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BY THE COMPTROLLER GENERAL

Report To The Congress

OF THE UNITED STATES

HEW Progress And Problems In Establishing Professional Standards Review Organizations

The Department of Health, Education, and Welfare's effort to establish professional standards review organizations has been hindered by

--organizational limitations,

--resource constraints,

--delays in issuing program regulations and guidance, and

--the lack of aggressive contract administration.

It has also been hindered by physician opposition.

Although many of the problems appear to be solved, action is required to promulgate needed regulations and improve contract administration. In addition, the Congress should consider using a demonstration phase before authorizing full scale implementation of similar programs.

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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

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To the President of the Senate and the
Speaker of the House of Representatives

This report discusses progress achieved and problems encountered by the Department of Health, Education, and Welfare in implementing the Professional Standards Review Organization program required by the October 1972 amendments to the Social Security Act. Program implementation has been slow. Although many of the problems appear to be solved, additional action by the Department is needed.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53) and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

We are sending copies of this report to the Director, Office of Management and Budget, and the Secretary of Health, Education, and Welfare.

Comptroller General
of the United States

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

HEW PROGRESS AND PROBLEMS IN ESTABLISHING PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

D I G E S T

Concerned by rapidly rising Federal health care expenditures, the Congress in 1972 passed legislation creating a Professional Standards Review Organization program in the Department of Health, Education, and Welfare (HEW).

The program is to have local physicians establish peer groups to determine whether services to patients under the Medicare, Medicaid, and Maternal and Child Health programs are medically necessary, provided in accordance with medical standards, and provided in an appropriate setting.

HEW has made progress in implementing the program, but this progress has been slowed by several factors. HEW estimates that the program will not be fully implemented for several years.

IMPLEMENTING THE PROGRAM

The legislation provides for designating Professional Standards Review Organization geographic areas, establishing Review Organizations and advisory councils, enrolling physicians, and implementing medical review systems.

HEW has designated 203 geographic areas. By June 1977, almost 5 years after passage of the legislation, only 62 planning and 108 conditional Professional Standards Review Organizations had been established. Since then many Review Organizations have been added, so that by June 1978 there were 37 planning and 153 conditional Review Organizations. However, HEW does not expect to have any of the Review Organizations beyond the conditional stage until after October 1978.

In addition, HEW created a national and six statewide advisory councils, enrolled 35 percent of the Nation's physicians, and implemented review systems in 38 percent of the Nation's hospitals. (See ch. 2.)

A number of geographic areas, however, including three entire States, were without Review Organizations for a long period of time, and many of the functions the organizations are responsible for were being done only on a limited basis. (See ch. 4.)

ORGANIZATIONAL LIMITATIONS

During the initial years of the Professional Standards Review Organization program, HEW had several organizational units putting the program into effect. But because of organizational shortcomings, inadequate authority, and fragmented responsibility, they were ineffective. (See p. 11.)

HEW attempted to correct these deficiencies by establishing the Bureau of Quality Assurance to implement the program and by assigning policymaking responsibility to the Office of Professional Standards Review. This did not completely solve the problem. Review Organizations continued to have problems with State and HEW agencies in determining review authority, implementing long term care review, and obtaining hospitals' support. (See p. 11.)

In March 1977, HEW reorganized and established the Health Care Financing Administration, which is responsible for administering the Medicare, Medicaid, and Professional Standards Review Organization programs. The consolidation of the three programs within one agency should facilitate coordination and cooperation and the clarification of the policymaking responsibilities of the Assistant Secretary for Health. (See p. 15.)

RESOURCE CONSTRAINTS

Less than anticipated funding and staff limitations have resulted in (1) delaying conversion of planning Review Organizations to conditional status, (2) restricting the number of planning contracts, and (3) adopting a cautious attitude toward organization development. (See p. 16.)

Limitations with staffing and travel resources during fiscal years 1974 and 1975 hindered the ability to promptly review and evaluate plans and activities of or provide assistance to organizations applying for or having planning or conditional Review Organization contracts. (See p. 19.)

LACK OF TIMELY REGULATION ISSUANCE AND INADEQUATE GUIDANCE

HEW has been slow to issue regulations and provide guidance. As of February 1978, only 8 of 18 final regulations had been issued, making it difficult for Review Organizations to conduct medical reviews and to collect hospital data needed to assess the quality of health care. (See p. 21.)

Additionally, the untimely issuance of some guidance has impeded conversion of organizations from planning to conditional status and delayed others in acquiring adequate data processing systems. (See p. 24.)

LACK OF AGGRESSIVE CONTRACT ADMINISTRATION

Four of the 17 organizations GAO reviewed experienced delays because of various management problems. These delays could have been minimized if HEW had taken timely, aggressive action to enforce contractual requirements and resolve management problems. (See p. 26.)

PHYSICIAN SUPPORT OF THE PROGRAM

Active physician involvement is critical to the overall success of the program, but so far most of the Nation's physicians have not enrolled in the program. Consequently, some areas were without organizations, while others that had planning organizations were unable to convert them to conditional status.

The current law required that until January 1, 1978, preference had to be given to physician-sponsored organizations when establishing Review Organizations. HEW is proceeding to seek a non-physician-sponsored organization

for Nebraska because of physician opposition. (See p. 32.)

RECOMMENDATIONS TO THE SECRETARY OF HEW

The Secretary should require the Administrator of the Health Care Financing Administration to:

--Issue instructions to hospitals and fiscal intermediaries on the statutory obligation of participating hospitals to cooperate with Professional Standards Review Organizations

--Issue final program regulations as quickly as possible.

--See that prompt corrective actions are taken to resolve known problems delaying program implementation.

--Coordinate with the Director, Bureau of Community Health Services, to provide adequate guidance for review of Maternal and Child Health patient care.

--Promptly designate alternate organizations as Review Organizations in areas where a physician-sponsored organization refuses to establish a Review Organization.

AGENCY COMMENTS

HEW agreed with GAO's recommendations. It also commented on the need to consider other factors impeding the program--the revolutionary nature of the program and the complexities of coordinating with State Medicaid agencies. GAO agrees that many factors hindered more rapid program implementation but believes that the problems it identified were the major ones.

RECOMMENDATION TO THE CONGRESS

The Congress, when establishing new national programs, should consider using the demonstration concept before authorizing full program implementation.

Contents

ABBREVIATIONS

BQA	Bureau of Quality Assurance
GAO	General Accounting Office
HEW	Department of Health, Education, and Welfare
HSA	Health Systems Agency
OMB	Office of Management and Budget
PSRO	Professional Standards Review Organization

CHAPTER 1

INTRODUCTION

Expenditures for health care in America have more than tripled since 1965. During the 11-year period ended in 1976, health care expenditures increased 12 percent annually--from $38.9 billion to $139.3 billion, or from 5.9 percent to 8.6 percent of the gross national product.

Concern over the increasing Federal health care expenditures prompted the Congress, in October 1972, to amend the Social Security Act (Public Law 92-603) by replacing an ineffective medical utilization review system with the Professional Standards Review Organization (PSRO) program.

The act stipulated that the Secretary of the Department of Health, Education, and Welfare (HEW) should divide the country into appropriate areas to allow for the review of health services provided under the Medicare, Medicaid, and Maternal and Child Health programs. Medicare, which is funded through the Social Security Trust Fund, provides health insurance benefits to the aged, disabled, and certain others. Medicaid--a Federal-State program--provides medical services to the needy and the medically needy. Federal grants to States are also provided under the Maternal and Child Health programs to enable the States to expand and improve services to reduce infant mortality and otherwise promote the health of mothers and children, especially those in rural and poverty areas.

The act also authorized the Secretary to enter into agreements with nonprofit organizations, preferably those composed of practicing physicians, for developing and implementing systematized review of medical care provided under the three programs in hospitals and long-term care facilities.

Conceptually, local practicing physicians would organize and operate peer review mechanisms to reduce costs and improve the quality of health care provided under the programs. PSROs would determine whether services provided to patients in hospitals and long-term care facilities are (1) medically necessary, (2) provided in accordance with professional standards, and (3) provided in the appropriate setting.

The act also provided for the establishment of Statewide and National Councils. The functions and status of these organizations and PSROs are discussed in chapter 2.

Under the program being developed by HEW, PSROs are to establish a system for review of care provided to inpatients in short-stay hospitals and develop a phased plan for the later review in long-term care facilities (that is, specialty hospitals, skilled nursing facilities, and intermediate care facilities). October 1977 amendments to the Social Security Act (Public Law 95-142) require PSROs to review noninstitutional (ambulatory) care. In short-stay general hospitals, the PSRO is responsible for:

1. Concurrent admission certification and continued stay reviews--ongoing reviews of inpatient hospital admissions to assure medical necessity and quality of care.

2. Medical care evaluation studies--retrospective in-depth reviews of care or medical management practices to assess the quality or utilization of health services. A completed medical care evaluation study should identify a potential or actual problem, initiate an action plan, and assess the impact of the corrective action.

3. Profile analyses--retrospective reviews through which aggregate patient care data is compiled to analyze the patterns of health care services and lengths of stay. Such reviews give the PSRO and the hospitals information for determining needed medical care evaluation studies and are an effective means of monitoring concurrent review activities.

PSROs are required to delegate responsibility for concurrent review and medical care evaluation studies to qualified hospitals that are willing and able to assume such functions (delegated hospitals). PSROs also work with Medicare, Medicaid, and Maternal and Child Health administrative and fiscal agents in implementing their review program.

LEGISLATIVE CHANGES TO THE PSRO PROGRAM

Since October 1972, the PSRO legislation has been amended twice. The first amendments (Public Law 94-182) were enacted in December 1975. In part, these amendments affected the PSRO program by (1) authorizing the use of the Social Security Trust Fund for financing all hospital review costs (previously, only delegated hospital review activity could be so financed), (2) extending for 2 years (from January 1, 1976, to January 1, 1978) the date preference is to be given for physician-sponsored organizations as PSROs, and (3) authorizing

the polling of practicing physicians in each PSRO area of a State that has multiple PSRO areas and no designated PSROs to determine if they support a change from the original PSRO area configuration to a single Statewide PSRO area.

The amendments of October 1977 (Public Law 95-142), among other things, (1) provide for a waiver of other legislatively mandated review requirements, such as utilization review, when a conditional PSRO is found competent to perform PSRO review activities, (2) require that a PSRO undertake ambulatory care review not later than 2 years after it has become operational, (3) authorize the use of agreements or grants, rather than contracts, as the means for binding the relationship between the Government and the PSROs, (4) provide for a PSRO monitoring role for State Medicaid agencies, and (5) provide for the exchange of data with health systems agencies.

PROGRAM ADMINISTRATION

The PSRO program is being implemented by the Health Standards and Quality Bureau within HEW's Health Care Financing Administration, which is responsible for administering the program, issuing regulations and guidelines, and distributing funds. The Health Care Financing Administration was established in March 1977. Before that time the PSRO program was administered by the Bureau of Quality Assurance (BQA) of the Health Services Administration, Public Health Service.

The Health Care Financing Administration also assumed responsibility for administering the Medicare and Medicaid programs. The former had been administered by the Bureau of Health Insurance, Social Security Administration, and the latter by the Medical Services Administration, Social and Rehabilitation Service. 1/

PSROs operate under contract with HEW. Early in the program, HEW decided to use contracts to avoid delays that would have resulted in promulgating regulations authorizing the use of agreements. The PSROs are entirely federally funded. As shown below, total program funding has grown from about $5 million in fiscal year 1973 to an estimated $147 million in fiscal year 1978.

1/Since our fieldwork was done before the Health Care Financing Administration was established, we will continue to refer to the agencies formerly responsible for the activities discussed in this report.

PSRO Program Funding

Fiscal year	Appropriations	Medicare Trust Fund	Total
	(000 omitted)		
1973 (note a)	$ -	$ -	$ 4,775
1974	33,650	(b)	33,650
1975	36,208	(b)	36,208
1976	47,645	(b)	47,645
Transitional quarter	11,977	(b)	11,977
1977	62,000	41,000	103,000
1978 (note c)	72,234	75,000	147,234

a/Funds were provided by the Social Security Administration.

b/The Medicare Trust Fund was used before fiscal year 1977 for delegated hospital review only; however, the amounts specifically used were not available, because hospitals were not required to report to the Social Security Administration costs associated with delegated review activities.

c/Estimated.

The PSRO program is funded through two separate mechanisms. Hospital review activities are financed through the Medicare Trust Fund and Medicaid appropriations. Medicare reimbursement mechanisms are used to make payment for both Medicare and Medicaid review; however, the Trust Fund is later reimbursed by Medicaid for the cost of reviewing care provided to Medicaid patients. No reimbursement is made by the Maternal and Child Health program because HEW considers the patient volume to be insignificant.

Formerly, Health Services Administration annual appropriations were used to fund all other PSRO activities (such as program management and support, long-term care and ambulatory care review activities, BQA salaries and expenses, and general contracts). Health Care Financing Administration appropriations are now used to fund such activities. The annual appropriation also includes specific transfers from Social Security Trust Funds to cover Medicare's share of PSRO activities not directly related to patient care review.

SCOPE OF REVIEW

Our review was made at HEW headquarters in Washington, D.C.; the Health Services Administration (later the Health Care Financing Administration) in Rockville, Maryland; and at HEW regional offices in Atlanta (region IV), Boston (region I), Denver (region VIII), Dallas (region VI), and San Francisco (region IX). We also reviewed the activities of 17 PSROs in Massachusetts, New Hampshire, Connecticut, Alabama, Florida, Tennessee, New Mexico, South Dakota, Utah, Wyoming, and California. These 17 organizations represent PSROs in various stages of development.

We reviewed applicable legislation, regulations, program guidelines and instructions, and HEW project and contract files. In addition, we interviewed appropriate State officials and officials of the 17 PSROs visited.

In March 1977, we sent a questionnaire (see app. II) to 103 PSROs to help us assess the status and problems of PSRO implementation. At the conclusion of our fieldwork, responses had been received from 93 (90 percent) of the PSROs.

Our review covered the period October 1972 through December 1977.

CHAPTER 2

SLOW PROGRESS

IN IMPLEMENTING THE ACT

PSRO legislation is based on the concept that health professionals are the most appropriate ones to evaluate the quality of and need for medical services and that effective local peer review is the soundest method for assuring the appropriate use of health care resources and facilities. To implement this concept, the act provides for designating PSRO geographic areas, establishing PSROs as soon as practicable, establishing advisory councils, enrolling physicians, and implementing medical review systems promptly.

HEW, despite serious obstacles, has implemented some of the program's elements, but progress has been slow. Although the Department has been implementing the program for over 5 years, officials estimate it will take several more before the program is fully operational.

DESIGNATION OF PSRO SERVICE AREAS

The act required HEW to designate PSRO service areas throughout the United States by January 1, 1974. The size and characteristics of a PSRO area were to be determined by HEW based on the number of practicing physicians, service areas, and State and county boundaries. Several controversies, including the desire of many States to have statewide PSRO areas, delayed area designation until March 1974.

The Secretary designated 203 PSRO areas throughout the Nation. 1/ Twenty-eight States received statewide designation; the other 22 States were divided into between 2 and 28 multi-PSRO areas.

ESTABLISHMENT OF PSROS

PSROs are generally developed in three stages--planning, conditional, and fully designated. In the planning stage, PSROs are expected to establish an acceptable organizational structure, recruit physician members, and formulate plans for undertaking review activities. In the conditional stage,

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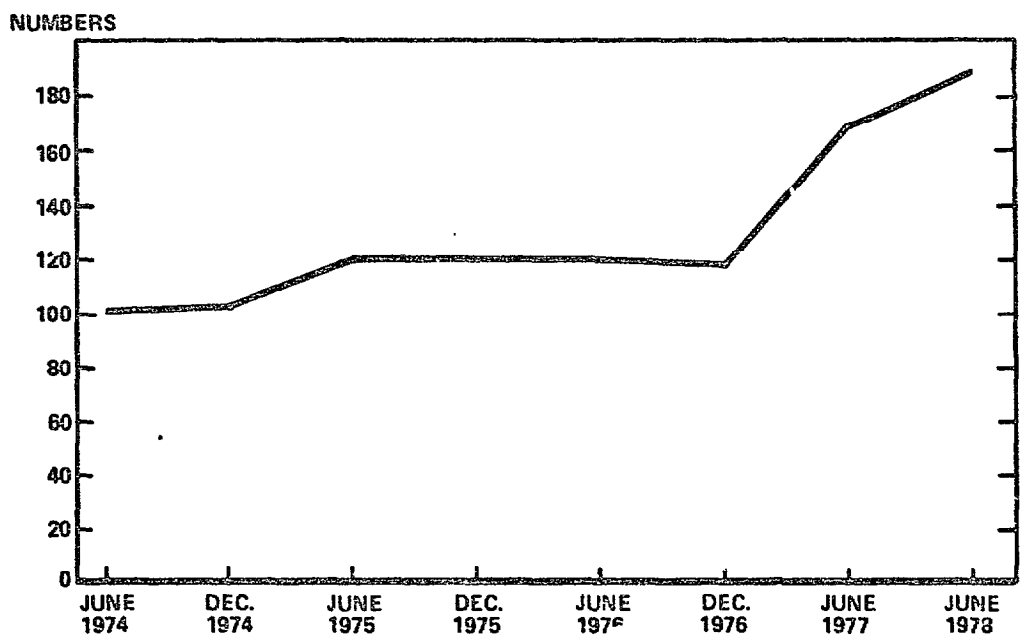
1/Includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Trust Territory of the Pacific Islands.

PSROs select norms and develop standards and criteria for review activities in hospitals and long-term care facilities, implement or delegate review activities, and make medical care evaluation and profile analysis studies. Once a conditional PSRO has met HEW's organizational requirements and is capable of fulfilling its responsibilities, including long-term care review, it can become fully designated.

In March 1974, HEW made its first request for proposals from physician organizations interested in becoming PSROs. In June 1974, it awarded 102 contracts--91 planning and 11 conditional. The conditional contracts went to organizations HEW believed were ready to begin review either immediately or after a short planning phase.

By June 1977, only 170 PSROs were in place--108 conditional and 62 planning. Since that time, the number of PSROs in place has increased to 190--153 conditional and 37 planning. Many were in the planning stage for lengthy periods. (See app. IV.) HEW does not expect to have a fully designated PSRO until October 1978. The growth in the number of PSROs is depicted in the following graph. Graphs depicting the growth of planning and conditional PSROs separately are included in appendixes III and V.

TOTAL PLANNING AND CONDITIONAL PSRO'S



As shown in the graph, PSRO growth has been slow; as of June 30, 1977, 1/ 33 areas were still without a PSRO. These areas included the entire States of Texas, Georgia, and Nebraska. Additional information on the status of the 33 areas is discussed on page 32.

NATIONAL AND STATEWIDE PROFESSIONAL STANDARDS REVIEW COUNCILS AND ADVISORY GROUPS

The act requires HEW to establish a National Professional Standards Review Council and, in States with three or more PSROs, Statewide Professional Standards Review Councils. Each Statewide Council and PSROs in States not qualifying for Statewide Council membership are required to have an Advisory Group.

The National Council is to advise th Secretary of HEW on PSRO program administration and review the performance of local PSROs and Statewide Councils. In May 1973, HEW established the Council with 11 physician members appointed by the Secretary. The Council, since its inception, has been advising the Secretary on program development and has sponsored a program evaluation recently completed by HEW's Office of Planning, Evaluation and Legislation.

Statewide Councils are to coordinate activities of PSROs in the State and assist the Secretary in evaluating PSROs and arranging for qualified replacements for PSROs when necessary. Based on the designation of PSRO geographic areas, HEW will be required to establish 18 Statewide Councils when PSROs are formed in all areas. As of June 1975, six States qualified for Statewide Councils; however, these Councils were not established until after May 1977. Establishment of Councils in five other qualifying States began in February 1978. Delays in establishing conditional PSROs postpone establishment of the other required Statewide Councils.

Advisory Groups provide an ongoing, formal mechanism for providing input to the PSRO program of nonphysician health care practitioners (dentists, nurses, pharmacists, etc.) and representatives of hospitals and other health care facilities. As of February 1978 only two of the six established Councils had appointed an Advisory Group. In addition, when all

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1/By June 30, 1978, only five areas were without a PSRO. These areas included the entire States of Texas and Nebraska.

PSROs are established, 39 of them will require Advisory Groups. As of October 1977, 33 PSROs qualified for Advisory Groups but only 16 had established them.

PHYSICIAN ENROLLMENT

Active physician support and participation is essential to PSRO success. Physician involvement, therefore, is an important measure of the progress of program implementation. To qualify as a PSRO, an organization must have as members at least 25 percent of the practicing physicians in its area.

The enrollment of active practicing physicians in the Nation has grown from 3 percent in 1974 to 35 percent in 1977. In 1977 the number of physicians enrolled in conditional PSROs was over 40 percent of those eligible. (See app. IX.) This matter is discussed further in chapter 4.

IMPLEMENTATION OF MEDICAL REVIEW SYSTEMS

The act requires HEW to review Medicare, Medicaid, and Maternal and Child Health patient records in short-stay hospitals and long-term care facilities. As amended, it also requires PSROs to review patient records in ambulatory care settings. PSROs are required to delegate review activities to hospitals willing and able to assume this function.

Hospital review activity

HEW estimates that, in fiscal year 1977, the Nation's 7,000 hospitals had 14.5 million discharges under the three Federal health care programs. PSRO review activity covered 32 percent (about 4.6 million) of these discharges. As of September 1977, PSRO review activity included approximately 2,650 (about 38 percent) of the hospitals. Review activity at 1,850 of the 2,650 hospitals was delegated.

As part of their review activity, PSROs are to undertake medical care evaluations and profile analysis studies. They are responsible for completing at each hospital between 4 and 12 medical care evaluation studies annually, depending on the number of hospital admissions, or for requiring the hospital to participate in areawide medical care evaluations. PSROs have reported completing over 9,500 medical care evaluation studies during 1977, but accurate information on compliance with the requirements was not available because of computer programing delays. Accordingly, progress in this area could not be determined. Our questionnaire showed that, as of March 1977, only 29 percent of the PSROs had initiated areawide studies.

HEW did not issue specific guidelines to help PSROs make profile analysis studies until January 1978. Only 12 of the 93 PSROs responding to our questionnaire reported activity in this area.

Long-term and ambulatory care

In 1976, BQA began emphasizing expansion of the PSRO review system to care provided in long-term facilities and ambulatory settings. Although eight PSROs were involved in long-term care reviews before this time, these reviews were continuations of an earlier HEW effort.

In September and October 1976, HEW selected 20 PSROs to participate in a 2-year demonstration and assessment program--15 (including 4 of the 8 PSROs mentioned above) for long-term and 5 for ambulatory care review. The results of the demonstration projects are not expected to be available until after February 1979.

CONCLUSIONS

Although HEW has made progress in implementing the PSRO program, the program will not be fully implemented for several years. As of June 1977, a number of geographic areas, including three entire States, were without PSROs. There were no fully designated PSROs. Moreover, physicians have been slow to support the program, and many of the functions PSROs are responsible for implementing were being done only on a limited basis. Several factors have hindered HEW's progress in implementing the PSRO program. These factors are discussed in chapters 3 and 4.

CHAPTER 3

PROBLEMS IN PROGRAM ADMINISTRATION

A number of complex, interrelated factors impeded the timely implementation of the PSRO program. The delays minimized the program's opportunity to reduce medical costs and to ensure the quality of patient care under the three Federal health care programs. The factors included organizational limitations, resource constraints, delays in issuing program guidance, and the lack of aggressive contract administration. These problems are similar to those we have found in other health programs administered by HEW.

ORGANIZATIONAL LIMITATIONS

During the initial years of the program, HEW established several organizational entities to implement the PSRO legislation. Because of organizational shortcomings, including inadequate authority and fragmented program responsibility, these entities were ineffective.

PSRO legislation was passed in October 1972. In November, HEW established, within the Office of the Assistant Secretary for Health, the Office of Professional Standards Review to direct program implementation and develop program policy. To implement the program, task forces were set up in the Health Services and Mental Health Administration, 1/ the Social Security Administration, and the Social and Rehabilitation Service. By April 1973, nine HEW organizations had some PSRO program responsibility.

The task force arrangement proved ineffective. The Office of Professional Standards Review acknowledged that it did not have the line authority, budget, or staff to effectively develop the program. In addition, the Office did not have a Director until 5 months after it was established. In July 1973, BQA was established within the Health Services Administration to handle program implementation. Because the Office and BQA did not have enough staff to carry out their responsibilities, the two staffs were combined. This arrangement also proved ineffective. BQA's placement within the Health Services Administration was not at a high enough level

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1/Effective July 1, 1973, the Health Services and Mental Health Administration was abolished. Its functions relating to PSROs were transferred to the Health Services Administration.

to enable it to deal effectively with the Social Security Administration; the Social and Rehabilitation Service; and the Bureau of Community Health Services, Health Services Administration, Public Health Service. 1/ An internal HEW study team assessing PSRO program management concluded that a distinct office and staff was needed to direct policy formation and oversee program operations.

On July 1, 1974, The Office of Professional Standards Review was reestablished as a separate organizational entity and assigned responsibility for oversight, coordination, and policy guidance. Program administration remained with BQA. This change still failed to provide an organizational structure with sufficient authority to deal with the other HEW agencies involved in PSRO implementation. Problems continued to exist in (1) establishing working agreements with State agencies, (2) implementing long-term care review activities, and (3) resolving problems with uncooperative hospitals. Each of these problems is discussed below.

Working agreement with State agencies

BQA required PSROs to establish agreements with State Medicaid and Maternal and Child Health Care agencies before beginning review of patients assisted by these programs. Over 34 percent of the PSROs visited or polled said they experienced either substantial or very great problems in negotiating an agreement with the State Medicaid agency, and only 2 of the 17 PSROs visited had negotiated agreements with State Maternal and Child Health agencies. This delayed review of the records of hospital patients served by these programs.

The problem with State Medicaid agreements involved the carrying out of a February 1975 secretarial policy giving conditional PSROs authority to make binding decisions (for reimbursement purposes) on the necessity of hospital care provided Medicaid patients. For example, three PSROs in one State, despite the Secretary's decision, took an average of 6 months to negotiate an agreement because of the State's concern over the PSRO's authority.

The Social and Rehabilitation Service, which had a direct influence over State Medicaid agencies through approval of the State plan for the Medicaid program, did not take prompt, aggressive action to help resolve this

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1/The Bureau of Community Health Services administers the Maternal and Child Health programs.

disagreement between PSROs and State Medicaid agencies. BQA advised us that this problem could have been minimized had the Service been more timely in implementing the February 1975 secretarial policy concerning PSRO authority. The Service advised the States of the policy decision in June 1975; however, it did not issue an instruction implementing the policy until September 1976.

The problems PSROs encountered with State Maternal and Child Health agencies resulted from the failure of BQA and the Bureau of Community Health Services--the administrator of the Maternal and Child Health care program--to clarify PSRO and State agency relationships. Although this issue was tentatively resolved in July 1976 with the issuance of joint instructions to PSROs clarifying these relationships, specific guidance promised at that time had not been issued as of February 1978.

Implementation of long-term care review activity

BQA and the Social and Rehabilitation Service had responsibilities for the review of long-term care patients. HEW, however, had not clearly defined the procedures to be followed to avoid duplication and ensure effective review activities.

Since as early as May 1976, the Service and the BQA were unable to agree on whether or not the Secretary should waive certain review activities required under the Social Security Act when PSROs implement long-term care review. The act, as amended by Public Law 92-603, required that:

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

BQA maintained that, when a PSRO has assumed review responsibility, all other review activities should be waived. The Social and Rehabilitation Service contended that the PSRO

responsibilities do not fulfill the unique provision of the Medicaid statute requiring (1) medical review for skilled nursing patients and the mentally ill and (2) independent professional review for residents in intermediate care facilities.

In July 1976, the issue was submitted to the HEW General Counsel. In May 1977, the Counsel ruled that PSRO long-term care reviews supersede the medical and independent professional reviews required under the Medicaid program. An instruction to the State Medicaid agencies implementing the Counsel's ruling was finally issued in January 1978.

This problem has delayed PSRO reviews of Medicaid patients in long-term care facilities. In June 1977, one PSRO characterized HEW's implementation of the PSRO long-term care activity as a "street brawl" among the responsible HEW agencies. This organization further stated that it had been placed in a "totally ridiculous situation where:

(1) The State wants relief and a transfer (of long-term care review activities) to PSROs;

(2) The law allows (and requires) this transfer;

(3) We have been trying for over a year to officially assume this responsibility;

(4) HEW does not want to, but must, assess (the State with) non-compliance penalties;

(5) Nursing homes do not know who is responsible for what; and

(6) We have been performing all the required functions while it is debated whether or not we have the capability and authority to do so."

In another instance, the efforts of BQA and the Social and Rehabilitation Service were not fully coordinated. In 1975, the Service awarded a $1.4 million grant to a State Medicaid agency to develop and implement medical criteria for the review of long-term care and ambulatory services. The grant was awarded before (1) the State Medicaid agency had coordinated its activities with the cognizant PSROs and (2) BQA agreed with the goals and methodology of the project. Although the Service said it would not release all the project funds until the PSRO's objections were resolved, over $400,000 was released by June 1976. Agreement was not reached until the following May.

Uncooperative hospitals

Several hospitals in at least five States had refused to permit PSRO review. For example, 19 hospitals in one area of a State refused to implement review because they wanted to continue under an existing utilization review system.

In October 1975, BQA asked the Social Security Administration to issue general instructions to hospitals and fiscal intermediaries regarding the statutory obligation of hospitals participating in the Medicare program to cooperate with PSROs. The instructions were not issued, and in April 1976, BQA repeated its request. Although Social Security has dealt with this problem on a hospital-by-hospital basis, as of February 1978 the requested instructions had not been issued. In commenting on a draft of this report, HEW stated that it is proceeding to issue the instructions and that they would have been more helpful had they been issued when the request was first made.

A number of respondents to our questionnaire also commented that the delays experienced in program implementation related to HEW's organizational problems. As one PSRO said:

> "* * *--There needs to be high level decisions made regarding 'who has the stick' BQA, SSA [the Social Security Administration] or SRS [the Social and Rehabilitation Service]. This must be transmitted to BHI [the Bureau of Health Insurance] and single state agencies. PSROs are forced to serve three masters. We need a consistent approach to enable PSROs to respond to the PSRO law for all Federal patients, not have to develop separate approaches for interface with BQA, the Medicare program or the Medicaid program.--* * *"

Establishment of Health Care Financing Administration

In March 1977, HEW announced a major reorganization. This action included establishing the Health Care Financing Administration. Among the activities transferred were the administration of Medicaid, Medicare, and the PSRO program. As a result of the establishment of the new agency, in June 1977 HEW announced changes in responsibilities of the Office of the Assistant Secretary for Health.

In June 1977, the Subcommittee on Health, Senate Committee on Finance, requested us to determine if the reorganization resolved or continued the fragmentation of authority and responsibility under PSRO and other programs. In July 1977 we testified before the Subcommittee that, although the Health Care Financing Administration was given operating responsibility for the PSRO program, the Office of the Assistant Secretary for Health would retain responsibility for setting program policy--thus retaining the policy-operation split that contributed to the implementation problems discussed in this report. Some HEW officials who foresaw continued problems were largely depending on the informal organizational and personal relationships to alleviate such problems.

In responding to our testimony, the Secretary of HEW acknowledged that the reorganization of the Office of the Assistant Secretary was prematurely announced without his review or approval. He agreed to rewrite the formal announcement to clearly define the role of that Office in formulating quality assurance and health care financing standards. The revised announcement, published in October 1977 and revised in December 1977 and January 1978, clarified the policy-setting responsibilities of the Assistant Secretary relating to the PSRO program.

RESOURCE CONSTRAINTS

Less than anticipated program funding and staff limitations delayed program expansion, hindered program management, and may have resulted in the inefficient use of Government funds.

Office of Management and Budget and congressional program funding restrictions

The growth of the PSRO program was limited by program funding. The following table compares the funding requested with that actually appropriated.

Program Funding Levels

Fiscal year	HEW request	President's budget	Appropriations
	(000 omitted)		
1974	$34,200	$33,650	$33,650
1975	57,900	57,000	36,208
1976	84,286	50,145	47,645
Transitional quarter	13,011	13,011	11,977
1977	87,000	62,000	62,000
1978	77,500	72,234	72,234

In analyzing the budget data, we noted that:

--In fiscal year 1975, the Congress appropriated about $21.7 million (about 37.5 percent) less than HEW and the Office of Management and Budget (OMB) requested for the program.

--In fiscal year 1976, OMB did not approve funding for any new planning PSROs.

--In fisal year 1977, OMB approved funding for a maximum of only 120 conditional PSROs.

The fiscal year 1978 funding is intended to provide enough funds to establish conditional PSROs in all areas.

The Congress restricted funding of the PSRO program because of its concern about the lack of significant progress in program implementation and the lack of any evaluation of program effectiveness. The lack of demonstrated effectiveness also influenced OMB funding decisions.

We can appreciate the reasons for congressional and OMB restrictions on funding; however, the impact of limited funding was felt at both the program management and local PSRO levels. About 36 percent of the PSROs responding to our questionnaire indicated that insufficient funding hindered their development to a moderate or very great extent. For example, one PSRO commented:

"Lack of adequate funding delayed progress for months and led to much apathy among physicians who saw no urgency to become active because

of the uncertainty of the life of the planning contract which, since June 1974, has had eleven extensions and/or modifications, some with modest additional funding and some with none."

Congressional and OMB funding reductions and the uncertainty of future funding levels caused program management to (1) delay conversion of planning PSROs to conditional status, (2) limit the number of planning contracts, and (3) adopt a cautious attitude toward PSRO development.

Delayed conversion to conditional status

BQA did not convert about 28 planning PSROs to conditional status when they were technically qualified because of its uncertainty over future funding. These PSROs completed their planning requirements during the last quarter of fiscal year 1975 or the first quarter of fiscal year 1976, but they did not receive conditional contracts until May or June 1976. BQA would not initiate the conditional contract award process until it had some assurance that HEW, OMB, and the Congress would provide enough funds to sustain these conditional PSROs in the future.

Many of these PSROs were given extended planning tasks, through contract modifications, so that they would be productive while awaiting funds to convert to conditional status and begin review activities. The tasks included limited activities that had been otherwise required under a conditional designation. Officials from some PSROs we visited and respondents to our questionnaire indicated that they could have begun review activities sooner if they had received their conditional contracts earlier in fiscal year 1976.

For example, one PSRO we visited completed its planning requirements in April 1975, but did not receive its conditional designation until June 1976. Most of the delay resulted from BQA's decision not to initiate the conversion process until it had assurance that enough funds would be available to sustain future review activities. To keep the PSRO in existence during this period, BQA provided about $140,000 for extended planning tasks. The PSRO officials stated that the tasks performed could have been done after conditional designation.

Restrictions on the number of planning PSROs

BQA had to delay awarding PSRO planning contracts to many organizations because of insufficient funding. In fiscal year 1974, BQA awarded its first planning contracts to 91 organizations. During fiscal year 1975, it could only award 16 additional contracts, primarily because of funding restrictions. BQA could not award any new planning contracts in fiscal year 1976 because OMB would not approve funding for them.

The next PSRO planning contracts were not awarded until funding became available in February 1977. In February and March, BQA awarded 51 such contracts. Many of these organizations had been waiting for more than a year for funding.

Cautious attitude

As a result of early funding restrictions, BQA officials adopted a cautious attitude toward implementing the PSRO program. According to BQA officials, they discouraged PSROs from rapid development. For example, one PSRO was experiencing serious staffing problems; however, BQA and regional staffs did not act to resolve the problem "because they weren't spending much money and funds were not available to convert them to conditional status."

Another PSRO was told to slow down because its conditional contract proposal was going to be completed by the end of 1975 and no funding was going to be available. In January 1976, this delay was reported to be hurting physician interest and support.

Funding problems resolved

In December 1975, legislation was enacted authorizing expanded use of the Medicare Trust Fund for hospital review activities. Also, the Congress has provided higher funding levels in fiscal years 1977 and 1978. Although guidelines for implementing the December 1975 legislation were not issued until March 1977, these actions should alleviate funding constraints on program growth and development.

Limited resources for program management

Limitations on staffing and travel resources during fiscal years 1974 and 1975 hindered BQA's ability to promptly review and evaluate plans and activities of, and provide

assistance to, organizations applying for or having planning and conditional PSRO contracts.

Generally, for a PSRO to be converted to conditional status, BQA must approve the PSRO's formal plan for carrying out review activities, including the collection of hospital data. PSROs began submitting draft plans in October 1974. However, BQA did not have enough experienced personnel to evaluate these plans or monitor PSRO activities promptly. Furthermore, several BQA project officers said they had difficulty performing their evaluations or monitoring PSRO activities because of limited training, inadequate guidance, and limited travel funds.

Because of its inability to promptly evaluate proposals or applications, BQA extended several PSRO contracts and provided additional funds to maintain the PSROs while their plans were being reviewed. Between January and May 1975, BQA extended contracts for 40 PSROs at a cost of over $800,000 so it could complete its evaluations. BQA also cited the lack of staff as a justification for awarding several contracts to outside organizations for technical assistance.

Staffing resources improved

In May 1977, the Director of BQA reported that the current staffing level was adequate to administer the program but that additional personnel would be required to support program expansion (that is, additional conditional PSROs and expanded PSRO review activities that are required under Public Law 95-142).

In addition, many training programs have been conducted in the past 2 years. In March 1977, a project officer's manual was issued to help project officers meet their responsibilities.

PROGRAM REGULATIONS AND GUIDANCE

HEW has been slow in issuing regulations and providing internal and external program guidance. As a result, planning PSROs have been delayed in converting to conditional status, conditional PSROs have been delayed in reviewing care provided to Medicare and Medicaid hospital patients, and duplication of effort may occur between PSROs and Health Systems Agencies (HSAs) established pursuant to the National

Health Planning and Resources Development Act of 1974 (Public Law 93-641). This act provides for the establishment of areawide and State health planning agencies. These agencies are to assess and develop plans and goals to improve the health systems in their areas.

About 38 percent of the respondents to our questionnaire indicated that untimely regulations were a substantial or very great problem hindering PSRO development. Likewise, 40 percent indicated that untimely program guidance was a substantial or very great problem.

Regulations

Full implementation and enforcement of the PSRO program has been impeded by the lack of final regulations. As of February 1978, only 8 of the 18 regulations HEW was developing to implement the PSRO program had been published in final form. Of the other 10, 2 had been published as proposed regulations with solicitation of public comment and 8 were being developed. (The status of each regulation is shown in app. VI.) In its comments on a draft of this report, HEW stated that, of the eight regulations under development, two have been published as proposed regulations and the other six will be published as proposed regulations by September 1978. All regulations are to be published in final form by late 1978 or early 1979.

The questionnaire respondents cited the lack of regulations on PSRO review authority and disclosure of confidential information as the greatest problems in PSRO development.

Regulation implementing review authority

A regulation on the authority of PSROs to conduct binding review activities was deemed necessary by HEW in September 1974. Although, as discussed on page 12, the Secretary issued a decision addressing the matter in February 1975, a final regulation was not issued until February 1978. Shortly after the decision was issued, a new Secretary was appointed and some hospitals and State Medicaid agencies refused to comply until the decision had been reaffirmed.

This was done in January 1976, but some hospitals and State agencies still refused to accept PSRO authority because of the lack of final regulations.

Legislation enacted in October 1977 (Public Law 95-142) gives States a stronger role in the PSRO review process, but leaves with PSROs the sole responsibility and final determination on the quality, necessity, and appropriateness of the medical care provided under Medicaid and Medicare. The States can monitor PSRO performance and, if it is found deficient, recommend suspension of PSRO review activity.

Regulation implementing confidentiality safeguards

A final regulation on the confidentiality of PSRO data is not expected to be issued until December 1978. A proposed regulation permitting disclosure of public information and aggregate hospital data was published in December 1976, and BQA issued instructions to PSROs providing for limited release of such information and data. However, some hospitals have been reluctant to provide data in the absence of a final regulation, fearing that they might be violating legislative restrictions. Unlawful disclosure of PSRO information is subject to a fine and imprisonment. For example, in one State, three PSROs were delayed several months in reviewing Medicaid patients for several reasons, including disputes with the State Medicaid agency over the release of PSRO data. Although the dispute was eventually resolved, the PSROs, in absence of a final regulation, were not providing all the data requested by the State.

In addition, the lack of a final confidentiality regulation could damage relationships between PSROs and HSAs established under the National Health Planning and Resources Development Act of 1974. HSAs and PSROs share certain goals and problems. Both are supposed to improve the quality of care and to contain health care costs. They are also both charged with improving the health care system, though in different ways. Consequently, there is an obvious need for them to cooperate and coordinate with each other. A basic, initial need is to share data.

To carry out their health planning responsibilities, HSAs must obtain data on the need for, and use of, health resources. PSROs collect part of this data in performing

their duties, but some have been reluctant to share it with HSAs until HEW publishes a final regulation specifying what data can be provided.

The National Health Planning and Resources Development Act of 1974 requires HSAs to (1) coordinate with PSROs and (2) make their data available to the public. PSRO legislation, on the other hand, restricts the release of data and imposes penalties for improper disclosure. Despite BQA's encouragement to cooperate with HSAs, some PSROs are reluctant to do so because of the legislative restriction and lack of final regulation. Public Law 95-142, passed in October 1977, provides the legislative mandate for coordination of PSRO and HSA data requirements. PSROs are to provide HSAs with aggregate statistical data (without identifying any individual) on a geographic, institutional, or other basis reflecting the volume and frequency of services furnished. By promptly implementing this legislation, HEW should be able to resolve the data coordination problem between HSAs and PSROs.

In commenting on a draft of this report, HEW stated that in December 1977 a joint policy statement on PSRO/HSA relationships was issued. According to HEW, the policy guidance is intended to establish a strong coordinative relationship between the programs, ease concerns about potential duplication, and facilitate data sharing.

Reasons for the delays

BQA officials attributed the delays in issuing final regulations to (1) the complex interrelationship between the PSRO program and the Medicare and Medicaid programs, (2) insufficient legal staff, (3) amendments to PSRO legislation, and (4) changes in HEW's procedures for developing regulations.

1. As part of the regulation development process, drafts of proposed legislation must be circulated to the several agencies involved in the PSRO program. (See p. 11.) In some cases, this has resulted in delays in reaching agreement. For example, a proposed regulation for review of hospital services was completed by BQA in July 1976, but differences with the Social Security Administration were not resolved until January 1977. (See apps. VII and VIII.)

2. Legal assistance provided to BQA to develop regulations was limited. This problem was compounded by the need to provide legal assistance on such PSRO matters as the eligibility of non-physician-supported organizations, the composition of advisory groups, and the authority of conditional PSROs.

3. Legislative amendments necessitated changes to existing and in-process regulations and contributed to the delay in the development of final regulations. For example, the regulation governing the financing of hospital reviews was delayed when new legislation was enacted that changed the mechanism by which hospitals would be reimbursed for review activities.

4. To increase public involvement in the regulation development process, HEW initiated new procedures in July 1976. The revised procedures included a requirement that HEW agencies develop an implementation plan and publish a notification of intent in the Federal Register. The plan had to be approved before the notification of intent was published. A BQA official estimated that time spent preparing the implementation plans and notifications of intent delayed the development of regulations about a year. In September 1977, HEW again revised its regulation development process in an attempt to issue shorter, clearer regulations more promptly.

Guidance

In addition to issuing regulations, BQA provides internal and external program guidance through manuals, letters of transmittal, and other written instructions. BQA, initially slow to develop and issue the necessary program guidance, has improved its performance in this area. The earlier difficulties hindered PSROs in converting to conditional status and acquiring data systems.

Delays in converting to conditional status

In June 1974, BQA awarded 91 six-month planning and 11 conditional 1/ contracts. PSROs were prohibited from beginning review activities until BQA had approved their conversion plans. To help PSROs develop their plans, HEW provided some guidance. This guidance proved inadequate, and BQA advised the PSROs that more would be provided. BQA planned to furnish this guidance before the PSROs had completed their plans. This was not done, and some PSROs received the guidance either shortly before or after they submitted their plans. Over 30 PSROs that received the guidance after submitting their draft plans needed 1 to 5 months to make revisions.

For example:

--One PSRO was awarded a planning contract in June 1974 and was to submit a plan for conversion to conditional status within 6 months. In January 1975, the PSRO submitted its plan to BQA. In February 1975, BQA sent the PSRO additional guidelines on preparing a conversion plan and told the PSRO to revise its plan accordingly. The PSRO required about 3 months to reorganize the information to conform to the new format and provide additional information that was not previously required.

In May 1975, the PSRO submitted its revised plan to BQA, and BQA gave the PSRO additional tasks to keep it operating until it could further refine its plan and be converted to conditional status. In September 1975, BQA approved the PSRO's plan, but the PSRO was not converted to conditional status until June 1976 because of funding constraints. Officials at this PSRO indicated that they could have used the funds received for additional tasks more productively had they been designated a conditional PSRO.

--In a second case, a PSRO, initially awarded a conditional contract that included a 4-month planning phase, spent about $62,000 unnecessarily because BQA failed to provide timely guidance on developing

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1/Four of the conditional contracts provided for a planning phase of 4 to 6 months.

a formal plan. The executive director of the PSRO agreed that, because the PSRO was unable to convert to the conditional status, some of the staff were not needed until later.

Acquiring a data system

PSROs are required to collect extensive data on patients' records reviewed under the three Federal health care programs. They must also be capable of processing this data for medical care evaluation and profile analysis studies.

BQA's failure to promptly issue guidance to PSROs on designing a data system, acquiring a data processor, and developing criteria and procedures to approve both, delayed PSROs in developing an adequate data collection capability. Some BQA project officers said they lacked expertise on data systems and were reluctant to advise PSROs on how to formulate a data plan. The problem was further complicated by BQA's staffing limitations. (See page 19.) For example, one PSRO said it was unable to process data collected manually for more than a year because BQA took 7 months to approve its request for proposals for a data processor. Additionally, 4 of 17 PSROs reviewed were delayed at least 6 months in acquiring automatic data processing capability.

Lacking such capability, PSROs were hindered in performing medical care evaluation and profile analysis studies--the two principal mechanisms for assuring the quality of medical care.

LACK OF AGGRESSIVE CONTRACT ADMINISTRATION

BQA did not always take timely, aggressive action to enforce PSRO contractual requirements or to see that PSROs resolved management problems that delayed or hindered program implementation. For example:

--One PSRO, contrary to its contractual commitment, decided to reduce the rate of implementation of hospital review activity until it acquired data processing capability. Although BQA advised the PSRO to acquire temporary help and space to manually collect and store the data, the PSRO did not do so and BQA did not formally direct the PSRO to comply.

--Fourteen PSROs have remained in the planning phase for extended periods (eight as long as 3 years), some as a result of internal management problems. One PSRO that was in the planning phase for almost 3 years had only a part-time executive director, and for 25 months it had filled only one other position--and three different persons had held it.

--Fourteen hospitals in one PSRO area would not allow hospital review activities because they refused to subscribe to the PSRO's data abstracting service. The hospitals claimed the service merely duplicated their own and that a changeover would be unnecessarily costly and contrary to HEW policy. BQA, rather than clarify this issue, advised the PSRO to work with the hospitals toward a solution.

Our review showed that BQA's inaction contributed to delaying full and prompt implementation of review activities in 4 of the 17 PSROs reviewed.

CONCLUSIONS

The PSRO program has been beset by a number of complex, interrelated problems that delayed program implementation and expansion, and lessened the opportunities to reduce medical costs and assure the quality of medical care under the three Federal health care programs.

These problems included (1) organizational constraints that were compounded by HEW's failure to fully define the roles and responsibilities of the several agencies involved and to require their full support and cooperation, (2) staffing and funding limitations, (3) untimely issuance of regulations and guidance, and (4) lack of aggressive contract administration.

As a result, PSROs were delayed in organizing and in converting to conditional status and they experienced problems in developing working relationships with various State agencies, hospitals, and health systems agencies.

These problems are similar to those that have impeded the progress of other HEW-administered health programs. 1/ Use of a demonstration concept might have given HEW a chance to identify and resolve at least some of these problems before full implementation, thus minimizing their impact and facilitating the program's orderly expansion. Resources no longer appear to be a constraint, and many of the problems attributable to organizational limitations may be alleviated by the establishment of the Health Care Financing Administration. The consolidation of three programs--Medicare, Medicaid, and PSRO--within one agency and the clarification of the policy-making responsibilities of the Assistant Secretary for Health for the PSRO program should facilitate coordination and cooperation.

RECOMMENDATIONS TO THE SECRETARY OF HEW

We recommend that the Secretary require the Administrator of the Health Care Financing Administration to:

--Issue instructions to hospitals and fiscal intermediaries on the statutory obligations of participating hospitals to cooperate with PSROs.

--Issue final PSRO program regulations as quickly as possible.

--Improve PSRO contract administration so that prompt corrective actions are taken to resolve known problems delaying program implementation.

--Work jointly with the Director, Bureau of Community Health Services, to provide adequate guidance to PSROs for the establishment of agreements with State agencies for the review of Maternal and Child Health patient care.

1/These factors are similar to those we described in the following reports on other HEW-administered programs.

"Progress, But Problems in Developing Emergency Medical Services Systems" (HRD-76-150, July 13, 1976).

"Factors That Impede Progress in Implementing the Health Maintenance Organization Act of 1973" (HRD-76-128, Sept. 3, 1976).

RECOMMENDATION TO THE CONGRESS

We recommend that the Congress, when establishing new national programs similar to the PSRO program, consider using the demonstration concept before authorizing or requiring full program implementation.

AGENCY COMMENTS AND OUR EVALUATION

HEW agreed with our recommendations and said that it is:

--Issuing the necessary instructions to hospitals and intermediaries.

--Moving aggressively to issue the remaining regulations.

--Devoting significant effort to improve the capabilities of the project officers in the administration of PSRO contracts.

--Planning to issue guidance shortly to PSROs on the review of Maternal and Child patient care.

In addition, HEW had four general comments on our conclusion that the progress of program implementation was slow.

First, HEW felt we did not indicate to what extent the slow progress can be attributed to the fact that the PSRO legislation was a significant departure from what the Government had previously required of physicians in quality assurance and utilization control activities. HEW explained that the legislation required essentially "state-of-the art" activities and is in many ways revolutionary.

We recognize that certain program aspects represent a departure from what was required under utilization review. This provides additional support for our recommendation to the Congress that it consider using the demonstration concept for any future programs of this nature before authorizing full implementation. However many program management factors that contributed to slow progress--for example, the failure to provide timely guidance and aggressive contract administration--are not related to the Government's departure from previous requirements for quality assurance and utilization controls.

Second, HEW stated that the report does not adequately recognize the program's major achievements--that in the face of physician resistance, organizational difficulties, and

other problems, PSROs have been implemented almost nationwide and physicians have been given an opportunity to demonstrate the effect of peer review.

The data in chapter 2 adequately recognizes the program's progress in establishing PSROs, National and Statewide Professional Standards Review Councils, and advisory groups; enrolling physician members; and implementing the medical review system. And yet, although nearly 6 years has elapsed and PSROs have been established almost nationwide, little evidence is available to demonstrate their effectiveness. The Office of Planning, Evaluation, and Legislation (in HEW's Health Services Administration) had made a $1 million study of the program's effectiveness and concluded that, as of October 1977, the program was not effective in reducing Medicare hospital utilization. However, this conclusion was not accepted by many who reviewed the report, including the National PSRO Council, as being representative of the program because of the limited number of PSROs that had progressed sufficiently for evaluation. In addition, in June 1978 we testified before the House Committee on Ways and Means Subcommittee on Oversight on the results of a validation of claimed savings by six PSROs. The claimed savings, in most cases, were grossly overstated because of deficiencies in the data used, computations made, and the methodologies applied.

Third, HEW stated that the report does not focus clearly enough upon what it views to be a major problem that delayed and continues to delay program implementation--the lack of cooperation from State Medicaid agencies. HEW explained that the original PSRO legislation was deficient in not clearly delineating the relationships between PSROs and the States.

The lack of cooperation from State Medicaid agencies has delayed program implementation. However, we believe that at least some difficulties with State Medicaid agencies could have been resolved under the original legislation had the cognizant HEW agencies cooperated in taking positive, assertive action toward that end. In addition, although legislation was enacted in October 1977 to assure States of a continuing role in PSRO matters, HEW stated that the program implementation is still being delayed somewhat because of the lack of full cooperation from a few Medicaid State agencies.

Fourth, although acknowledging some of the organizational shortcomings noted in the report, HEW maintained that they

did not significantly delay program implementation. HEW claimed that, even with ideal administration, the program could not have been implemented more quickly because of physician resistance and problems of coordinating the new program with utilization review performed by State Medicaid agencies.

We believe that information on pages 11 to 16 adequately identifies the organizational shortcomings as a major factor contributing to the delay in program implementation. The impact of such shortcomings was noted in resolving problems with State agencies in implementing long-term care and dealing with uncooperative hospitals. Also, a number of PSROs responding to our questionnaire cited the instability or inadequacy of HEW's organization and administration of the program as hampering their ability to implement their programs in a timely manner.

CHAPTER 4

PHYSICIAN SUPPORT OF THE PROGRAM

PSRO legislation requires that HEW give preference to physician organizations when establishing PSROs. Active physician involvement in PSRO activity is critical to the program's overall success. Initially, many physicians opposed the PSRO program to the point of actively seeking repeal of the legislation. Although HEW believes it has managed to dissipate much of this opposition, lack of physician support has continued to impede PSRO development in some areas. As a result, some areas were without a PSRO, while others with planning organizations were unable to convert to conditional status.

UNSERVICED AREAS

As of June 1977, 33 areas in the country lacked PSROs. HEW was in the process of awarding planning contracts for six of these areas. Ten areas were without coverage because of disagreements over area designation. The other 17 areas, including two entire States, did not have coverage because of lack of physician support. For example, Nebraska physicians had taken a wait-and-see attitude toward the PSRO program; therefore, a PSRO had not been organized in the State. Although Georgia physicians formally opposed the establishment of the program, this single-State PSRO area did submit an application for a planning contract, but included a request that it not be considered until December 16, 1975. That date was 15 days before expiration of the original statutory requirement that HEW give physician organizations preferential consideration. When the statutory expiration date was changed to January 1978, the Georgia physicians once again requested that the application not be considered until 15 days before expiration of the extended preferential date--December 16, 1977. In Florida, the medical society influenced two physician-sponsored organizations to withdraw their applications for designation as planning PSROs.

Generally, the physicians opposing the program disagree with the PSRO concept. They feel it represents too much Government involvement in medicine.

As discussed on page 34, HEW is developing a regulation addressing this issue.

INABILITY TO CONVERT
TO CONDITIONAL STATUS

To qualify for conditional designation, a PSRO must have as members at least 25 percent of the practicing physicians in the area. To assure that the PSRO represents the area physicians, the Secretary of HEW must file public notice when the PSRO is to be granted conditional status. If requested by at least 10 percent of the area physicians, the Secretary had to conduct a poll to determine if the proposed conditional PSRO is representative of the practicing physicians. If more than 50 percent of the physicians responded unfavorably, HEW was authorized to establish a different PSRO. 1/

Two planning PSROs have been prevented from converting to conditional status because they were unable to obtain the required physician representation in a poll. BQA terminated the planning contracts of these PSROs. One of these areas, in which the planning contract was terminated in September 1975, still did not have a PSRO 2 years later. The cognizant HEW regional project officer reported that HEW's inaction in this area has hampered PSRO development in four adjacent areas. He said that, because of this inaction, lack of physician interest has been a problem in these areas.

In another area, the planning PSRO has been unable for more than a year to recruit 25 percent of the eligible area physicians and had consequently been unable to convert to conditional status. Still another planning PSRO was experiencing strong physician opposition in five of the six counties in its area. BQA was reluctant to poll the physicians for fear that the PSRO will lose and have to terminate operations.

In some instances, physician opposition has been so intense that PSRO members have been harassed and ostracized. A project officer in one area filed this report:

> "We almost wept after visiting this PSRO * * *. At last reading, the PSRO had its sign torn down, * * * the Chairman of the PSRO had been completely ostracized both socially and professionally, the other two physicians openly associated with the PSRO were losing referrals by the day, and the list of the remaining few PSRO members was locked in a safe."

1/This polling requirement expired on January 1, 1978.

LACK OF REGULATIONS PREVENTS USE OF NON-PHYSICIAN-SPONSORED ORGANIZATIONS

Initially PSRO legislation required that until January 1, 1976, preference be given to physician-sponsored organizations when establishing PSROs. A December 1975 amendment to the Social Security Act (Public Law 94-182) extended this date to January 1, 1978. Should no organization of physicians come forward, BQA could designate a non-physician-sponsored organization as the area PSRO. The December 1975 amendment also provides that preference need not be given to physician-sponsored organizations when

--an organization proposed to be designated by the Secretary has lost a poll or

--a membership organization representing the largest number of doctors of medicine in an area, or in the State in which such area is located, if different, has adopted by official procedure a formal policy position of opposition to or noncooperation with the established program of professional standards review.

The legislation prohibits these provisions from being implemented until regulations are issued. HEW began to develop a regulation on alternatives to physician-sponsored PSROs in July 1976, but work on it has not yet been completed.

CONCLUSIONS

A number of PSRO geographic areas remain unserviced because of a lack of physician support. In four areas where PSROs had been established, the lack of physician support caused two planning PSROs to be terminated and has prevented two others from being converted to conditional status. Some evidence suggests that this opposition has also hampered program development in adjacent areas. The future impact of physician opposition could be lessened with the issuance of the required regulation and the prompt designation of alternate organizations as PSROs.

RECOMMENDATION TO THE SECRETARY OF HEW

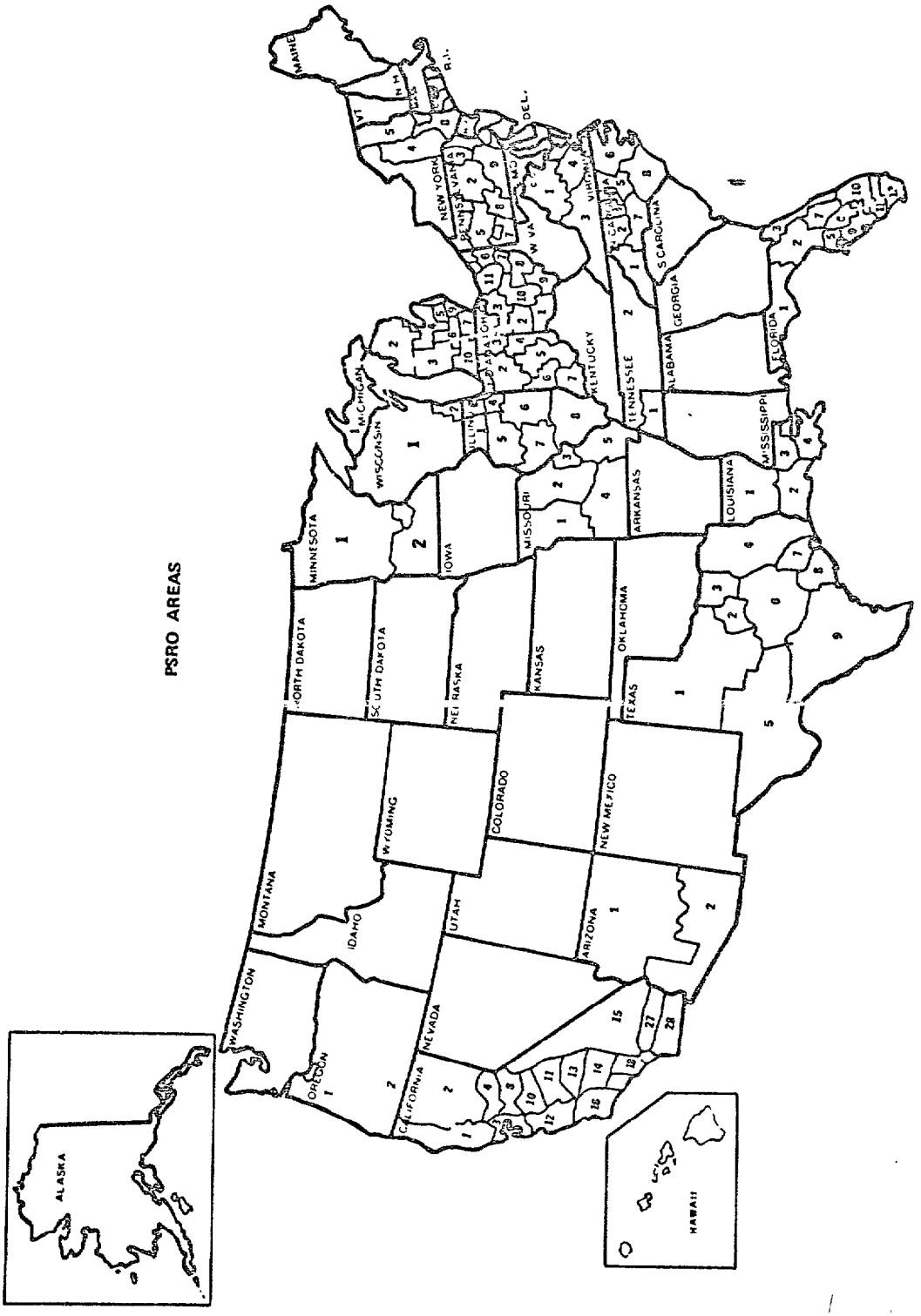
We recommend that the Secretary require the Administrator of the Health Care Financing Administration to promptly designate alternate organizations as PSROs in areas where a physician-sponsored organization refuses to establish a PSRO.

AGENCY COMMENTS

HEW concurred with our recommendation, but explained that only one area--Nebraska--does not have a physician group willing to become a PSRO. HEW stated that the final regulation for designating alternate organizations is scheduled to be published in August 1978.

APPENDIX I

PSRO AREAS



APPENDIX II

U. S. GENERAL ACCOUNTING OFFICE
SURVEY OF THE PSRO PROGRAM

PURPOSE AND INSTRUCTIONS

The U.S. General Accounting Office--the agency responsible for the Congressional oversight of the Federal agencies--is conducting a review of the PSRO Program. The objective of this review is to assess the status and the problems of the PSRO implementation. This questionnaire is an important part of this review. The purpose is to survey the experiences and recommendations of people like yourself who are responsible for this implementation and report to the Congress.

Most questions can be answered quickly by either checking the appropriate boxes or filling in the blanks. However, a few of the "fill in the blank" items may take a few minutes since you may have to consult your records. Some of the participants found it faster to go through the questionnaire first so they knew what information to get from these files. In either case, the entire form can be written in about 30 minutes. In addition, it may take from 30 to 60 minutes (depending on the accessibility of your records) to record some dates and numbers from your files.

We realize that the extent of your knowledge and perceptions goes far beyond your own PSRO, however, in this case we ask you to base your opinions and observations on your experiences with this particular PSRO. You may, of course, seek counsel from knowledgeable associates or key staff whenever you feel this to be necessary. It is important that you provide a reasonable answer to every question. In those few cases where the information is difficult to obtain, please provide us with your best estimate rather than delay or fail to respond.

Be assured your responses will be treated with the strictest of confidence. Your questionnaire is numbered for follow-up and analysis purposes only. As an agency of Congress, we are not part of HEW, BQA or any other Federal Department, and we will not disclose information that identifies the individual to these or any other agency. Furthermore, the names of the individual PSRO's will not be published without the expressed permission of the respondent providing the data. Names are not important, but what you have to say to the U.S. Congress is. So please give us your most frank and honest assessments.

Please return the completed form in the enclosed self-addressed, franked, envelope within 10 days after receiving this questionnaire. If you have any questions call (301) 443-3596. Doug Maring will be standing by to render assistance. We are most grateful for your consideration and cooperation.

I. PSRO BACKGROUND

A. Status

1. Which of the following contractual stages of development best describes the current status of the PSRO? (Check one.)

- ☐ 1. Planning
- ☐ 2. Planning: extended task
- ☐ 3. Conditional (achieved without a formal planning contract with the Bureau of Quality Assurance, BQA).
- ☐ 4. Conditional (achieved via a formal planning contract with the Bureau of Quality Assurance, BQA).

B. Membership

2. What is your PSRO's estimate of the number of physicians and doctors of osteopathy (D.O.'s) that practice within your PSRO area?

_____(Total number of physicians and D.O.'s)

(Note: Identify the source if you used data from sources other than your PSRO's estimate,e.g., BQA, AMA, etc.) _____(Source)

3. How many of these physicians and D.O.'s are members of your PSRO?

_____(Number of M.D.'s and D.O.'s)

C. Service Population: Hospitals

4. How many short term acute care hospitals are in your PSRO area?

_____(Number of Hospitals)

D. Service Population: Federal Admissions

5. How many Federal admissions were recorded in the hospitals in your PSRO area during December 1976?

_____(Number of Federal Admissions)

APPENDIX II

E. Approval History

6. Was there a prototype, precursor, prePSRO or pilot study performing functions similar to that of the PSRO activity operating in your area prior to the start of the PSRO Program?

☐ 1. Yes

☐ 2. No

☐ 3. Not sure

7. What was the effective date of your planning contract? (Note: Skip to question 11 if you indicated in question 1 that you had achieved conditional status without a formal planning contract with BQA. Otherwise continue.)

_____ Month _____ Year

8. When did your PSRO first submit a "Draft Formal Plan" to BQA?

_____ Month _____ Year

9. To what extent, if at all, did your PSRO revise this "Draft Formal Plan" before obtaining a "Final Formal Plan" approval from BQA?

☐ 1. To little or no extent — Go to 11

☐ 2. To some extent

☐ 3. To a moderate extent

☐ 4. To a substantial extent — Continue

☐ 5. To a very great extent

10. If you made moderate or more extensive revisions before BQA approval, what was the approximate date of the last revision? (Exclude minor changes.)

_____ Month _____ Year

11. Did you obtain a "Final Formal Plan" approval from BQA?

☐ 1. Yes

2. If yes, give date approved & continue.

_____ Month _____ Year

☐ 3. No (If no go to 13)

12. On formal plan approval, which of the two contract modifications (if any) was awarded? (Check one.)

☐ 1. Extended Planning contract

☐ 2. Conditional contract

☐ 3. No change

Note: If conditional was approved, but received extended plan because of lack of program funds check extended planning contract.

13. Did your PSRO submit to BQA all the necessary "Memorandums of Understanding" negotiated with 1) the involved Medicare Intermediaries and 2) the State Medicaid agencies? (Check one and fill in blanks if appropriate.) (Answer 13 and 14 regardless of whether or not you were an original PSRO or negotiated these items as a prototype PSRO.)

1) Involved Medicare Intermediaries

☐ 1. Yes

2. If yes, give date of last submission.

_____ Month _____ Year

☐ 3. No (If no continue)

2) State Medicaid Agencies

☐ 1. Yes

2. If yes, give date of last submission.

_____ Month _____ Year

☐ 3. No

If no to both, go to 30, unless you have conditional status, otherwise continue.

APPENDIX II

14. Did BQA approve all the necessary "Memorandums of Understanding" that were negotiated with 1) the involved Medicare Intermediaries and 2) State Medicaid agencies? (Check one and fill in blanks if appropriate.)

1) Involved Medicare Intermediaries

☐ 1. Yes

2. If yes, give date of last approval.

_____ Month _____ Year

☐ 3. No (If no continue)

2) State Medicaid Agencies

☐ 1. Yes

2. If yes, give date of last approval.

_____ Month _____ Year

☐ 3. No

If no to both, go to 30, unless you have conditional status, otherwise continue.

F. Peer Review History

15. Has your PSRO implemented concurrent "Admission Certification" and "Continued Stay Review" procedures for either Medicare or Medicaid patients? (Check yes or no for both).

1) Medicare ☐ 1-Yes ☐ 2-No

2) Medicaid ☐ 1-Yes ☐ 2-No

If yes, to either, give dates first started.

1) Medicare _____ Month _____ Year

2) Medicaid _____ Month _____ Year

(If no to both, go to 30)

16 In how many PSRO area hospitals has this concurrent review process (i.e., binding review) been implemented?

_____(Number of hospitals)

17. In how many of the area PSRO hospitals has this concurrent review process been "fully" delegated?

_____(Number fully delegated hospitals)

18. How many Federal admissions were reviewed by your PSRO during the month of December 1976?

_____(Number reviewed in 12/76)

19. Has your PSRO initiated a profile analysis (as specified in the PSRO legislation) on one or more PSRO area practitioners?

☐ 1. Yes

2. If yes, give the date of the first profile analysis

_____ Month _____ Year

☐ 3. No (If no, go to 21)

20. If yes, how many of these practitioners profile analyses have been completed as of December 1976?

_____ (Number of practitioner analysis completed as of 12/76)

21. Also, has your PSRO initiated a profile analysis on one or more PSRO area hospitals?

☐ 1. Yes

2. If yes, give the date of the first profile analysis.

_____ Month _____ Year

☐ 3. No (If no, go to 23)

22. If yes, how many of these hospital profile analyses have been completed as of December 1976?

_____ (Number of hospital analyses completed as of 12/76)

23. Has your PSRO started one or more area wide "Medical Care Evaluations"?

☐ 1. Yes

2. If yes, give date the first area wide "MCE" was started.

_____ Month _____ Year

☐ 3. No (If no, go to 25)

24. If yes, how many of these area wide "Medical Care Evaluations" have been completed as of December 1976?

_____ (Total number of area wide MCE's completed as of 12/76)

APPENDIX II

25. To what extent, if at all, are you using Norms, Criteria and Standards to perform Peer Reviews (Review Analysis and Evaluation)? "By Use", we mean norms, standards and criteria that are uniform and generally accepted throughout your PSRO and which were specifically developed, adapted or implemented in order to meet what you consider to be the intent of the PSRO legislation and available BQA directives. (Check one column for each row.)

	1-To little or no extent	2-To some extent	3-To a moderate extent	4-To a substantial or great extent	5-To a very great extent
1. Norms					
2. Criteria					
3. Standards					

26. If you checked to a Substantial, Great or Very Great extent (Cols. 4 or 5) for any of the above rows continue, otherwise, go to 27.

We realize that the use of Norms, Standards and Criteria is a continuing and periodically updated process which is difficult to date, but, nevertheless, we would be most grateful if you would try to give us the approximate date as to when you feel these Norms, Standards "or" Criteria were in use to either a substantial or great or very great extent.

	Approximate Date in use to Great or Very Great Extent	
	Month	Year
1. Norms		
2. Criteria		
3. Standards		

27. To what extent, if at all, did your PSRO use the AMA's Model Screening Criteria to establish the Criteria used in your PSRO Peer Review process?

- ☐ 1. To little or no extent
- ☐ 2. To some extent
- ☐ 3. To a moderate extent
- ☐ 4. To a great extent
- ☐ 5. To a very great extent

28. Has your PSRO submitted a request to BQA to let out a sub-contract(s) for data processing services to support the Peer Review process?

- ☐ 1. Yes
- 2. If yes, give date submitted.

  Month _____ Year _____
- ☐ 3. No (If no, go to 30)

29. If yes, has BQA approved these data processing subcontract(s)?

- ☐ 1. Yes
- 2. If yes, date approved.

  Month _____ Year _____
- ☐ 3. No

30. Is your PSRO served by a Formal Statewide Advisory Council?

- ☐ 1. Yes
- ☐ 2. No

31. Regardless of whether or not there is a Statewide Advisory Council, has your PSRO organized a formal (non physician) Advisory Council?

- ☐ 1. Yes
- 2. If yes, give approx. date orgenized.

  Month _____ Yes _____
- ☐ 3. No

G. Long Term Care Approvals

32. Does your PSRO area also have a PSRO Long Term Care demonstration contract?

- ☐ 1. Yes
- ☐ 2. No

APPENDIX II

33. Has your PSRO submitted to BQA, what you consider to be, a formal plan for the "Peer Review" in long-term care hospitals and facilities? (Do not consider your submissions for long-term care demonstrations.)

☐ 1. Yes

2. If yes, date submitted.

_____ Month _____ Year

☐ 3. No (If no, go to 37)

34. Has BQA approved your long term care plan?

☐ 1. Yes

2. If yes, date approved.

_____ Month _____ Year

☐ 3. No (If no, go to 37)

35. Has your PSRO started "Peer Review(s)" in one or more long-term care facilities?

☐ 1. Yes

2. If yes, date of first review start.

_____ Month _____ Year

☐ 3. No

36. If yes to 34, how many long-term care facilities have started "Peer Review" as of December 1976?

_____ (Number of long-term facilities or hospitals in which Peer Review has been started as of 12/76)

H. Ambulatory Care Approvals

37. Does your PSRO area have a PSRO Ambulatory care demonstration contract?

☐ 1. Yes

☐ 2. No

38. Has your PSRO submitted to BQA, what you consider to be a formal plan for the "Peer Review" in Ambulatory care offices, clinics or facilities? (Do not consider your submissions for ambulatory care demonstrations.)

☐ 1. Yes

2. If yes, give date submitted.

_____ Month _____ Year

☐ 3. No (If no go to 42)

39. Has BQA approved your Ambulatory care plan?

☐ 1. Yes

2. If yes, give date approved.

_____ Month _____ Year

☐ 3. No (If no go to 42)

40. Has your PSRO started one or more "Peer Review(s)" in Ambulatory care facilities?

☐ 1. Yes

2. If yes, give date of first review start.

_____ Month _____ Year

☐ No (If no, go to 42)

41. If yes to 40, how many Ambulatory care facilities have started "Peer Review" as of December 1976?

_____ (Number of Ambulatory care facilities in which Peer Review has been started as of 12/76.)

APPENDIX II

II PSRO DEVELOPMENT IMPACT AREAS

A. PSRO Regulations

42. Although certain policy directives have been issued through letters of transmittals, with two exceptions, BQA has not issued the Final regulations for governing the development of a PSRO. Consider each of the areas listed below which either still lack regulations or did not have regulations until very recently. Then rate the degree to which you found this lack of regulations to be a problem or not to the development of your PSRO. (Check one column for each row.)

Areas lacking Regulations	1-Little or no problem	2-Somewhat of a problem	3-A moderate problem	4-A substantial or great problem	5-A very great problem	0-No basis to judge
1. Conditional Designation and Planning Agreements						
2. The extent to which review authorization was delegated to the PSRO's and the authority relationships between the local PSRO's, and State and Federal agencies						
3. Hospital Review requirements						
4. Hearing of appeals procedures						
5. Confidentiality of information						
6. Statewide councils						
7. Local PSRO advisory councils						
8. Statewide PSRO advisory councils						
9. Sanctions						

B. Statewide Council

43. Does your state have three or more conditional PSRO's (a requirement for a Statewide Professional Standards Review Council)?

/___/ 1. Yes (Continue)

/___/ 2. No (Go to 45)

44. As of June 1976, at least six states had requirements for a Statewide Professional Standards Review Council. In December of 1976, the secretary of HEW began organizing the first of two such councils. The question is, how much help, if any, would a Statewide Council have been, assuming they had been in existence when you were developing your own area PSRO? Answer for each of the development activities listed below. (Check one column for each row.)

PSRO development activities which may have benefited from council assistance.	DEGREE OF HELP: 1-Little or no help	2-Only some help	3-A moderate amount of help	4-A substantial amount of help	5-A very great amount of help	0-No basis to judge
1. Negotiating of Medicare Intermediary MOU's						
2. Negotiating State Medicaid MOU's						
3. Negotiating Hospital MOU's						
4. Establishing a data processing system						
5. Developing review criteria						
6. Hiring and organizing the initial staff						

APPENDIX II

C. Negotiating Memorandum of Understanding

NOTE: Continue only if you are a "Conditional PSRO" otherwise go to #6.

43. It may be possible to trace some problems in implementing Hospital Peer Reviews to the Memorandum of Understanding (MOU) negotiations. Consider your own situation. To what extent, if at all, can you attribute the problems encountered in implementing Hospital Peer Reviews to the MOU negotiations with each of the parties listed below? (Check one column for each row.)

	1 - To little or no extent	2 - To some extent	3 - To a moderate extent	4 - To a substantial or great extent	5 - To a very great extent	U - No basis to judge
1. Medicare Intermediaries						
2. State Medicaid office						
3. Hospitals						

D. User Group Cooperation and Assistance

44. In developing a PSRO it is important to have good cooperation with and among the various user group officials and influentials (your PSRO officials, HEW program officials, State Medicaid officials, etc.). However, as you can see from the matrix below, for some PSROs this may involve a complex web of interfaces. We have listed each of the major parties likely to be involved by row and by column. Hence any row-column cross tabulation can identify a specific interface between two parties. We would like you to identify those interfaces where a lack of cooperation has caused your PSRO a problem. Do this by checking the appropriate boxes. For example, if you felt that a lack of cooperation between the State Medicaid officials and your PSRO officials caused problems, you would check the box indexed by row - 5, column A. On the other hand, if you also felt that some of your difficulties were due to poor cooperation between the HEW Headquarters program officials and the State Medicaid officials you would also check the box indexed by row - 3, column B. (Check all appropriate boxes where poor cooperation has resulted in problems for your PSRO.)

	A - Your PSRO officials	B - Headquarters HEW officials	C - Regional HEW officials	D - State Medicaid officials	E - Medicare Fiscal Intermediary officials	F - State or local Medical Society officials or specific physicians who are influential
1. Headquarters, HEW officials						
2. Regional HEW officials						
3. State Medicaid officials						
4. Medicare Fiscal Intermediary officials						
5. State or local medical society officials or specific physicians who are influential						
6. Local hospital officials						

APPENDIX II

E. Physician Support

47. In addition to the user group officials it is essential to have the support of the individual practicing physicians and Doctors of Osteopathy (M.D.'s D.O.'s). M.D.s and D.O.s serve as PSRO members, advisors, officials and chair and staff the operational committees. To what extent, if at all, has your PSRO experienced difficulties in recruiting practicing physicians and DOs for the roles listed below. Answer regardless of whether or not this difficulty was in a delegated or non-delegated hospital. (Check one column for each row.)

Physician PSRO Support Roles	1-To little or no extent	2-To some extent	3-To a moderate extent	4-To a substantial or great extent	5-To a very great extent	0-No basis to judge
1. PSRO member						
2. A committee member assigned to develop norms, standards and criteria						
3. A physician advisor						
4. Other committee member assignments						
5. PSRO officials (e.g., Ex. Director, etc.)						
6. Other roles (specify) _____						

48. To what extent, if at all, are the practicing physicians and Doctors of Osteopathy within your PSRO area willing to accept judgements based on the norms, standards, and criteria established by the PSRO in the hospital review process?

- ☐ 1. To little or no extent
- ☐ 2. To some extent
- ☐ 3. To a moderate extent
- ☐ 4. To a substantial or great extent
- ☐ 5. To a very great extent

- ☐ 0. No basis to judge

49. Most experts believe that a PSRO must enroll a certain proportion or percent of the physicians and osteopaths who practice in the PSRO area as members before the PSRO can be expected to operate efficiently and effectively. However, this minimum effectiveness membership proportion is also dependent on the amount of active support that the PSRO can receive from the area M.D.s or D.O.s. What do you think this proportion or percent should be, 1) with and 2) without active support from the M.D. & D.O. community leadership.

1. With active support from M.D. and D.O. leadership.
   - ☐ 1. Under 25%
   - ☐ 2. From 25 to under 50%
   - ☐ 3. From 50 to under 75%
   - ☐ 4. Over 75%

2. Without active support for M.D. and D.O. leadership.
   - ☐ 1. Under 25%
   - ☐ 2. From 25 to under 50%
   - ☐ 3. From 50 to under 75%
   - ☐ 4. Over 75%

APPENDIX II

F. LONG TERM CARE

50. To what extent, if at all, have the following possible problem areas "hindered" your PSRO's efforts to implement Peer Reviews in long term care facilities? Do not consider LTC demonstrations. (Check one column for each row.)

	1-To little or no extent	2-To some extent	3-To a moderate extent	4-To a substantial or great extent	5-To a very great extent	0-No basis to judge
1. Lack of regulation transmittal directives and guidelines from HEW for implementing long term care reviews						
2. Inadequate funding levels						
3. Medicaid State Agency's reluctance to relinquish review authority						
4. Difficulties in developing norms, criteria, and standards						
5. Limited emphasis on long term care review by HEW						

G. STATEWIDE SUPPORT CENTERS

51. Statewide Support Centers were authorized by the Secretary of HEW in 13 States. Was your State one of the 13?

- ☐ 1. Yes (Continue)
- ☐ 2. No (Go to 54)
- ☐ 3. Not sure (Go to 54)

52. As you know, the Statewide Support Centers were established to stimulate and support the development and operations of the State and particularly the local PSRO Programs. We have listed below several of the areas in which the legislation and HEW policy have authorized the Statewide Support Centers to provide assistance. To what extent, if at all, has your local PSRO program been supported by the Statewide Center in each of these areas? (Check one column for each row.)

	1-To little or no extent	2-To some extent	3-To a moderate extent	4-To a substantial or great extent	5-To a very great extent	0-No basis to judge
1. Developing an organizational structure						
2. Developing by-laws						
3. Recruiting physicians						
4. Completing the planning application						
5. Developing a formal plan						
6. Developing hospital review procedures						
7. Presenting alternative hospital review procedures						
8. Developing norms, criteria and standards						
9. Selecting physicians as reviewers						
10. Planning for the inclusion of non-physician personnel in review activities						
11. Coordinating with Medicare and Medicaid organizations						
12. Other (specify) _____						

53. In general, how much, if any, has the Statewide Support Center contributed to the development and implementation of your local PSRO program? (Check one.)

- ☐ 1. Little or no contribution
- ☐ 2. A minor contribution
- ☐ 3. A moderate contribution
- ☐ 4. A substantial contribution
- ☐ 5. A very great contribution

APPENDIX II

H. Summary of the Major Factors Affecting PSRO Development

54. In the following question we have summarized many of the possible problem areas which may or may not have hindered your PSRO development. To what extent, if at all, have each of the listed problem areas hindered the development of your PSRO? (Check one column for each row.)

	1-Little or no extent	2-To some extent	3-To a moderate extent	4-To a substantial or great extent	5-To a very great extent	0-Not applicable or no basis to judge
1. Untimely funding						
2. Insufficient funding						
3. Untimely HEW "final formal" plan approvals						
4. Untimely approval from HEW on any of the necessary MOU's. Medicare, Medicade, area hospitals, etc.						
5. Difficulty in developing PSRO norms, criteria and standards						
6. Lack of or untimely final PSRO Regulations from HEW/BQA (exclude transmittal letters)						
7. Lack of or untimely program guidelines, policies and procedures in any critical area, e.g., PSRO program manual, financial management and accounting manual, contract management and procurement manual, Data Collection & ADP methods and procurement directives, etc. (Include transmittal letters.)						
8. Lack of availability, cooperation or assistance from any key user group official of any of the necessary levels of government, i.e., HEW (headquarters or regional) or State and local (Medical, Medicaid or Medicare)						
9. No Statewide Professional Review Council						
10. Difficulties in negotiating any of the necessary MOU's with either Medicare or Medicaid or Hospital officials						
11. Difficulties in obtaining active support of local physician and osteopaths						
12. Limited assistance from Statewide Support Centers						
13. Untimely long term care final formal plan approvals						
14. Other difficulties in implementing long term care peer reviews						
15. Difficulties in obtaining and training qualified people						

APPENDIX II

I. For Conditional PSRO's Only

55. (If not a conditional PSRO go to 57)

The following two questions refer to certain, specific documents that were included with the description and scope of work of your initial planning contract: e.g. organizational by-laws, a plan and time table establishing a non-physician advisory council, etc. We ask that you answer regardless of whether or not you achieved conditional status without a formal planning contract, since all PSRO's must eventually be concerned with these documents.

When you were first designated as a conditional PSRO, which if any, of the documentation for the following final formal plan parts or sections had been completed (Check only those completed.)

- ☐ 1. Organizational by-laws
- ☐ 2. A plan and a time table for establishing a non-physician advisory council
- ☐ 3. Initial assessment of the size of scope of your PSRO area: number of practicing physicians and D.O.s, number of hospitals and facilities, etc.
- ☐ 4. A plan for evaluating the effectiveness of the "in house" peer reviews conducted by delegated hospitals
- ☐ 5. A plan for the collection of baseline data
- ☐ 6. A plan for peer reviews in short stay hospitals
- ☐ 7. A phased plan for peer reviews in long term care facilities (Exclude LTC demonstrations.)
- ☐ 8. A methodology to develop various criteria and standards
- ☐ 9. A plan to train personnel
- ☐ 10. A plan for acquiring the PSRO staff, facilities and equipment and consultation and other necessary operational resources (Exclusive of funding).

56. Again, regardless of whether or not you had completed any or all of the various documentation items which are listed above and which pertain to certain sections of your final formal plan. Since receiving conditional approval, about how much additional effort, if any, has been or need to be expended to revise or up date or to complete each of these documentation items? (Check one column for each row.)

	1-Little or no effort	2-Some effort	3-A moderate amount of effort	4-A substantial or great amount of effort	5-A very great amount of effort	0-No basis to judge
1. Organized by-laws						
2. A plan and a time table for establishing a non-pysician advisory council						
3. Initial assessment of the size of scope of your PSRO area: number of practicing physicians and D.O.s, number of hospitals and facilities, etc.						
4. A plan for evaluating the effectiveness of the "in house" peer reviews conducted by delegated hospitals						
5. A plan for the collection of baseline data						
6. A plan for peer reviews in short stay hospitals						
7. A phased plan for peer reviews in long care facilities (Exclude LTC demonstrations)						
8. A methodology to develop various criteria and standards						
9. A plan to train personnel						
10. A plan for acquiring the PSRO staff, facilitie and equipment and consultation and other necessary operational resources exclusive of funding						

TURN PAGE FOR LAST QUESTION NO. 57.

APPENDIX II

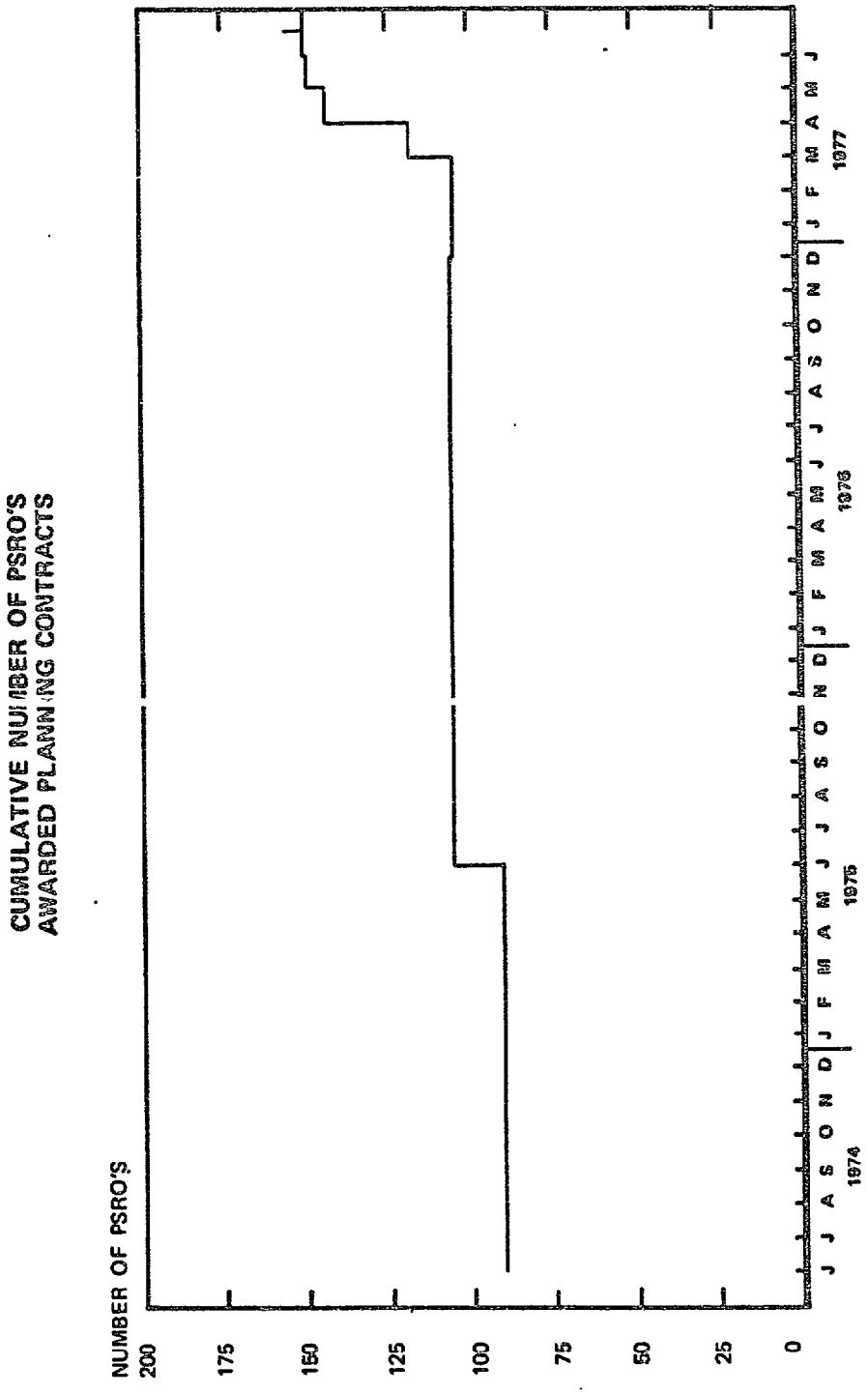
J. ADDITIONAL COMMENTS

57. Is there anything else that you would like to tell us concerning the issues raised by the questions on this form?

If there is or if there are other questions about the development of PSRO's which you think we should have asked but did not, please feel free to express your comments on this page. Attach an additional sheet if necessary. Any information you can give us will be greatly appreciated.

Thank you.

APPENDIX III



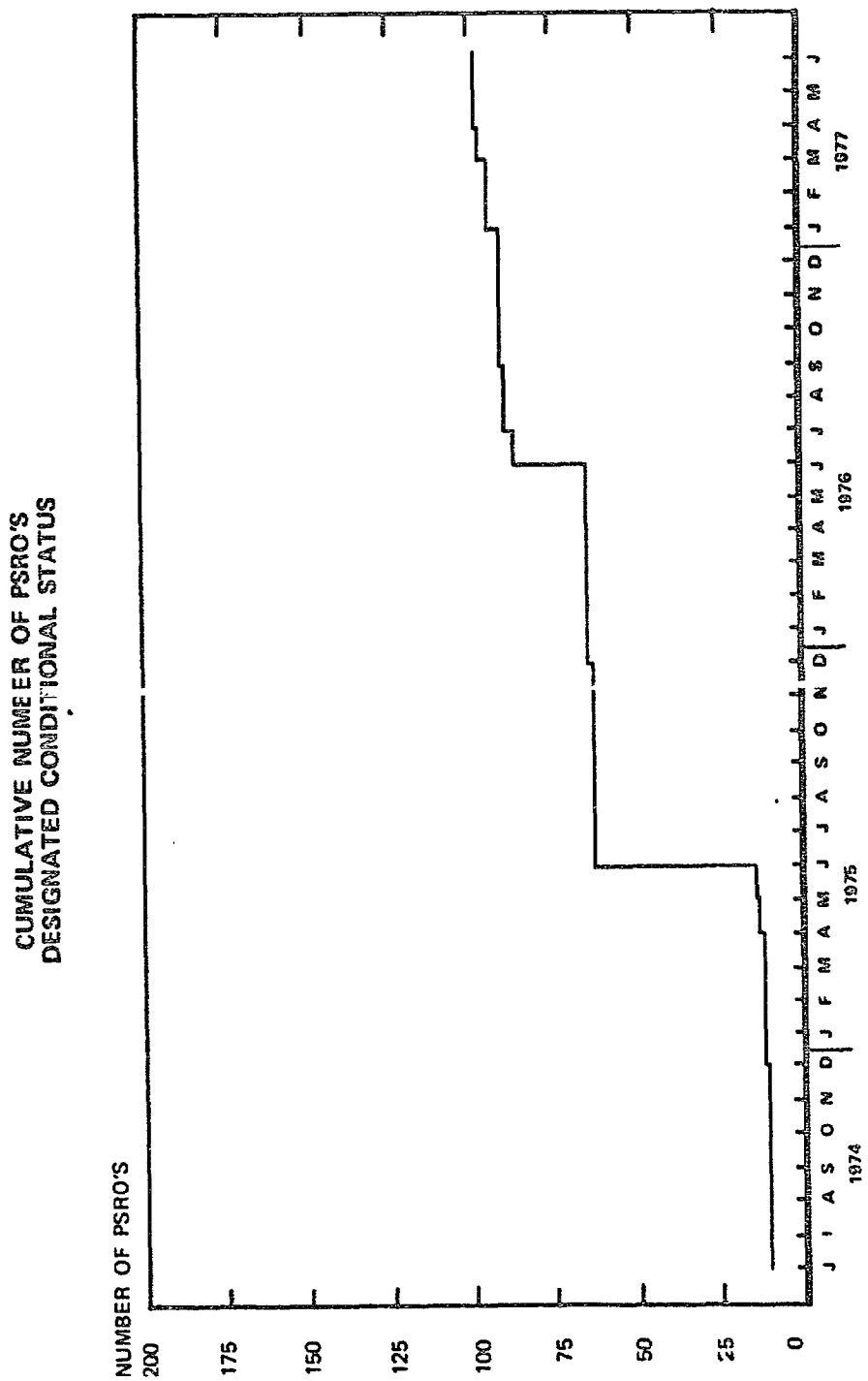
TIME FRAMES FOR CONVERSION OF PLANNING PSRO's TO CONDITIONAL STATUS [1/]

PLANNING CONTRACTS AWARDED	No.	CONVERTED TO CONDITIONAL STATUS													TOTAL		
		6/75	9/75	12/75	6/76	7/76	9/76	12/76	1/77	2/77	3/77	4/77	5/77	6/77	Converted	Lost Polling	Remain Planning
JUNE 1974	9	49	(1)	2	20	1	8	–	1	–	2	–	–	–	84	1	6
JUNE 1975	16	–	–	–	2	1	3	(1)	3	–	1	–	–	–	10	1	5
FEBRUARY 1977	14	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	14
MARCH 1977	25	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	25
APRIL 1977	5	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	5
MAY 1977	1	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	1
JUNE 1977	6	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	6
	158	49	(1)	2	22	2	11	(1)	4	–	3	–	–	–	94	2	62

1/ Excludes 14 PSRO's awarded conditional designation without formal planning contract.
(1) Indicates PSRO Lost Polling Process.

APPENDIX IV

APPENDIX V


CUMULATIVE NUMBER OF PSRO'S
DESIGNATED CONDITIONAL STATUS
NUMBER OF PSRO'S
200
175
150
125
100
75
50
25
0
J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J J A S O N D J F M A M J
1974
1975
1976
1977

APPENDIX VI

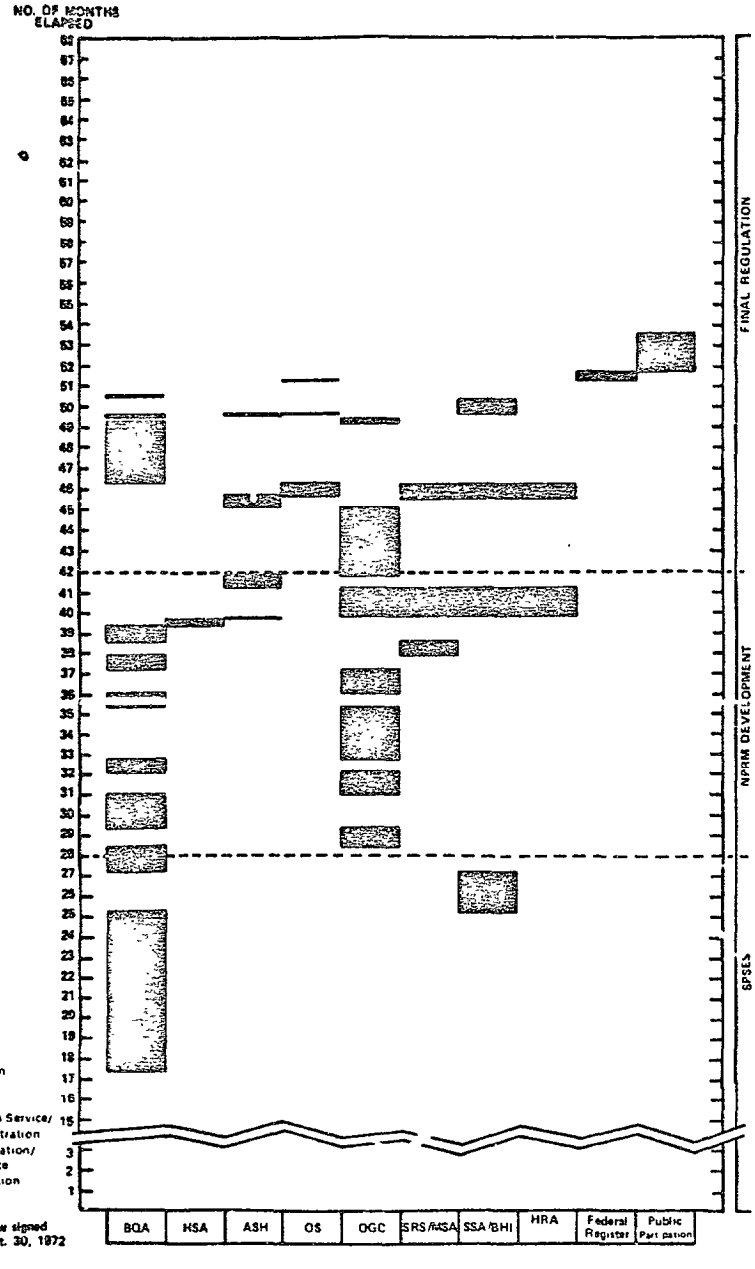
STATUS OF PSRO REGULATIONS
As of February 1978

Regulations governing	Date final regulation issued	Date interim regulation published for comment
1. Designation of PSR service areas	3-18-74	
2. Notification--polling of physicians	5-07-74	
3. Designation of statewide areas		4-28-76
4. Advisory groups to PSROs	7-12-76	
5. Advisory groups to statewide councils	1-04-78	
6. Statewide PSRO councils	12-09-77	
7. Assumption of review responsibility by conditional PSROs	2-22-78	
8. Waiver of liabilities		(a)
9. Interim hearings and appeals of PSRO determinations	1-25-77	
10. Reconsideration of PSRO determinations		(a)
11. Appeal of PSRO determinations		(a)
12. Procedures for review of hospital services		1-25-77
13. Financing of hospital reviews		(a)
14. Interim confidentiality and disclosure of data and information	1-16-78	
15. Confidentiality and disclosure of PSRO data and information		(a)
16. Grants		(a)
17. Sanctions		(a)
18. Designation of alternate organizations		(a)

a/ Under development.

APPENDIX VII

APPROXIMATE PERIODS FOR DEVELOPING AND PROCESSING REGULATION ON PROCEDURES FOR REVIEW OF HOSPITAL SERVICES



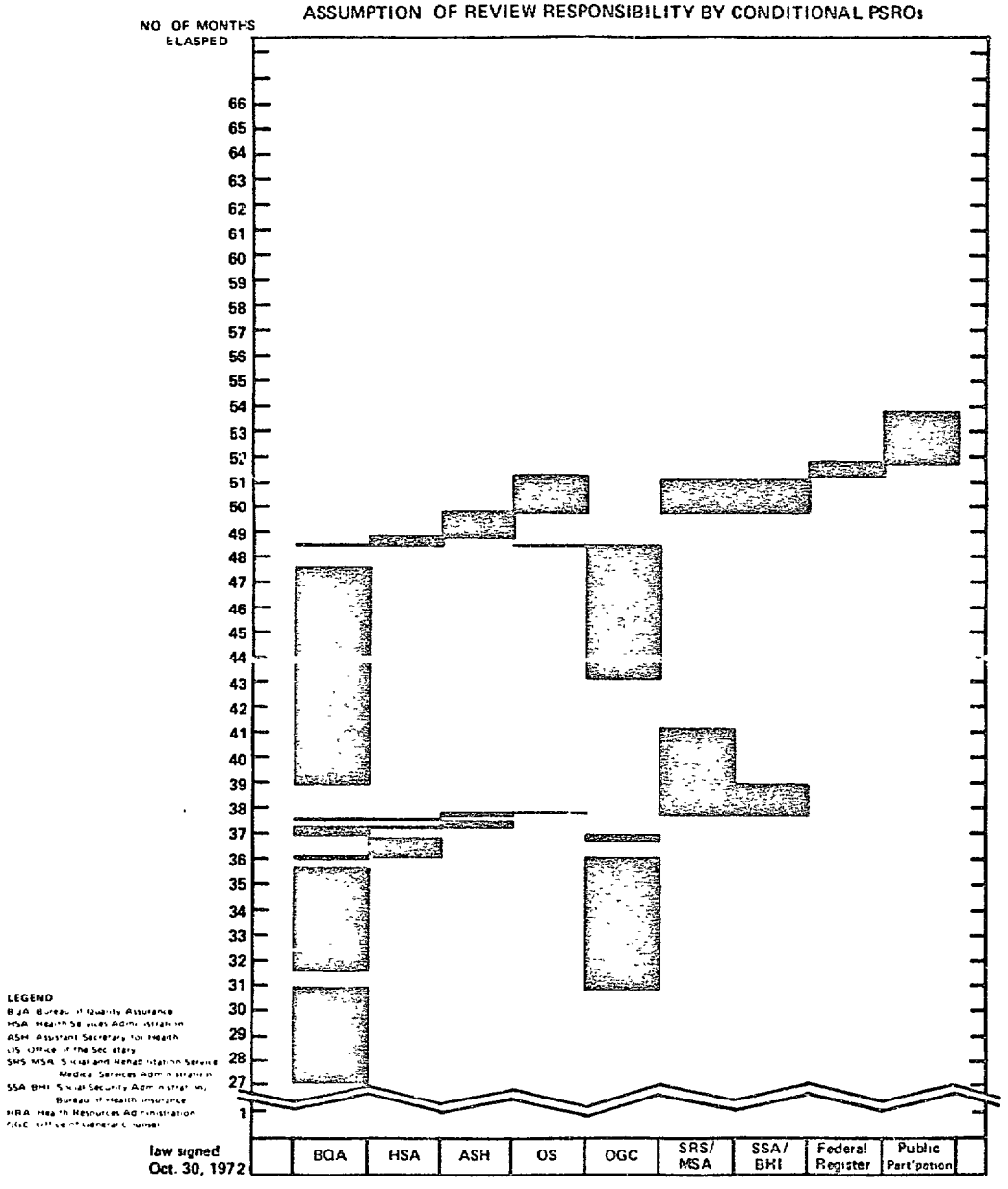
LEGEND
BQA- Bureau of Quality Assurance
HSA Health Services Administration
ASH Assistant Secretary for Health
OS- Office of the Secretary
SRS/MSA- Social and Rehabilitation Service/ Medical Services Administration
SSA/BHI- Social Security Administration/ Bureau of Health Insurance
HRA- Health Resources Administration
OGC- Office of General Counsel

— — — — UR Regulations were originally scheduled to be effective 2/1/75. Court suit brought by AMA caused regulations to be withdrawn and to be redrafted. Because efforts of BQA and OGC had to be directed to getting out UR regulations, progress in development of PSRO hospital review regulations were delayed during this period.

NOTE: The months required to publish a proposed or final regulation are numbered vertically. The agencies and offices within HEW on which the regulation was developed or cleared are listed horizontally by organization. Periods provided for public participation by comments, suggestions, or objectives for a proposed regulation are also provided. Shading for two or more levels during the same period indicates interaction between these levels.

APPENDIX VIII

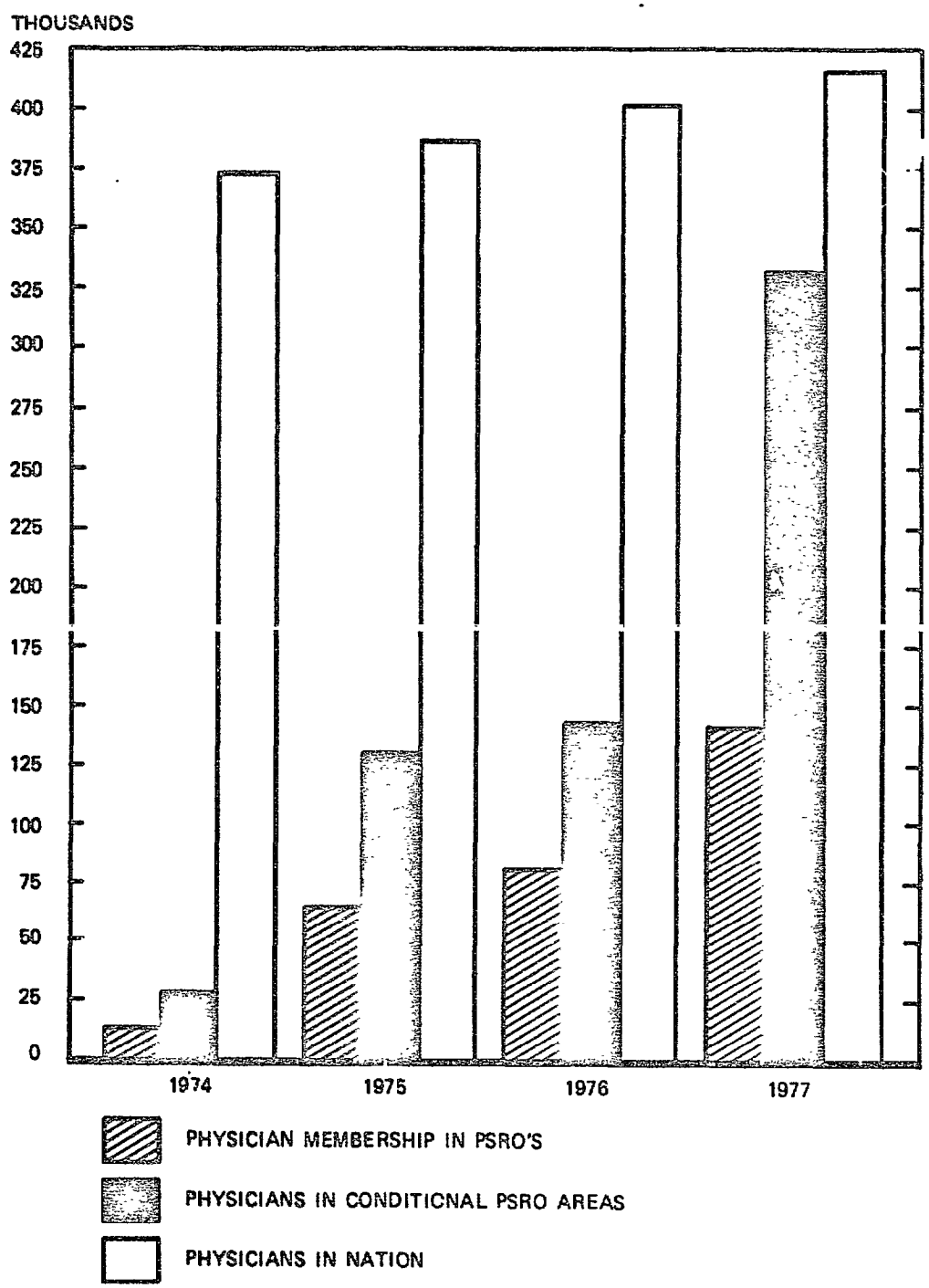
APPROXIMATE PERIODS FOR DEVELOPING AND PROCESSING REGULATION ON ASSUMPTION OF REVIEW RESPONSIBILITY BY CONDITIONAL PSROs



NOTE The months required to publish a proposed or final regulation are numbered vertically The agencies and offices within HEW on which the regulation was developed or cleared are listed horizontally by organization Periods provided for public participation by comments suggestions, or objections for a proposed regulation a. also provided Shading for two or more levels during the same period indicated interaction between these levels

APPENDIX IX

PHYSICIAN MEMBERS (THOUSANDS)



APPENDIX X

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20201

July 15, 1976

Mr. Gregory J. Ahart
Director, Human Resources
Division
United States General
Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Progress But Problems in Establishing Professional Standards Review Organizations." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

Thomas D. Morris
Inspector General

Enclosure

APPENDIX X

Comments of the Department of Health, Education, and Welfare on the General Accounting Office's Draft Report Entitled, "Progress But Problems in Establishing Professional Standards Review Organizations (PSROs)"

Overview

The GAO has concluded that establishment of PSROs nationwide has been slow, and they then indicate the reasons for this slow progress in implementing the program. Four points about this need to be made. First, the GAO report does not indicate the degree to which the PSRO legislation represented a significant departure from what the government had previously required of physicians in quality assurance and utilization control activities. The PSRO legislation required essentially "state of the art" types of activities which many physicians were not ready to undertake. The PSRO program is in many ways revolutionary, and the implementation of the program had to proceed with the recognition that major changes in physicians' attitudes could not be achieved overnight.

Second, the GAO report does not adequately recognize the major accomplishments achieved by the program over the last 6 years. In the face of significant physician resistance, organizational and other problems, PSROs have been implemented almost nationwide, and physicians have been given an opportunity to demonstrate the effect of peer review.

Third, the GAO report does not focus clearly enough upon what we view to be one of the major problems that delayed PSRO program implementation--the complexities of coordination with State Medicaid agencies.

The original PSRO legislation did not clearly enunciate the relationships between PSROs and the States. This matter became so acute that additional legislation was required (P. L. 95-142) to assure States of a continuing role in PSRO matters. Even now, program implementation is being delayed somewhat because of continuing complexities of coordination with a few Medicaid State agencies.

Fourth, the GAO report noted that HEW's "organizational shortcomings, including inadequate authority and fragmented program responsibility" were factors in delaying PSRO implementation. While we acknowledge that some of these problems did exist, we do not believe they significantly delayed program implementation. Even with ideal administration, the program could not have been implemented more quickly, because of the resistance from physicians and problems of coordinating the new program with utilization review performed by State Medicaid agencies.

GAO Recommendations

That the Secretary of HEW require the Administrator of the Health Care Financing Administration to:

1. Issue instructions to hospitals and fiscal intermediaries on the statutory obligations of participating hospitals to cooperate with PSROs.

2. Issue final PSRO program regulations as quickly as possible.

3. See that PSRO contract administration is improved so that prompt corrective actions are taken to resolve known problems delaying program implementation.

4. See that adequate guidance is provided for PSRO review of Maternal and Child Health patient care.

Department Comments

1. We concur.

   The Department is proceeding to issue the necessary instructions to hospitals and intermediaries. However, at this stage of PSRO program implementation, the issuance of these instructions will not be as helpful as they would have been had the instructions been issued when the request was first made. We are not now experiencing the kinds of problems with hospitals cooperating with PSROs as we did earlier in the development of the program.

2. We concur.

   The Department is moving aggressively to issue the remaining regulations. The complexity of the program made the regulations development process slower than normal as did interagency disagreements which have since been overcome with the creation of HCFA. We do not believe, however, that the delay in issuing regulations had a significant impact on delaying the overall implementation of the program. Sufficient guidance was provided to the PSROs in the framework of PSRO Transmittals and the PSRO Program Manual to allow them to implement their review systems in the absence of published regulations.

   Of the 8 regulations identified by GAO as currently under development, 2 have been published as Notice of Proposed Rulemaking. The remaining 6 will be published as notices during the next 2 months. All will be completed in final by late 1978 or early 1979.

APPENDIX X

3. We concur.

Since the time of the GAO study, we have devoted significant effort to improving the capabilities of the project officers in the regions through technical assistance and training activities. The quality of overall administration and management of PSRO projects have increased as a result of these activities. In addition, beginning with the contracts which expired June 30, 1978, all PSRO contracts will be converted to a grant method of financing. All contracts will have been converted by June 30, 1979. This should streamline our overall operation.

4. We concur.

The detailed instruction mentioned by GAO in their report will be issued shortly. In addition, we are now examining the statutory role of PSROs with respect to their review of Maternal and Child Health (MCH) patients. The PSRO legislation requires PSROs to review the health care of MCH patients. However, because the Maternal and Child Health program already had a distinct system in place to review the utilization of MCH services, the legislation did not give PSROs authority to make determinations of medical necessity which would be binding on the payment agency. This places the PSRO in a difficult situation. Because of this problem, the National Professional Standards Review Council has decided to review the entire issue of PSRO review of MCH patients.

GAO Recommendations

That the Secretary of HEW require the Administrator of the Health Care Financing Administration to promptly designate alternate organizations as PSROs in those areas where a physician sponsored organization refused to establish a PSRO.

Department Comments

We concur.

Currently, only one area - the State of Nebraska - does not have a physician group willing to become a PSRO. Final regulations setting forth procedures to be followed in designating an alternate organization to serve as the PSRO are scheduled to be published in August 1978.

Additional Departmental Comments

1. Page 6, lines 6 through 8, should be revised as follows to make the account of hospital review reimbursement accurate: " . . . mechanisms. Hospital review activities are financed through the Medicare Trust Funds and Medicaid appropriations. Medicare reimbursement mechanisms are used to make payment for both Medicare and Medicaid review; however, the Medicare Trust . . . ."

2. On page 20 of the report, the General Accounting Office (GAO) states that the Bureau of Quality Assurance, now the Health Standards and Quality Bureau, Health Care Financing Administration (HCFA), and the Bureau of Community Health Services (BCHS), PHS, had tentatively clarified the relationships between PSROs and the Maternal and Child Health programs. However, GAO reported that, as of February 1978, no specific guidance had been issued. As noted in our response to Recommendation No. 4, the jointly developed guidance material is scheduled to be issued shortly.

   It should also be noted that BCHS sponsored several conferences at both the national and regional levels in 1976 and 1977 which addressed the PSRO-Title V (Maternal and Child Health and Crippled Children's Services) relationships. In addition, BCHS supported a contract, completed in December 1976, entitled, "A Review of Quality Assurance Methodologies and Procedures as Practiced in Title V Programs and the Status of PSRO Quality Assurance Efforts". The findings resulting from this contract effort were presented to the National PSRO Council in March 1977 and made available nationwide to PSROs, State Title V programs and other parties interested in PSRO activities.

3. GAO, on page 32 of the report, states that the potential exists for duplication of effort between PSROs and Health Systems Agencies (HSAs). On December 5, 1977, the Joint Policy Statement on PSRO/HSA Relationships, signed by HCFA and PHS, was issued and distributed to the PSROs and health planning agencies. This policy guidance is intended to establish a strong coordinative relationship between the programs, ease concerns about the potential for duplication of effort by PSROs and HSAs, and facilitate the sharing of data by PSROs with HSAs.

4. The GAO statistics on the percent of PSRO review activity in hospitals is somewhat misleading. Page 14 of the draft report states that as of September 30, 1977, there was PSRO activity in "3950 hospitals, or about 56% of the hospitals". Although there were approximately 3950 hospitals in PSRO conditional areas as of September 30, 1977, only 2631 were actually performing PSRO review.

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