6. **Professional Standards Review Organizations**

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Professional Standard; Review Organizations

INTRODUCTION AND BACKGROUND

As noted in chapter 5, the Social Security Act authorizes the medicare program to pay only for services that are "reasonable and necessary," and these criteria have been generally regarded as met when a new technology is perceived to have moved beyond experimental status toward full clinical application and acceptance by the local medical community. The current policy of the Department of Health and Human Services (DHHS) is to use "broad strokes to sketch the boundaries of accepted good medical practice, and (to leave) the fine-tuning of the system to the 'back-end' mechanism, the Professional Standards Review Organizations (PSROS)" (98).

The PSRO program is one of the principal expressions of Federal policy concerning the use of medical services. The PSRO program, established in 1972 by Public Law 92-603, is administered by the Health Standards and Quality Bureau (HSQB), formerly the Bureau of Quality Assurance, of the Health Care Financing Administration. The purposes of the program are to help improve the quality and control the costs of medical services reimbursed through Federal payment programs. The program operates by setting standards and criteria for the desired level and quality of medical services and by evaluating against these standards the services actually provided. This process is designed to ensure that payment will be made only when services are medically necessary.

The PSRO program is based on the concept that medical professionals are the most appropriate individuals to evaluate the quality of medical services and that effective peer review at the local level is the soundest method for ensuring the appropriate use of medical care resources and facilities. The PSRO program is made up of separate and independent organi-

zations covering 195 geographic areas. Each PSRO must be substantially representative of all practicing physicians in an area. The PSRO program is new and is not yet fully implemented. Of the 203 PSRO areas in March 1977, only 120 PSRO agencies had been funded; 100 were in "conditional" status; 20 were in "planning" status. By April 1979, the areas had been consolidated to number 195. Of these, 182 had PSROS in "conditional" status, and 13 were being planned or were inactive.

Currently, PSROS are required to review institutional care—care provided in hospitals and long-term care (nursing home) facilities—and are authorized to regulate ambulatory care. PSRO activities at present are concentrated on inpatient care provided in short-stay hospitals. The PSRO can delegate its review responsibilities to the hospitals, or, if a hospital is not qualified or not willing to conduct the reviews, the PSRO conducts them itself. Review of long-term care can be delegated if such care is a "distinct part" of a short-stay hospital.

PSROS conduct three types of review (42 CFR, part 466):

- concurrent review of the medical necessity and appropriateness of admission to and continued stay in a hospital;
- 2. medical care evaluation studies to assure the quality and improve the nature of the utilization of health care services; and
- 3. analyses of health care practitioner, institutional, and patient profiles.

Medical care evaluation studies and profile analyses are used to focus concurrent review on problem areas.

As specified in the statute, PSROS review services to determine whether:

- such services and items are or were medically necessary;
- the quality of such services meets professionally recognized standards of health care; and
- such services and items proposed to be provided in a hospital or other health care facility on an inpatient basis could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type.

The law requires that PSROS use norms, criteria, and standards in evaluating medical services. This approach allows nonphysicians to perform many of the reviews and also enhances the objectivity of the review process. Standards are developed by a consensus of physicians, based on typical patterns of practice in the area and on such regional or national information as may be available and considered applicable by the PSRO.

In its early stages, the PSRO program has concentrated on determining the need for hospitalization. Now PSROS are beginning to move beyond the question of necessity for hospitalization to review of surgical procedures and review of ancillary services.

PSRO decisions on medical care utilization and quality can be enforced in several ways. Reimbursement for services provided can be withheld by medicare and medicaid (medicaid regulations are established in each State and vary somewhat). For serious and repeated violations of PSRO standards, a physician's right to be reimbursed through medicare and medicaid can be suspended or revoked.

Each State with three or more PSROS has a statewide Professional Standards Review Council. Among other duties, the statewide councils have the responsibility to disseminate information and data among the PSROS within the State. At the national level, a National Professional Standards Review Council is established by law. This Council has several functions, one being to "provide for the development and distribution, among Statewide Professional Standards Review Councils and Professional Standards Review Organizations of information and data which will assist such review councils and organizations in carrying out their duties and functions." Such information is specified as including regional norms and standards. Local PSROS are not required to accept model standards issued by the National Council. However, the National Council has authority to disapprove local standards that deviate from model standards if the Council determines that the differences are not medically justified. The National PSRO Council has provided general guidance and sample criteria sets developed by several organizations, including the American Medical Association, under contract with DHHS. The main purpose of these contracts has been to develop criteria on medical necessity for hospitalization for different disease categories. HSQB hopes that technical assistance and norms and standards will have an important educational effect, as well as a direct effect on practice through reimbursement policy.

REVIEW CRITERIA

Criteria used in evaluating the quality of medical care are usually grouped according to structural, process, and outcome measures. Structural measures assess both the availability of medical care resources (e.g., facilities, equipment, and health care personnel) and the qualitative aspects of medical care personnel (e.g., extent of educational background, specialty

board certification); process measures assess the appropriateness of the medical care that has been provided; and outcome measures reflect the effect of medical interventions on patient health status. PSROS, in their reviews, have relied primarily on process measures and, to a lesser extent, on outcome measures.

Generally, research on quality of care assurance and on the application of quality of medical care techniques has been process oriented,

assessing the appropriateness of medical care as judged by the medical profession. PSRO concurrent review of admission to and continued stay in hospitals is also process oriented. In practice, moreover, review activities of PSROS have been even more narrowly focused. The cost concerns of the Federal reimbursement program, together with the controversial nature and the uncertain state-of-the-art of reviewing the quality of medical care, have limited reviews to assessment of 1) whether a diagnosed problem justified hospital admission, and 2) whether continued hospitalization was justified after a specified number of days of inpatient care.

Recently, some PSROS have tried out slightly more sophisticated reviews than those based on length-of-stay indicators. Beginning in 1977, the Delmarva Foundation for Medical Care of the eastern shore of Maryland began to use a technique called "care level and timeliness review" (CLTR) to help hospitals find and eliminate medically unnecessary hospital days (358). By retrospective audit, the Delmarva Foundation has evaluated both the timeliness of services and the level of medical care supplied. As alternatives to weekend and night admissions through the emergency room (which contribute to unnecessary hospitalization) and to lack of full laboratory services on weekends (which can lead to extra days of hospitalization until tests have been completed), the Foundation examined "swing beds" with additional staffing for observation of patients to determine whether or not they should be admitted, and expansion of laboratory services from 6 to 7 days. In both cases, the reduction of unnecessary days was not enough to justify the extra costs.

COST-EFFECTIVENESS APPLICATIONS

In exploring the actual and potential applicability of cost-effective analysis/cost-benefit analysis (CEA/CBA) in the review activities of PSROS, it is necessary to delineate several separate concepts. First, PSROS do not normally take a specific medical problem or diagnosis and determine which of several effective treatment approaches is the least costly. Instead, they focus on reducing or eliminating unnecessary inpatient care. For a given diagnosis, PSROS perform their review with reference to standards based on medical opinion that hospitalization for that diagnosis is or is not needed. They also review against standards of how many additional days of hospitalization are needed. The PSRO evaluation does not, systematically at least, extend to a further determination that days of hospitalization beyond the standard (and the medical care provided during this period) are not needed at all or could be just as effectively provided through outpatient visits. With the explicit goal of current PSRO reviews being to minimize unnecessary hospitalization—not to determine whether hospitalization, outpatient care, or no medical care at all is most effective for a

given medical problem —PSROS are focused on reducing medical care that is of almost no value to the patient, but for which reimbursement is nevertheless being provided.

Second, although outcome measures, or the effect of medical interventions on patient health status, are often viewed as the best criteria for evaluating the quality of medical care, these have been the most difficult criteria to develop. Hence the reliance on process, or medical opinion, criteria. For most medical problems, however, alternative avenues of treatment—not clear-cut, single choices—have been the rule. Furthermore, the effectiveness of even established treatments is continually under question. Taken together, the use of several methods of treatment for specific medical problems and the often uncertain correlations between specific medical interventions and the patient's health status make the development of additional criteria to decide which interventions should or should not be reimbursed very difficult. Nevertheless, the development of such criteria, especially for many of the common interventions that are subject to review by PSROS, is not impossible. Because PSROS in effect concentrate on deviant practice by establishing ranges of acceptable behavior, boundaries can be set to allow reasonable divergence based on the possibilities of individual patient response. In concept at least, the ranges of acceptable behavior by institutions or physicians under review could be based on information that incorporates cost or cost-effectiveness-related data. The ranges could also be based on a more, though only slightly, common form of data—efficacy and safety.

These two aspects of the use of medical technologies—efficacy and safety, and cost effectiveness—together define the appropriate use of technologies. The PSRO legislation established a framework by which appropriate use of medical technologies could be evaluated by physicians acting in organized groups rather than as individuals. PSRO'S decisions, however, are still based largely on traditional sources of information, so customary practice patterns, whether appropriate or not, become accepted as standard. The lack of scientifically derived information on indications for use and, especially, on the cost effectiveness of various technological applications hampers the development of appropriate standards. Provided with such information, PSROS could perhaps become a more effective mechanism for evaluating medical care. In its absence, PSROS are developing local standards for medical services based primarily on prevailing patterns of medical practice, with little comparison of costs to benefits.

On the other hand, cost-effectiveness approaches have been used in managing some PSROS and in evaluations of the national PSRO program itself. Even with the current focus on reducing medically unnecessary inpatient days in short-stay hospitals, cost-effectiveness techniques can be used for PSRO management purposes. For example, a PSRO might use analytical techniques to decide which of a number of diagnoses to focus on to reduce, by a targeted number, the medically unnecessary days in a given year.

Incentives to use cost-effectiveness approaches to reduce medically unnecessary bed

days already exist and have influenced specific PSROS in choosing among problem areas. The PSROS' administrative budgets are funded by annual Federal grants, and their hospital review activities for medicare, medicaid, and the maternal and child health and crippled children programs' patients are paid from the medicare trust funds (Public Law 94-182). Congress set a limit on the use of fiscal year 1979 medicare trust funds for such hospital reviews (44 F.R. 26770, May 7, 1979).

Each PSRO is evaluated annually with regard to its impact on reducing medically unnecessary hospitalization and must negotiate formal annual "objectives" with the Federal Government. Objectives are stated in terms of "impact" (e.g., "reduce the incidence of medically unnecessary days in PSRO hospitals to 5 percent or less as measured by CLTR").

Two Maryland PSROS, the Delmarva Foundation for Medical Care and the Baltimore City PSRO, illustrate the effect of budget constraints on seeking alternative approaches to reducing unnecessary hospitalization (358). In late 1977, the Delmarva Foundation for Medical Care decided that its own collection of hospital data did not enhance its capability to reduce unnecessary hospitalization or assist materially in identifying problem areas. By deciding to eliminate data collection as a PSRO activity and accepting discharge abstracts prepared by the hospitals, this PSRO was able to reduce the concurrent review cost per discharge from \$6.50 to \$5.00.

The Delmarva Foundation also changed its concurrent review process in order to increase its efficiency. Nonessential tasks such as coding, norm assignment, and abstracting are no longer performed by reviewers. Review procedures have been simplified to concentrate only on the clinical indications for the need for continued hospitalization. A patient receiving intravenous therapy, for example, is automatically considered to be appropriately placed in the hospital. By focusing only every other day on the clinical indications for hospitalization, as opposed to assigning a normative length of stay in advance for a particular diagnosis, this PSRO dramatically shortened the amount of time required for review per patient. As a result, the concurrent

review cost per discharge dropped from \$5.00 to \$3.25, yet the PSRO'S capacity to reduce unnecessary hospitalization, as measured by CLTR, has not been affected. OTA has no information on whether the quality of the data itself was affected.

In 1979, in an attempt to cut costs further, Delmarva began exempting hospitals with low levels of inappropriate use from admission review, continued stay review, or total review. Consequently, concurrent review costs have dropped below \$2.50 per discharge. The impact of this action on appropriate hospitalization has not yet been evaluated.

Recently, the Delmarva Foundation has attempted to improve its utilization review process by employing, on a test basis, the appropriateness evaluation protocol (AEP), a recently developed technique that compares care delivered with an objective ideal. Like CLTR, AEP measures unnecessary days of care created by organizational problems and clinical judgments that are grossly out of tune with mainstream practices. AEP goes one step beyond CLTR, however, because it questions clinical practices that are in local general use. In addition to providing more timely and complete information than CLTR, AEP promises to be less costly.

This same PSRO has begun using cost-effectiveness-type analyses to identify unnecessary days of care and to change modes of physician practice on a diagosis-specific basis. In selecting topics for evaluation, Delmarva focuses on finding relatively low-cost opportunities for making substantial impacts. A model developed by the PSRO'S statistician is used to select topics for regional medical care evaluations that will have the most impact. This model not only identifies differences in utilization between the PSRO area and regional norms, but also identifies differences within the PSRO area in utilization that can be changed through local educational programs.

The Baltimore City PSRO, partially in response to the cap on review costs, has taken a different approach to maximizing its impact under financial constraints. Specifically, it has used its data base and computer capabilities to

rank hospital and diagnoses according to excess utilization rates, thereby enabling the PSRO to focus its attention on those hospitals and diagnoses that produce the highest incidence of unnecessary hospital days.

Excessive hospital days may not be true indicators of excessive costs. Nevertheless, it has been the experience of the Baltimore PSRO that hospitals which have problems with diagnosisspecific lengths-of-stay also tend to have problems with high costs and higher than average death rates. Given these facts and the PSRO'S limited budget, the Baltimore organization believes that length-of-stay analysis is an appropriate way to identify inappropriate and unnecessary medical care. By identifying problem areas under the length-of-stay analyses, the PSRO is able to focus its concurrent review, medical care evaluation, and profile analysis efforts on those hospitals and diagnoses where the impact can be greatest.

This technique seems to have worked for the Baltimore PSRO. In the first study of this type, that PSRO undertook a very careful review of the hospital that ranked first in excess utilization. Review of the hospital's data indicated potentially serious problems with several specific diagnostic and cost levels. The hospital has since confirmed the existence of these problems and corrected the excess utilization problem.

Evaluations of the national PSRO program have been conducted by the General Accounting Office (GAO) (243), the Congressional Budget Office (CBO) (121), and DHHS (285,288). Currently, GAO is conducting a general review of PSROS, with the intent of focusing future studies on more specific components of the program (404). CBO is also currently updating its evaluation (122), as is DHHS (138).

The GAO report was a general review of the progress and problems in establishing PSROS. The CBO report more specifically addressed the effect of PSROS on health care costs and whether the estimated savings (if any) derived from the program outweighed the program costs.

DHHS'S 1977 study (288) found no reduction in unnecessary hospital days was achieved

through PSRO activities. Its 1978 medicare rate study (285) concluded that there was a l.5-percent utilization reduction, leading to an estimated savings of \$50.0 million. With medicare review costs of \$45.9 million, the study concluded, there was a net benefit of \$4.6 million (a savings-to-cost ratio of 1.1 to 1) or 10 percent of review costs.

CBO analyzed the same data used by DHHS, but reached a different conclusion. CBO addressed the effectiveness of PSROS by posing the following three questions:

- 1. How effective is the program in reducing hospital utilization?
- 2. Are the savings associated with the program large enough to justify the costs of the program itself?
- 3. Are the program's net-savings large enough to warrant the expectation that PSROS will play a major role in containing health care costs?

CBO concluded that PSROS have brought about a decrease in days of care of roughly 2 percent for medicare beneficiaries in short-stay hospitals. Its analysis of the DHHS data led CBO to the conclusion that utilization savings would be about 30 percent less than review costs, in contrast to DHHS'S conclusion that savings would be 10 percent greater then review costs. (Both estimates, however, were subject to wide margins of error.) CBO further concluded

that, even if the 10-percent net savings were accepted, those savings would still be extremely small relative to Federal expenditures for acute patient care—amounting to less than 0.1 percent of medicare reimbursements for inpatient care in short-stay general hospitals.

One problematic issue is the opposite conclusions reached by CBO and DHHS after analyzing the same data, i.e., utilization savings 30 percent less than review costs versus savings 10 percent greater than review costs. The CBO report lists a number of methodological problems that could shift the conclusion of the cost effectiveness of the PSRO program either to a net loss or to a net savings position, and the persuasiveness of either conclusion might well rest in the eye of the beholder. Perhaps more importantly, however, these analyses do not examine costs in relation to changes in health outcomes that may result from PSRO reviews. Interestingly, these evaluations, which sometimes show a small cost savings and sometimes show a small net cost increase, are critiqued in terms of the value of the national PSRO effect. Implicit in such a criterion is a view of PSROS as a costcontainment mechanism. Yet, if this is indeed the rationale of the PSRO program, what does it matter if the program does cost slightly less than the amount it saves? That net saving is still infinitesimal compared to the total cost of the programs that the PSROS are supposed to be constraining.

USE OF CEA/CBA BY PSROS: GENERAL FINDINGS

The PSRO program has the broad responsibility of seeing that Federal funds are used for health care services and items that are medically necessary, meet professionally recognized standards of care, and are provided at the most economical level possible consistent with quality care. In practice, however, the program has concentrated on weeding out wasteful care. Even in this limited approach, cost-effectiveness approaches (loosely, and not formally, defined) have potential applicability in: 1) setting standards of medical care against which actual practices are judged, 2) the internal management of

individual PSROS, and 3) evaluations of the national PSRO effort.

It is theoretically possible that standards based on CEA/CBA or on other analyses incorporating consideration of costs in relation to effectiveness could be developed at the national or regional level and adapted for local use by PSROS. Development of such criteria will be difficult, and acceptance by PSROS may not be gained easily. Criteria for identifying quality medical care have gone beyond gross measures such as length-of-stay norms to (still modest)

criteria such as the timeliness of services and the level of medical care supplied (i.e., CLTR) and objective standards such as the AEP. If usable and relevant data on the appropriate uses of

various medical technologies are developed and made available to PSROS, there may be non-siderable potential for applying CEA/CBA in PSRO review activities.