BACKGROUND MATERIAL RELATING TO

PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS (PSRO's)

COMMITTEE ON FINANCE UNITED STATES SENATE RUSSELL B. Long, Chairman



MAY 8, 1974

Prepared by the staff and printed for the use of the Committee on Finance

U.S. GOVERNMENT PRINTING OFFICE WASHINGTON: 1974

32-768 O

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CONTENTS

	
I.	Summary of the legislative history of the Professional
	Standards Review Organization (PSRO) provision
TT	Excerpts concerning PSRO from the Senate Finance
.,,	Committee Report on H.R. 1—October, 1972
TTT	Status of implementation of the PSRO program
111. Tit	Dissiplined an animation of the FSKO program.
11.	Physicians' organizations seeking to participate in the
	PSRO program
٧.	Response of Senator Wallace F. Bennett to allegations
	concerning the PSRO program:
	A. Extent of congressional consideration
	B. Norms of health care
	C. Confidentiality of patient records
	D. Costs of PSRO
	E. Sanctions against physicians
17 T	Appendix:
γ 1.	
	A. Statutory language from Public Law 92-603 re-
	lating to PSRO
	B. Introductory statements to the Senate by Senator
	Wallace Bennett concerning the PSRO legisla-
	tion
	C. PSRO regional map

(111)

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 com-

mittee 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 require-

ments and activities re 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 Commis-

sion, issued in November 1967. That report stated:

"Peer review should be performed at the local level with profes-

sional 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 medi-

caid 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 necessary 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 would 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 im-

prove 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.

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.

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

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State of Puerto Rico Puerto Rico	Foundation for Medical Care of Puerto Rico	Planning.
	Area I—PSRO Region II	Do.
	Passaic Valley PSRO	Do.
IVdodo	Essex Physician Review Organization, Inc.	Do.
I New York	Erie Region PSRO, Inc.	Do.
IIdodo	Genessee Region PSRO, Inc.	Do.
IIIdo	PSRO of Central New York, Inc.	Do.
IVdo	Five-County Organization for Medical Care and	Do.
	PSR.	
Vdo	Adirondack Professional Standards Review Or-	\mathbf{Do} .
	ganization.	_
IXdodo	Area 9 PSRO of New York, Inc	Do.
Xdodo	Professional Standards Review Organization of	Do.
	Rockland.	_
XIdodo	New York County Health Services Review	$\mathbf{D_0}$.
	Organization.	
XIIdodo	Richmond County, New York PSRO, Inc	Do.
XIII	Kings County Health Care Review Organization	Do.
XIV	Medical Society of County of Queens	Do.
XVdodo	Nassau Physicians' Review Organization	Do.
XVI	Bronx Medical Services Foundation, Inc.	Do.
State of New Yorkdo	Medical Society of New York State	Support center.
State of New Jersey New Jersey	New Jersey Foundation for Health Care Evalu-	Do.
	ation.	

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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	West Virginia	West Virginia Medical Institute, Inc	Do.
Virginia.			
II	Pennsylvania	Central Pennsylvania Area II PSRO	Do.
IV	do	Central Pennsylvania Area II PSROEastern Pennsylvania Health Care Foundation, Inc.	Do.
VT _	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.
		Baltimore City Professional Review Org., Inc	Do.
III	do	Montgomery County, Md. Medical Care Foun-	Do.
		dation. Inc.	
IV 1	do	Prince George's Foundation for Medical Care,	Do.
		Inc.	
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	$\mathbf{Do}.$
State of Maryland	do	Maryland Foundation for Health Care, Inc	Support center.
State of Virginia	Virginia	Medical Society of Virginia	Do.

REGION IV

II	Florida do do do Alabama Georgia Kentucky South Carolina North Carolina do do Mississippi	Tennessee Foundation for Medical Care, Inc. Jacksonville Area PSRO. Pinellas County PSR, Inc. Brevolco PSRO, Inc. Dade-Monroe PSRO, Inc. Alabama Medical Review, Inc. PSRO of Georgia. Kentucky Peer Review Organization, Inc. South Carolina Medical Care Foundation. Old North State PSRO. Piedmont Medical Foundation, Inc. North Carolina Area VII Peer Review Corp. Mississippi Foundation for Medical Care, Inc.	Conditional. Planning. Do. Do. Do. Do. Do. Do. Do. Do. Conditional.
		North Carolina Medical Peer Review Founda-	
		tion, Inc.	
REGION V	•		.
ţ	Wisconsin	Wisconsin Professional Review Organization	Planning.
11	do	(The Foundation for Medical Care Evaluation of Southeastern Wisconsin, Inc.).	⊅ ₀.
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	\mathbf{Do} .
I	Indiana	Calumet Professional Review Organization	\mathbf{Do} .

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PSRO area number	State	Name of applicant organization	Type of application
REGION V—	Continued		1
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.
[Ohio	Medco Peer Review, Inc	Do.
Ι	do	Western Ohio Foundation for Medical Care	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	Physicians' Peer Review Organization Medical Advances Institute	Support center.
		Michigan State Medical Society	
State of Indiana	Indiana Indiana	Indiana Physicians Support Agency	Do.

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REGION VI AND VII

State of Iowa Iowa State of Kansas Kansas I Missour II do III do	Arkansas Foundation for Medical Care Plannin Iowa Foundation for Medical Care Do Kansas Foundation for Medical Care Do Northwest Missouri PSRO Foundation Do Mid-Missouri Foundation Do Central Eastern Missouri Professional Review Do Organization Committee.	•
Vdo.		
	Iexico New Mexico Standards Review Organization Conditi	
	ri Health Care Foundation of Missouri Support	
State of Louisiana Louisian	na Southeastern-Southwestern PSRO Statewide Do Support Center.	•
REGION VIII	••	
State of South South I Dakota.	Dakota South Dakota Foundation for Medical Care Plannin	ıg.
State of Colorado Colorad	do Colorado Foundation for Medical Care Conditi	onal.
State of Montana Montar	na Montana Foundation for Medical Care Do	٠.
State of Utah Utah	Utah Professional Review Organization Do	٠.
State of Wyoming Wyoming	ing Wyoming Health Services, Co Do) .
REGION IX		
State of Nevada Nevada	a	œ.
	Hawaii Foundation for Medical Care Do	
	Pima Foundation for Medical Care, Inc Do	
I Californ	nia Redwood Coast Region PSRO Do) .
IIIdo	Do Marin Foundation for Medical Care, Inc Do).

PSRO area number	State	Name of applicant organization	Type of application
[V	do	Medical Care Foundation of Sacramento	Conditional.
		San Francisco Medical Society Health Plan, Inc	
		San Mateo County Medical Society	
/III	do	San Joaquin Area PSRO	Conditional.
X	do	San Joaquin Area PSRO Foundation for Medical Care of Santa Clara County.	Planning.
ζ	do	Stanislaus Foundation for Medical Care	Do.
KII	do	Monterey Bay Area PSRO	Do.
XIV	do	Kern County Medical Society	Do.
KVI	do	Organization for Professional Standards Review of Santa Barbara.	Do.
(VII	do	Ventura Area PSRO, Inc	Do.
XIV	do	East Central Los Angeles PSRO	Do.
XVII	do	Riverside County	Planning.
tate of California	do	East Central Los Angeles PSRO Riverside County United Foundations for Medical Care	Support center.
REGION X			
· 	Oregon	Multnomah Foundation for Medical Care	Planning.
	do	do	Conditional.
I	do	Greater Oregon PSRO	Planning.
tate of Washington	Washington	Washington State Medical Association	Do.
state of Idaho	Idaho	Idaho Foundation for Medical Care Inc	Do.
		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

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 Curris 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 pro-

gram 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 pecrs 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":

Have a content which:
 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 stültifying 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 profes-

sional 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) \dots "to make such audits of the records of providers as may be necessary to insure that proper payments are made under this part \dots "

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

(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..."

IIJ. 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 Welfarc, 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

(27)

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—

02 - October 30, 1972

"(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 organiza-

tion' 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

"Qualified organization," October 30, 1972

- 103 -

Pub. Law 92-603

86 STAT. 1431

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 sub-

section (b) (2); and

"((') 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 Agreement exp!-(other than an agreement established pursuant to section 1154) shall ration, prior be for a term of 12 months; except that, prior to the expiration of termination.

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.

"(e) In order to avoid duplication of functions and unnecessary Waiver. 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, Agreement 1976, under this part under which any organization is designated as notice. 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.

86 STAT. 1432

"(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

"TRIAL PERIOD FOR PROFESSIONAL STANDARD; 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.

Plan, approval,

Duties.

Termination. notice.

"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 recog-

nized 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 inputient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided on an out-patient 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 case oritoria, 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 Patient profiles, responsible for the arranging for the maintenance of and the regular maintenance and review of profiles of care and services received and provided with review. 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 Hospital care, care may be only those having active hospital staff privileges in at physician releast 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.

publication,

86 STAT, 1434

"(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 regu-

lations 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 perform-

ance 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 com-

mittees 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.

October 30, 1972

- 107 -

Pub. Law 92-603 86 STAT, 1435

"(e)(1) Each Professional Standards Review Organization shall Review committee utilize the services of, and accept the findings of, the review com- tees. mittees 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 pro-Regulations.

visions of this subsection.

"(f)(1) An agreement entered into under this part between the Agreement re-Secretary and any organization under which such organization is quirements. 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 HENESSES 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 condi-

tion 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

Ante, p. 1433. 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 t 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.

October 30, 1972

- 109 -

Pub. Law 92-603

86 STAT. 1437

"submission of reports by profesional standards review ORGAN'&ATIONS

"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 Post, p. 1438. 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).

79 Stat. 325; 81 Stat. 846. 42 USC 1395y, 139500. Ante, p. 1408.

"REQUIREMENT OF REVIEW APPROVAL AS CONDITION OF PAYMENT OF CLAIMS Arte, 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) 81 Stat. 921. for the provision of health care services or items shall be used (directly 42 USC 701. 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 Ante, p. 1433.

86 STAT. 1438

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.

- 110 -

"(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

"(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 .\ct-

"(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-

53 Stat. 1368. 42 USC 405.

October 30, 1972

- 111 -

Pub. Law 92-603 86 STAT, 1439

"(A) inputient 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 economi-

cally 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 Report and with the practitioner or provider concerned, any Professional Stand- recommendaards Review Organization submits a report and recommendations to tions the Secretary pursuant to section 1157 (which report and recom- Ants, p. 1437, mendations 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 eli-

gibility 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 79 Stat. 291. agreements), and shall remain in effect until the Secretary finds and 42 USC 1395. 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 reenr.

"(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.

53 Stat. 1368. 42 USC 405.

"(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 profes-sional 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 Organi-

zation 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

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.

Membership.

"Src. 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

"(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-

Duties.

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 Payments. 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 Member selection, which members of such advisory group shall be selected by the State-regulations, wide Professional Standards Review Council (or Professional Stand-

ards Review Organizations in States without such Councils).

"(3) The expenses reasonably and necessarily incurred, as deter-Expenses, mined 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.

"NATIONAL PROFESSIONAL STANDARDS REVIEW COUNCIL

"Sec. 1163. (a)(1) There shall be established a National Profes-Establishment; sional Standards Review Council (hereinafter in this section referred membership. 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, govern- 5 USC 101 et ing appointments in the competitive service.

"(2) Members of the Council shall be appointed for a term of three Term of member-

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 recog- Qualifications. nized 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 Consultants. make available, or arrange for, such technical and professional consultative assistance as may be required to carry out its functions, and the

seq.

86 STAT. 1442

Pub. Law 92-603

- 114 -

October 30, 1972

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.

5 USC 5332 note.

"(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.

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 Secre tary 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.

Report to Scoretary and Congress.

> "APPLICATION OF THIS PART TO CERTAIN STATE PROGRAMS RECEIVING PEDERAL 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 carlier-

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

October 30, 1972

- 115 -

Pub. Law 92-603

86 STAT, 1443

"(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

"Src. 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-gath-

cring capacity) between and among—

"(a) (1) agencies and organizations which are parties to agreements entered into pursuant to section 1816, (2) carriers which 79 Stat. 297. are parties to contracts entered into pursuant to section 1842, 42 USC 1395h. and (3) any other public or private agency (other than a Profes- 42 USC 1395u. sional 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.

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 infor- Penalty.

mation 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 OR-GANIZATIONS, 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 profes86 STAT, 1444

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 --

"(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 serv-

ices, 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 Stand-

ards Review Organization; and

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

Ante, p. 1430.

October 30, 1972

- 117 -

Pub. Law 92-603

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 BANATORIUMS

"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

45

Selected Speeches By Senator Bennett

[From the Congressional Record, July 1, 1970]

Professional Standards Review Organization Act of 1970

Mr. Bennert. 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 Asso-

ciation 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 undily 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 amend-

ment 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—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

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 nur-

sery 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 dayless 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 hosiptal 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 mod-

erate 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 ter-

minate 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 respon-

sibility 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 Sacra-

mento 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 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 designated

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.

Dutics 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 diffier 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.

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 PNROs

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. Bennert. Mr. President, today I offer an amendment to H.R. 1 authorizing the establishment of Professional Standards Review Orga-

nizations 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 amendament, 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

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 physicians 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. Bennert. 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 drainatic evidence of the PSRO potential. Additionally, they are finding and acting to correct cases of under-utilization such as materalty 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 Wilbür 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 to-ward 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" hosiptal 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. 1150. 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 Penaltics

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 5

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. 1169. 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.

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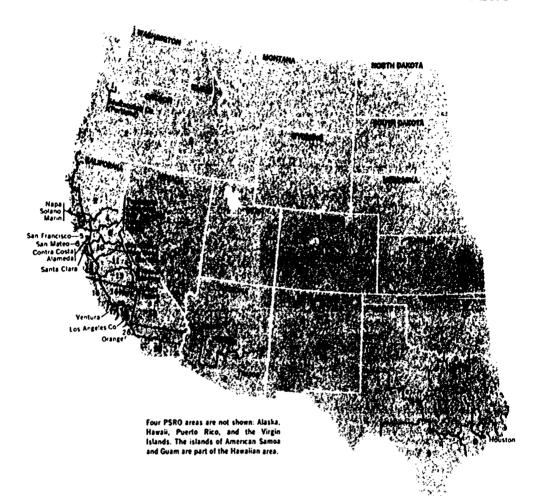
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Appendix C

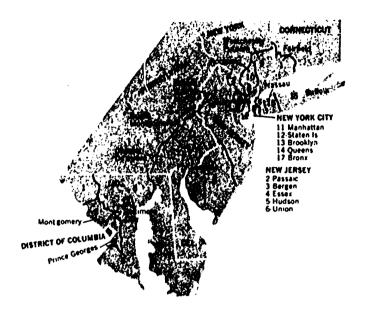
PSRO Regional Map

PSRO



REGIONS





Courtesy of Medical World News, March 15, 1974