad governmental intrusions in their privacy resides in part in the constitutional guarantee against unreasonable searches and seizures. The Supreme Court has said in Camara v. Municipal Court, 387 U.S. 523, 528 (1967) that

> The Fourth Amendment provides that, "The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and

> particularly describing the place to be searched, and the persons or things to be seized." The basic purpose of this Amendment, as recognized in countless decisions of this Court, is to safeguard the privacy and security of individuals against arbitrary invasions by governmental officials. The Fourth Amendment thus gives concrete expression to a right of the people which "is basic to a free society."

In the Camara case, the Court held invalid an ordinance that permitted city employees to enter and inspect premises on a routine basis for violations of the housing code, just as the law in question here compels disclosures and authorizes inspections on a routine basis for purposes of compliance surveillance. In Camara, the city defended this practice as necessary to protect the public's interest in maintaining the general health and safety of the general community. (387 U.S. at 533). The Court held that the warrantless searches authorized by the ordinance were prohibited by the Fourth Amendment. (387 U.S. at 533-34).

The rule of the Camara case was applied in a broader form and different context by the California Supreme Court in City of Carmel-By-The-Sea v. Young, 466 P. 2d 225 (1970). That case involved a state law that required a myriad of public officers and employees, and candidates for such positions, to make extensive disclosures of their personal financial affairs as a condition of holding public office. The Court found the statute to be an unconstitutional invasion of privacy:

> Differing aspects of the protection of privacy from intrusion by government are variously found to lie in the penumbra of the First Amendment, in the restrictions of the due process clause of the Fourteenth Amendment, or in the Ninth Amendment retained rights; other zones of privacy are affirmed in the Fourth Amendment "right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures," and in the Self-Incrimination Clause of the Fifth Amendment... [citing, inter alia, the Camara decision].

A three-judge district court in the Northern District of California has, in turn, followed the City of Carmel case in enjoining the Secretary of the Treasury from enforcing the domestic security surveillance program established by the Bank Secrecy Act. Stark v. Connally, 347 F.Supp. 1242 (1972), (prob. juris, noted 94 S. Ct 34 1973)). The Court held that the Act's broad requirement of routine disclosure (without previous judicial or administrative summons, subpoena or warrant) of bank customers' financial affairs as a surveillance device for discovery of possible wrongdoing constituted an invasion of their right of privacy amounting to an unreasonable search within the meaning of the Fourth Amendment. 247 F.Supp. at 1247-49. See also: United States v. Theodore, 479 F. 2d 749, 754 (4th Cir. 1973); United States v. Stanack Sales Co., 387 F.2d 849, 852 (3d Cir. 1968).

Defendant's only response to plaintiffs' objection to the invasions of privacy threatened by the disclosure and inspection requirements of

routine and warrantless PSRO surveillance is that the law contains safeguards against subsequent disclosure of the information so obtained (see defendant's memorandum pp. 33-34), except to the extent that disclosure is necessary to carry out the purposes of the Act. Defendant fails to recognize that it is the Act's compulsion of disclosure in the service of its purposes that constitutes the invasion of privacy to which plaintiffs object.

III. The duties and obligations imposed upon physicians by the PSRO law are unconstitutionally vague.

The statute in question imposes duties and obligations upon physicians in terms so vague "that men of common intelligence must necessarily guess at their meaning and differ as to their application" in violation of plaintiffs' right to due process of law. See Lanzetta v. New Jersey, 306 U.S. 451, 453 (1939); Connally v. General Construction Co., 269 U.S. 385, 391 (1926); YWCA of Princeton v. Kugler, 342 F. Supp. 1048, 1062 (D.C. N.J. 1972).

The language of the statute is vague in two respects: it is vague in the description of the duties and obligations it imposes, and vague in the description of the conduct that a PSRO will consider violative of those duties.

The statute requires that, in ordering, authorizing, directing, or arranging for the provision of health care services for a patient by "any other person", physicians must "exercise their professional responsibility" to the "extent" of their "influence and control" over the patient or such other persons to assure that the patient and such other persons will comply with the requirements of the law. [§1320c--9(a)(1)(C)]. The law also

imposes an obligation upon physicians, "within reasonable limits of professional discretion", "not to take any action" that would authorize hospitalization of a patient when care could be provided more economically in a different type of facility, unless there is no such facility in "the area" where the patient is located. [1320c--9(a)(2)].

If the defendant finds (upon a charge made by a PSRO) that a physician has "demonstrated" an "unwillingness", or a "lack of ability" to comply with these obligations, he may be temporarily or permanently barred from treating Social Security beneficiaries on a reimbursable basis--in addition to any other sanction provided by law. In the alternative, the defendant may exact from the physician the cost of the health care services found to have been wrongfully provided, up to $5,000. [§1320c--9(b)(1)&(3)].

Under the law, a PSRO may infer "unwillingness" or "lack of ability" from a physician's failure in a "substantial number" of cases to "substantially" comply with an obligation imposed by the law, or from "gross" and "flagrant" violation of any such obligation in one or more instances. [§1320c--9(b)(1)].

Thus, in treating a patient with an eye to whether a reviewing PSRO might find his conduct in violation of the law, a physician will be required to take into account a host of general and vague proscriptions to which he is expected to conform not only his conduct, but the conduct of others, as well. He must necessarily guess at what degree of effort to control the conduct of others would be viewed by a PSRO as an acceptable exertion of

"influence and control", or what conduct might be viewed by the PSRO as a "demonstration" of "unwillingness" or "lack of ability" to comply with the law, or what a PSRO might consider a "substantial" failure to comply, or a "gross" or "flagrant" violation. If he guesses wrong, he faces economic sanctions, blacklisting, and professional stigmatization. Defendant makes no attempt to defend these provisions of the law against plaintiffs' charge of vagueness.

Statutes couched in language so vague cannot withstand the test of constitutional due process. In YWCA of Princeton v. Kugler, supra, the Court held that a statute prohibiting the causing or procuring of an abortion "without lawful justification" was unconstitutionally vague because it didn't give adequate notice of the sphere of conduct prohibited. 342 F. Supp. at 1062. More to the point is Hewitt v. Board of Medical Examiners, 84 Pac. 39 (Calif. 1906), where the California Supreme Court held that a statute empowering the state board of medical examiners to revoke a physician's certificate to practice for making "grossly improbable statements" in medical advertising was void for vagueness. The same result is called for in this case.

IV. The provisions of Section 1320c--8 of the PSRO law are inconsistent with the requirements of procedural due process of law.

Under Section 1320c--4(a)(1) and (2) of the statute in question a PSRO is empowered to disapprove health care services and items provided

by a physician to a Social Security beneficiary as not medically necessary, or on the ground that the quality of his services did not meet professionally recognized standards (the "norms"), or that he hospitalized a patient who could have been cared for on an outpatient basis, or in a less expensive facility. Under that section, the PSRO may also disapprove in advance any elective admission to a hospital or other health care facility for treatment not meeting the requirements of the law, or on the ground that the particular elective treatment proposed would not meet the law's criteria if delivered by the particular physician proposing it.

Section 1320c--8 of the law provides that a beneficiary, recipient, or practitioner who is dissatisfied with a determination made by a PSRO in its exercise of the powers described above is entitled to have the PSRO "reconsider" its own decision. If the PSRO reaffirms itself, and if it is situated in a state that happens to have an optional state-wide review council in operation, and if the amount in controversy is $100 or more, that body can review the determination, and its decision is reviewable by the defendant Secretary.

The statute, however, provides no recourse from determinations of a PSRO in matters involving less than $100, nor does the statute provide for any semblance of a due-process type hearing or other opportunity for those whose rights are affected to participate in its decision-making process. Such persons may only request PSRO "reconsideration" of its own determination. Thus, it is possible for a PSRO to repeatedly make determinations

adverse to beneficiaries, recipients, and practitioners in matters where less than $100 is at issue without its decisions ever being subject to the test of an adversary process or review by a neutral third party.

Such procedures do not comport with constitutional requirements of due process of law. See Coral Cables Convalescent Home, Inc. v. Richardson, 340 F. Supp. 646 (S.D. Fla. 1972), holding that a nursing home from whom amounts due for services rendered under medicare had been withheld by a fiscal intermediary (to recoup alleged overpayments) was entitled to at least a post-reduction trial-type hearing before an impartial decision-maker. See also: Steinberg v. Fusari, 364 F. Supp. 922 (D.C. Conn. 1973), cert. granted 42 U.S.L.Wk. 3458, 2-19-74, which held that Connecticut procedures whereby unemployment compensation benefits could be terminated for causes other than exhaustion of eligibility without prior hearing (other than an interview at the compensation office at the time of denial of further benefits) was inconsistent with due process, and that beneficiaries were entitled to at least some advance notice of a hearing, notice of the precise issues to be considered, an opportunity to present evidence, and to be represented by counsel.

V. The immunity provisions of §1320c--16(c) of the PSRO law are inadequate and ineffective safeguards against the irreconcilable conflicts in a physician's legal duties that the law engenders.

In Section 1320c--16(c) of the statute in question, Congress purports to grant a physician immunity from civil liability to any person under any

law of the United States or of any State, or political subdivision thereof, "... on account of any action taken by him in compliance with or reliance upon professionally developed norms of care and treatment applied by a Professional Standards Review Organization..." (emphasis added), if such action is taken in the exercise of due care.

The Court will note that--while the PSRO statute imposes extensive duties upon physicians to comply with its norms of diagnosis, treatment and care--this particular section of the law purports to grant immunity only in connection with actions taken in accordance with the norms of "care" and "treatment". A physician is granted no immunity from a malpractice action arising out of injuries that might result from his following the diagnostic norms mandated by the law.

Thus, in situations where a physician's best medical judgment of what medical procedures should or should not be followed for the proper diagnosis of a patient's condition doesn't comport with the diagnostic procedures dictated by PSRO norms he will be faced with the unenviable choice of either conforming his conduct to a standard that would insulate him from a charge of negligence under the common law of torts, or to the standard that would insulate him from a charge of violating the instant statute. That Congress should so firmly plant physicians on the horns of this dilemma offends the fundamental concepts of fairness and justice embodied in the constitutional concept of due process of law. See Palko v. Connecticut, 302 U.S. 319, 325 (1937).

Neither is there any assurance that the immunity that is granted in

Section 1320c--16(c) would be honored by a state court of common law in a suit where it was set up as a defense to a claim of medical malpractice. The Supreme Court has said in Erie R. Co. v. Tompkins, 304 U.S. 64 (1938) that:

> Congress has no power to declare substantive rules of common law applicable in a State whether they be local in their nature of "general", be they commercial law or a part of the law of torts.
>
> * * *
>
> Supervision over either the legislative or the judicial action of the States is in no case permissible except as to matters by the Constitution specifically authorized or delegated to the United States. Any interference with either, except as thus permitted, is an invasion of the authority of the State, and, to that extent, a denial of its independence. [304 U.S. at 78-79]

Plaintiffs would not dispute that state legislatures may modify or abolish state common law rights and remedies (see, e.g., Silver v. Silver, 280 U.S. 117 (1929), cited by defendant at page 37 of his memorandum), and that Congress has an analogous power in those areas where the federal authority is exclusive, such as the regulation of labor relations of interstate carriers (see, e.g., Stumo v. United Airlines, 382 F.2d 780 (7th Cir. 1967), cited by defendant at page 37 of his memornadum), or the regulation of national banks (see, e.g., State of Texas v. National Bank, 290 F.2d 229 (5th Cir. 1961), cited by defendant at page 40 of his memorandum).

Plaintiffs also recognize that Congress has plenary authority over whether and to what extent the sovereign immunity of the United States shall be invoked in connection with the activities of federal agents and employees

while they are acting within the scope of their employment (see, e.g., Carr v. United States, 422 F. 2d 1007 (4th Cir. 1970), cited by defendant at page 37 of his memorandum). It is also true that Congress may have acted so extensively in a particular field that state law inconsistent therewith will be considered pre-empted by operation of the Supremacy Clause. See Pennsylvania v. Nelson, 350 U.S. 497 (1956).

In the instant case, none of these considerations constitutes a basis for congressional authority to grant immunity for common law medical malpractice liability. The common law of torts as applied in medical malpractice certainly is not a matter of exclusive federal jurisdiction, nor can it be said that Congress has legislated so extensively in this field that state common law has been pre-empted.

Neither can this congressional attempt to, in effect, abolish a cause of action for tortious injury of a particular class of citizens (consisting primarily of the poor and elderly) be explained as the quid pro quo for the higher quality of medical care that class allegedly will receive under the PSRO law -- because the immunity, of course, will only operate against those members of the class who are injured because they were treated in accordance with the dictates of federal norms. Defendant cannot seriously contend that the immunity provisions of the PSRO law were designed to enhance the quality of medical care rendered to Social Security beneficiaries; clearly they were designed only as a measure to avert the costs of damages actions brought by

those who are injured by the medical practices dictated by the law. Plaintiffs are aware of no authority suggesting that Congress simply may abolish a state common law tort remedy in order to achieve economies in a federal spending program no matter how well-settled or exclusive the federal authority to enact the program itself might be. Cf. United States v. Burnison, 339 U.S. 87 (1950).[4]

There is no question that plaintiffs have standing to seek a declaration from this Court on this issue. If the immunity Congress has attempted to grant proves not to be efficacious plaintiffs will be exposed to a serious risk of civil liability as a result of complying with the law. At least it appears that Congress thought the possibility of that exposure was serious enough to attempt to grant physicians immunity against it. In New York Central R.R. Co. v. White, 243 U.S. 188 (1917), a suit brought by employers to challenge the constitutionality of a workmen's compensation statute, the Court also

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[4] There is dictum in Stumo v. United Airlines, supra, to the effect that "Congress has the power to modify or abolish common law rights or remedies", but the two United States Supreme Court decisions cited by the Court as authority for that proposition (Silver v. Silver, 280 U.S. 117 and Mountain Timber Co. v. State of Washington, 243 U.S. 219) do not support it. Both of those cases involved a state's right to change state common law, not the federal government's right to change state common law.

considered the constitutionality of the law from the standpoint of the employees affected by it, because:

> In considering the constitutional question, it is necessary to view the matter from the standpoint of the employee as well as from that of the employer. For, while plaintiff in error is an employer, and cannot succeed without showing that its rights as such are infringed (Plymouth Coal Co. v. Pennsylvania, 232 U.S. 531, 544; Jeffrey Mfg. Co. v. Blagg, 235 U.S. 571, 576;) yet, as pointed out by the Court of Appeals in the Jensen Case, 215 N.Y. 526, the exemption from further liability is an essential part of the scheme, so that the statute if invalid as against the employee is invalid as against the employer. [243 U.S. at 197]

VI. The PSRO law grants quasi-judicial authority to private groups financially interested in its enforcement, in violation of plaintiffs' right to due process of law.

The Professional Standards Review Organizations created by the statute in question are to consist of medical practitioners until the end of 1975, then their functions may be performed by personnel from state and local health departments, medical schools, insurance carriers and intermediaries or other health insurers[5] -- groups that defendant admits may be biased (see memoramdum p. 40).

What is more significant is that these organizations will operate under contract with the defendant Secretary -- a contract that he may terminate if

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[5] Senate Finance Committee Report on H.R. 1, 92nd Cong. 2nd Sess. Sen. Rept. No. 92-1230 (Sept. 26, 1972).

he is not satisfied with the manner in which they are performing their functions under the law. (See §1320c--1). The defendant Secretary is to reimburse the PSRO's for their expenses [§1320c--4(f)(2)], presumably including the salaries of the persons performing the review functions, and the PSRO's are authorized to hire specialists and experts in various areas of health care, and to utilize the services of review committees of hospitals and other health care facilities or organizations operating in their areas [§1320c--4(b)(1) and (e)(1)].

As plaintiffs have pointed out earlier in this memorandum, a PSRO will have authority to initiate a broad range of economic sanctions and other deprivations against physicians it determines are not complying with the objectives and requirements of the statute, and will have an unreviewable power to repeatedly disapprove reimbursement in matters involving less than $100.

These organizations, and the individual employees and consultants being paid to carry out the review function, will have an economic interest in demonstrating a record of program cost reduction satisfactory to the defendant Secretary in order to maintain their operating agreement with him, and the influence and control over the medical profession that goes with it. The adjudication of disputes by persons who have an economic interest in their outcome is inconsistent with due process of law. See Tumey v. Ohio, 273 U.S. 510, 522-32 (1927).

VII. Plaintiffs' complaint adequately pleads the requisite jurisdictional amount.

An allegation, such as that in Part I, ¶1 of plaintiffs' complaint, that the matter in controversy exceeds, exclusive of interest and costs, the sum of $10,000 dollars is the accepted form for pleading the presence of the jurisdictional amount requirement of 28 U.S.C. §1331. See Federal Rules of Civil Procedure, Official Form No. 2; 1 Moore's Federal Practice ¶0.92[1] p. 834. Unless it appears positively from other allegations of the complaint that the action could not possibly involve that amount, the complaint should be considered sufficient in the face of motion to dismiss. See KVOS, Inc. v. Associated Press, 299 U.S. 269, 277 (1936); Opelika Nursing Home, Inc. v. Richardson, 448 F.2d 658, 666 (5th Cir. 1971); Ammex Warehouse Co. v. Dept. of Alcoholic Bev. Control, 224 F.Supp. 546, 550 (S.D. Calif. 1963), (Aff'd, 378 U.S. 124).

Defendant does not challenge the good faith of plaintiffs' allegation that the amount in controversy here exceeds the sum of 10,000 dollars, exclusive of interest and costs, and the other allegations of plaintiffs' complaint -- far from contradicting that allegation -- lend further support to it. One of the matters alleged to be in controversy is plaintiffs' right to practice their profession, which they allege will be impaired if the law is enforced. It certainly cannot be said on the pleadings alone that it would be impossible for plaintiffs to present proof that their property interest in their future earnings from their medical practices would have a value greater than 10,000 dollars

each. Compare Berk v. Laird, 429 F.2d 302, 306 (2d Cir. 1970). Plaintiffs' complaint draws into controversy the rights of them and their patients to receive reimbursement under the medicare and medicaid programs. Compare Opelika Nursing Home, Inc. v. Richardson, supra. The complaint draws into controversy the validity of the entire PSRO program, which certainly could be proved to involve expenditures greater than 10,000 dollars. Compare Illinois State Employees Union, Council 34 v. Hodgson, 335 F.Supp. 960, 962 (N.D. Ill. 1971).

Plaintiffs are entitled to an opportunity to flesh out these good-faith allegations with evidence showing the amounts of money they involve. See Opelika Nursing Home, Inc. v. Richardson, supra, at 662; Ammex Warehouse Co. v. Dept. of Alcoholic Bev. Control, supra, at 550; Moehl v. E. I. Du Pont De Nemours & Co., 84 F.Supp. 427, 431 (N.D. Ill. 1947).

The holding in the Opelika Nursing Home case is especially pertinent to this issue. There, the plaintiff nursing homes attacked "reasonable cost" regulations of the defendant Secretary of Health, Education and Welfare which affected their reimbursement under the medicaid program. As the Court explained in its opinion:

> In their complaint plaintiffs posited subject matter jurisdiction under 28 U.S.C.A. §1331(a) [footnote omitted]. To this end the complaint contained a formal allegation that the matter in controversy exceeded, exclusive of interest and costs, the sum of $10,000. However, plaintiffs failed to allege any jurisdictional facts tending to support this formal allegation. Indeed, plaintiffs admitted in their com-

> plaint that skilled nursing homes in Alabama might suffer no pecuniary loss by virtue of the "reasonable cost" regulation, for the complaint stated that "reasonable cost" might be "higher or lower" than "reasonable charges." On the basis of this admission, the trial judge concluded that any pecuniary loss which the plaintiffs might incur as a result of the enforcement of the "reasonable cost" regulation was "too speculative" to satisfy the "matter in controversy" requirement of 28 U.S.C.A. §1331(a) [footnote omitted]. Therefore, the court below concluded, solely upon the basis of the pleadings, that it did not have jurisdiction over the subject matter of the action. ***
>
> As a result of these adverse rulings, plaintiffs appeal, contending, inter alia, that the district court erred in denying them an opportunity to discharge their burden of proving that the claim satisfied the requisite jurisdictional amount. We agree with this contention, for we are convinced that the pleadings alone are not so conclusive that the plaintiffs should have been denied an opportunity to present facts in support of their jurisdictional claim [footnote omitted]. Accordingly, we remand for full development of the jurisdictional facts. [448 F. 2d at 662]

The allegations of the complaint in the instant case are far stronger than those discussed in the Opelika case, and more than suffice to invoke this Court's jurisdiction under 28 U.S.C. §1331. Defendant's motion for summary judgment for lack of jurisdiction should therefore be denied.

Conclusion

For the foregoing reasons, Plaintiffs pray that this Court enter its order denying the defendant's motion for summary judgment and setting a

date for the defendant to answer to the Complaint herein.

Respectfully submitted,

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STATE OF ILLINOIS)
) SS
COUNTY OF COOK)

ELLEN E. OSSEFORT, being first duly sworn on oath deposes and says that she served the foregoing Memorandum of Law in Opposition to Defendant's Motion for Summary Judgment on all attorneys of record by placing a true copy of said Memorandum of Law in an envelope properly addressed and depositing the same in the United States mail chute at 135 South LaSalle Street, Chicago, Illinois 60603 on the 11th day of March 1974, all postage prepaid.

Ellen E. Ossefort

Subscribed and sworn to before me this
11th day of March, 1974.

Margaret M. Egan
Notary Public