

Quality Assessment Activities by Selected Organizations

Various organizations are engaged in activities related to assessing the quality of medical care. This appendix describes the efforts of three groups: the American Medical Association (AMA); the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO); and utilization and quality control peer review organizations (PROS). As a professional organization, a nonprofit accrediting body, and governmental contractors, respectively, these organizations illustrate the diversity of interests involved in quality assessment. They also convey the evolutionary nature of quality assessment, since each group is adopting new approaches.

Quality Assessment Activities of the American Medical Association

To strengthen its commitment to high-quality care, the American Medical Association's (AMA) Board of Trustees created a new initiative on Quality of Medical Care and Professional Self-Regulation. The various elements that make up this initiative are outlined in Report QQ, adopted by the House of Delegates in June 1986 (33).

The AMA Physician Masterfile, currently the most comprehensive source of past and current information on physicians, contains data on every physician practicing in the United States (672). It also includes data for U.S. medical school students and graduates of foreign medical schools who are living in the United States. Information on each physician includes the physician's birthplace, age, address, medical school, residency training, specialty, board certification, hospital affiliation, States of licensure, and any State medical board disciplinary actions. Information is not added to the Masterfile unless verified by a primary source (e.g., State licensing agencies for information on a physician's licensure status and the American Board of Medical Specialties for information on board certification status). The AMA Masterfile is routinely used for verifying physician credentials by hospitals; national, State, and county medical associations; Federal and State agencies; and other organizations. Information on physicians is also available to individual consumers who write to request it.

Disciplinary actions taken by State medical boards that affect a physician's medical licensure are reported

to the AMA Masterfile by the Federation of State Medical Boards on a monthly basis (672). To prevent a physician who has lost his or her medical license in one State from obtaining a license in a different State, the AMA sends out "licensure action alert letters." When the AMA receives notice of a final disciplinary action taken against a physician who has held or currently holds multiple State licenses, it automatically alerts the other State licensing boards of the sanctioned physician. The AMA's first licensure action alert letter was sent in January 1985 (673). Since then, the AMA has sent State licensing boards an average of 100 to 120 alert letters (regarding 60 to 70 final disciplinary actions) each month. The AMA also sends alert letters in response to requests for information on or verification of the credentials of a physician, if the physician had a final State disciplinary action on his or her record. These letters advise the requestor to contact for details the appropriate State medical board that took the action.

The AMA's initiative *on the Quality of Medical Care and Professional Self-Regulation* delineates plans to improve and expand the Physician Masterfile by adding hospital disciplinary actions, malpractice claims and settlement data, and sanctions imposed by the U.S. Department of Health and Human Services (33). The AMA hopes to reduce the amount of time it takes to process a physician credential check to 5 days.

A section of the Health Care Quality Improvement Act of 1986 (Public Law 99-660) mandated the formation of a clearinghouse for information on physicians. The AMA and the Federation of State Medical Boards have formed a partnership in hopes of becoming the designated source of this clearinghouse (673). Data in the mandated clearinghouse include hospital and State disciplinary actions and physicians' paid malpractice claims. The 1986 law requires that hospitals report these data to the clearinghouse. Should the AMA Masterfile become the legal physician data bank, the proposed JCAHO standards to require hospitals to report disciplinary actions to the Masterfile and to use the Masterfile when making staff privilege decisions would become a legal requirement.¹

¹The national data bank did not receive funding for fiscal year 1988, although it is in the President's budget for fiscal year 1989 (669).

In addition to maintaining the Masterfile, the AMA maintains a file containing information on approximately 70,000 deceased physicians (672). Data in the Deceased Physician Report are made available to State licensing boards to prevent individuals from falsifying their records by using the credentials of a deceased physician.

The AMA plans to take the following steps to encourage the regulation of physicians' behavior by their peers (34):

- review the records of AMA members and expel any physician who has engaged in serious misconduct or has been found to be incompetent;
- publish a comprehensive list of peer review guidelines that will encourage active peer review and is intended to help protect physicians who participate in good faith peer review against liability;
- work with the U.S. Department of Justice to clarify the antitrust laws that impede good faith peer review, the hope being to expand the areas of peer review that can be performed without violating antitrust litigation; and
- assist in defending any physician or medical society that is accused of violating antitrust laws if the litigation resulted from good faith efforts at reporting incompetence.

Because of the increasing need to define and measure the quality of medical care, the AMA, through its Council on Medical Service, has defined eight essential attributes of high-quality care and has provided specific guidelines for quality assessment methods (34). The eight attributes of high-quality care areas follows:

1. It produces the optimal possible improvement in the patient's physiologic status, physical function, emotional and intellectual performance and comfort at the earliest time possible consistent with the best interests of the patient.
2. It emphasizes the promotion of health, the prevention of disease or disability, and the early detection and treatment of such conditions.
3. It is provided in a timely manner, without either undue delay in initiation of care, inappropriate curtailment or discontinuity, or unnecessary prolongation of such care.
4. It seeks to achieve the informed cooperation and participation of the patient in the care process and in decisions concerning that process.
5. It is based on accepted principles of medical science and the proficient use of appropriate technological and professional resources.
6. It is provided with sensitivity to the stress and anxiety that illness can generate, and with concern for the patient's overall welfare.
7. It makes efficient use of health care resources needed to achieve the desired treatment goal.

8. It is sufficiently documented in the patient's medical record to enable continuity of care and peer evaluation.

Favorable outcomes, according to the AMA Council on Medical Service, are an inherent characteristic of high-quality care. The AMA will further develop the council's guidelines for quality assessment methods and will encourage their implementation in professionally conducted quality assessment programs (34). It will also explore the feasibility of developing more specific criteria that can be used to measure the eight attributes of high-quality care.

A patient information brochure on the methods the medical profession currently uses to ensure quality of care and on how patients themselves can evaluate the quality of care they are receiving has been prepared by the Council on Medical Service (37).

The AMA intends to expand its activities relating to geographic variations in the utilization of health care services (266). The AMA publication *Confronting Regional Variations: The Maine Approach* describes an active approach to confronting a situation with many quality implications (39). By supplying feedback to physicians; based on health service utilization data for a specific area, providers can reassess clinical practice patterns, and perhaps improve the quality and efficiency of their services by adjusting inappropriate patterns. Such demonstration projects have also been proposed for Texas, Wisconsin, and Massachusetts (471). Funding for these studies is currently being discussed.

The AMA initiative also calls for the appointment of a commission that is to review the standards for evaluating the clinical performance of medical students and graduates of foreign medical schools (471). The commission is also expected to investigate how medical education could be modified to influence the behavior of physicians.

Quality Assessment Activities of the Joint Commission on the Accreditation of Healthcare Organizations

Since 1951, Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), formerly the Joint Commission on Accreditation of Hospitals, has operated a voluntary accreditation process designed to ensure the quality of medical care services provided in health care organizations. By using structure and process standards that could be evaluated in a survey, the Joint Commission intended to show that JCAHO-accredited organizations have the mechanisms in place to provide high-quality patient care. In 1987, JCAHO accredited approximately 5,000 hospitals and 2,600

other health care organizations, including psychiatric, alcoholism, drug dependence, and mental retardation/developmental disabilities organizations, ambulatory health care organizations, long-term care organizations, and hospices. JCAHO accreditation surveys for home care organizations and managed care organizations are going to be introduced in 1988 (524).

The Current JCAHO Accreditation Process

To be eligible for a JCAHO accreditation survey, a hospital or other health care organization must first meet certain criteria.² Among the criteria are having a governing body, an organized medical staff, and a nursing service; providing certain specified services, such as diagnostic radiology services and medical record services; and providing at least one acute care clinical service, such as obstetrics-gynecology or adult psychiatry. These prerequisites prevent health care organizations operating below a minimum level from receiving JCAHO accreditation. Thus, the fact that a hospital has JCAHO accreditation at all, independent of its degree of compliance with specified standards, may itself be an indicator of quality.

The current onsite JCAHO survey process typically lasts from 2 to 15 days, depending on the type and size of the organization. For each JCAHO standard, JCAHO surveyors assign a score on a scale between 1 (best) to 5 (worst), based on the facility's degree of compliance with the provision of the standard. For any score worse than 2, JCAHO surveyors document their reasoning. For hospitals, the individual scores for each JCAHO standard are aggregated into the 8 main categories and 43 elements in shown in table D-1. The JCAHO system for rating the 43 elements is shown in table D-2. For any element that receives a rating below 2, the hospital receives a "contingency."

Depending on the criticality and pattern of elements receiving a contingency, JCAHO may decide to require a written progress report from the organization within a specified period ranging from 1 to 9 months (depending on the issue), may conduct a more focused survey of the facility, or, if the element is particularly crucial, may refuse JCAHO accreditation. In most cases, an institution with a certain number of contingencies will be awarded JCAHO accreditation, with the requirement that the institution correct the deficiencies within a specified time. Each year, 93 percent of the hospitals that JCAHO surveys receive at least one contingency (238). The denial of JCAHO accreditation can

²These eligibility criteria may differ for different types of health care organizations.

Table D-1.—Main Categories and Elements of JCAHO Hospital Accreditation Surveys

1. Laboratory
 - a. Proficiency testing
 - b. Quality control
 - c. Administrative procedures
 - d. Safety
 - e. Professional staff
2. Medical records
 - a. Delinquency
3. Medical staff
 - a. Appointment/reappointment
 - b. Clinical privileges
 - c. Direction and staffing
 - d. Organization
4. Monitoring and evaluation
 - a. Ambulatory care services
 - b. Anesthesia services
 - Dietetic services
 - Emergency services
 - e. Home care services
 - f. Nuclear medicine
 - g. Pathological and medical laboratory services
 - h. Pharmaceutical services
 - i. Radiology services
 - j. Rehabilitation services
 - k. Respiratory care
 - l. Social work service
 - m. Special care units
5. Monitoring functions
 - a. Medical staff/departmental monitoring and evaluation
 - b. Drug review
 - c. Blood review
 - d. Medical record review
 - e. Pharmacy and therapeutics review
 - f. Surgical case review
 - g. Utilization review
 - h. Infection control
6. Nursing services
 - a. Nursing process
 - b. Licensure
 - c. Direction and staffing
 - d. Monitoring and evaluation
7. Plant, technology, and safety management
 - a. Life safety
 - b. Safety operations
 - c. Equipment management
 - d. Management of utilities
8. Quality assurance programs
 - a. Governing body/management support
 - b. Written plan
 - c. Quality assurance results a determinant of clinical competence/privilege
 - d. Evidence of actions

SOURCE: Joint Commission on Accreditation of Healthcare Organizations, "Hospital Accreditation Program: Accreditation Decision/Contingency Criteria," Chicago, IL, 1987.

result from the overall level of failure of a facility to be in substantial or significant compliance with JCAHO standards and/or from certain patterns of failure in especially critical areas. If JCAHO determines

Table D2.—System Used To Rate Elements and Assign Contingencies in JCAHO Accreditation Surveys

| Extent of institution's overall compliance with standards in an element | Rating | JCAHO'S contingency response ^a |
|---|--------|---|
| Substantial compliance | 1 | Accreditation/no contingency |
| Significant compliance | 2 | Accreditation/no contingency |
| Partial compliance | 3 | Accreditation with contingency |
| Minimal compliance | 4 | Accreditation with contingency |
| No compliance | 5 | Accreditation with contingency |
| Not applicable | NA | Not applicable |

^aThe contingency responses listed below are accompanied by JCAHO's recommendations for improvements that must be made within a specified time to bring the institution into full compliance with JCAHO requirements.

^bThe institution must submit a written progress report to JCAHO in a specified time period. The contingency score for the element may not be aggregated with other contingency scores to warrant a focused survey of the institution, but if a focused survey is conducted, the element must be included.

^cThe contingency score for the element may be aggregated with other contingency scores to warrant a focused survey of the institution or may result in nonaccreditation by JCAHO.

SOURCE: Joint Commission on Accreditation of Healthcare Organizations, *AMH/87: Accreditation Manual for Hospitals* (Chicago, IL: 1987).

that an organization may be denied accreditation, the facility is specially reviewed and given more individualized attention in an effort to bring it into compliance with the standards. Only 1 to 2 percent of JCAHO-surveyed hospitals each year do not come into substantial compliance in a timely fashion and are denied JCAHO accreditation (238).

Implementing New or Revised JCAHO Standards

Revisions in JCAHO standards are developed by JCAHO with the assistance of consultants or special task forces, and then forwarded to professional and technical advisory committees. If these advisory committees recommend the revisions, the proposed changes are sent to the Standards and Survey Procedures Committee of JCAHO'S Board of Commissioners along with a request that the Standards and Survey Procedures Committee approve the revisions and allow them to be reviewed further by 2,000 to 5,000 professional organizations, individuals, and other interested parties, including a percentage of the accredited organizations.

After the reviewers' comments are analyzed, JCAHO'S Department of Standards and the consultants or special task force may revise the standards. The proposed standards are presented again to the

professional and technical advisory committees and to the Standards and Survey Procedures Committee. Additional field reviews are undertaken, depending on the extent and nature of the revisions to the proposed standards. After all revisions have been made, the final proposed standards are submitted to JCAHO'S Board of Commissioners to adopt for use in JCAHO accreditation surveys (559).

Elements of new or revised JCAHO standards are occasionally placed in "implementation monitoring." Affected institutions are given additional time for effectively implementing a new or revised standard while JCAHO surveys and monitors their progress toward compliance, but the institution's level of compliance with the standard does not affect JCAHO'S accreditation decision. No less than annually, any standards in implementation monitoring are reviewed, and if institutions have had sufficient time to successfully implement the new or revised standards, the standards will be taken out of implementation monitoring and the organization's compliance will be considered in JCAHO'S accreditation decision (559).

JCAHO'S 1986 "Agenda for Change"

In September 1986, JCAHO announced an "Agenda for Change" that signified a major redirection in its approach to quality assessment (523). The principal initiative of this agenda centers around a new approach to the current JCAHO survey and accreditation process. In the past, JCAHO has relied exclusively on structure and process standards to evaluate the capability of an organization to provide high-quality care.³ Project Objective I of JCAHO'S Agenda for Change calls for the development of indicators to assess the actual clinical performance of the organization, including the outcomes of the medical care it provides.

JCAHO believes that with recent advances in health care research methods, it is now possible to monitor an organization's clinical performance and outcomes more precisely, moving beyond answering the basic question, "*Can* this organization provide quality health

³In the early 1970s, responding to criticism that it placed too much emphasis on physical and administrative structures, the Joint Commission on the Accreditation of Hospitals began to require outcome-oriented hospital quality review programs (333). By 1976, the Joint Commission had developed an outcome-oriented method to audit medical care that was based on retrospective review using preestablished criteria. This method (the Performance Evaluation Procedure for Auditing and Improving Patient Care) could be applied to any diagnosis or surgical procedure. In 1979, the Joint Commission eliminated the medical audit requirements because *while being costly*, they often focused more on the data collection process than on problem solving (10). Furthermore, the medical audit requirements focused on already suspected problems, rather than on identifying problems and opportunities to improve care. The requirements were replaced with an organization-wide quality assurance system.

care?" to answer the question, "Does this organization provide quality care?" (329)

With assistance from expert groups, task forces, medical specialty societies, and accredited institutions, JCAHO plans to develop valid indicators of clinical performance of health care organizations. The indicators will be selected from clinical areas associated with high-volume/high-risk and/or potentially problematic care (523). Task forces have already proposed clinical indicators for hospital-wide care and for obstetrics and anesthesiology, and in 1987, pilot tests of the indicators began in 17 hospitals (11). Some of the indicators will be aggregated rates and others will be single sentinel events; they will be used to evaluate both diagnostic and treatment activities. Structure, process, and outcome indicators will be selected so as to be applicable to organization-wide reviews, cross-departmental reviews, and specialty-specific reviews. Examples of organization-wide clinical indicators include mortality rates of patients with specified medical conditions; examples of cross-departmental indicators for surgical departments include specific complications for specified surgical procedures. JCAHO asserts that the clinical indicators of quality developed will not measure the quality of care directly, but rather will serve as "flags" to identify care that requires further analysis and review (329). By identifying potential quality-of-care problems and areas in which care can be improved, JCAHO and the health care institutions can focus directly on those areas of patient care that are in most need of attention.

Another aspect of JCAHO'S "Agenda for Change" are revisions in the organizational assessment of health care institutions. Project Objective II includes the development of valid intra-organizational indicators, using organizational research findings and the advice of experts. These indicators could be used to improve the monitoring of the organizational functions such as planning, resource allocation, leadership, and evaluation that are believed to influence the quality of care most directly (329).

The comparison of different organizations using clinical indicators could be improved by a valid method to adjust for differences in the severity-of-illness of the patients that the organization serves. Project Objective III of JCAHO'S "Agenda for Change" calls for the development of a method to adjust for patient differences so that equitable comparisons can be made among institutions. JCAHO, along with the help of experts in this area, plans to examine current severity-adjustment methods, and if necessary, to modify or create new methods that more adequately account for the confounding effects of patient variables on measures of institutional performance. With

the use of a valid severity-adjustment method, an institution could compare its own results for an indicator to the results of other institutions or to a standard norm, without confusion caused by differences in the severity of illness among the patient populations (329).

Project Objective IV of JCAHO'S "Agenda for Change" concerns the assessment of current institutional data bases and monitoring systems to test their applicability to the collection and analysis of data for clinical and organizational indicators of an organization's performance. JCAHO will provide technical assistance to those institutions that must develop a clinical and organizational data collection process that is more outcome oriented. JCAHO will also continue to provide assistance with the establishment and modification of appropriate internal quality assurance systems. The extent to which JCAHO data reporting requirements are coordinated or could be tailored to be coordinated with other external data reporting requirements, such as those of the Health Care Financing Administration (HCFA) Medicare data set, will also be determined (523).

The creation of an ongoing interactive monitoring system between the JCAHO and the accredited institutions is another aspect of Project Objective IV. Rather than only conducting onsite surveys of each health care organization every 3 years, JCAHO hopes eventually to collect data on the indicators from each organization three to four times per year (119). At these regular intervals, JCAHO will collect the data relative to the specified indicators of clinical performance and organizational performance that the organization's departments will be collecting continuously. These data would be submitted to the JCAHO either in writing, by diskette, by data tape, or by modem. After the JCAHO processes the information gathered, it plans to provide feedback, in the form of aggregate and facility-specific evaluations of clinical and organizational performance, including outcomes, to each health care facility. With these new data, each institution could then compare its performance to the standing of other similar facilities or to external expectations (based on national and regional performance standards). Continual feedback from JCAHO could complement an institution's own self-monitoring process and serve as an "early warning system" to draw attention to an area needing prompt evaluation. JCAHO plans to analyze further the issues of cost and feasibility of this ongoing interactive monitoring (329).

To accommodate the intensive monitoring system and the new focus on clinical and organizational indicator data, the JCAHO plans to revise the accreditation survey and the accreditation decisionmaking process. Project Objective V of the JCAHO'S "Agenda for

Change” addresses the assurance of the validity, reliability, and utility of the new data to be accumulated by each health care organization. Surveyors will evaluate the organization’s analysis of problem areas and assess the effectiveness of actions taken to resolve recognized problems. JCAHO will also examine how information from surveys and from the ongoing monitoring activities will be integrated into the accreditation decisionmaking process (329).

JCAHO realizes that with such an extensive data base on institutional performance and because of increasing demands for public accountability, confidentiality and disclosure policies must be discussed. Although currently JCAHO upholds strict confidentiality policies, it speculates that there is the potential for the release of aggregate data, but there are no current plans to release institution-specific data (523).

JCAHO plans to gradually implement the objectives of the “Agenda for Change” first in pilot tests and then in stages for accredited organizations. During the developmental process, JCAHO plans to monitor closely the capabilities of the health care institutions. During 1988, development of clinical indicators will begin for cardiovascular, trauma, oncology, and surgical care, for long-term care, and for mental health services. Implementation is scheduled to begin in 1989 with hospitals, with full implementation scheduled for the early 1990s first for hospitals, and then subsequently for psychiatric, ambulatory, and hospice services (329).

Quality Assessment Activities of Peer Review Organizations

Utilization and quality control peer review organizations (PROs) are federally mandated under the Tax Equity and Fiscal Responsibility Act of 1982 (Public Law 97-248) to monitor the quality of medical care provided to Medicare beneficiaries.⁴ To receive payment under Medicare’s hospital payment system based on diagnosis-related groups (DRGs), hospitals are required by the Social Security Act of 1983 (Public Law 98-21) to enter into agreements with PROs. PROs are mandated to review the care these hospitals provide to Medicare patients with the purpose of ensuring that the services are medically necessary, are provided in the most appropriate setting, and meet professionally recognized standards of quality medical care. Under the direction of HCFA of the U.S. Department of

⁴The PRO program was established as the successor to the Professional Standards Review Organizations program, which had been established by the Social Security Amendments of 1972 (Public Law 92-603). For more information on the Professional Standards Review Organizations program, see K.N.Lohr, “Peer Review Organizations (PROs): Quality Assurance in Medicare” (382)

Health and Human Services, PROs are able to deny payment for inappropriate services and to take necessary action to correct unacceptable medical practices (535).

HCFA enters into contracts with 54 PROs geographically distributed across the country. The District of Columbia, Puerto Rico, the Virgin Islands, Guam and American Samoa, and each of the 50 States are considered separate PRO areas. To qualify as a PRO, an organization must demonstrate either 1) sponsorship by at least 10 percent of the physicians practicing in the review area, or 2) physician accessibility, i.e., the involvement of at least one physician in every generally recognized specialty in the area (42 CFR 462.102-462.103).⁵ Third-party payers can obtain PRO contracts only if it is determined that no eligible organization other than a payer organization is available.⁶ In 1985, 41 PROs were supported by a State medical association (158).

The number of personnel working full time in each PRO varies depending on the caseload in the PRO’s area. The staff includes mainly nurses, medical-record analysts, clerks, secretaries, and financial managers. Physicians are usually involved on a part-time basis as first-line physician reviewers, consultants, or members of the board of directors. Physician reviewers must have active admitting privileges in one or more hospitals in the area; consultants must be physicians in active practice but do not necessarily have to have admitting privileges (e.g., anesthesiologists, pathologists, and radiologists).

PRO Contracts

Through a competitive bidding process, HCFA, since 1984, has awarded and renegotiated PRO contracts every 2 years.⁷ The scope and structure of PRO reviews are delineated in each PRO’s contract. Specified criteria in each contract reflect federally mandated objectives for PRO review, provisions specified by HCFA, and particular quality and admissions objectives specific to each of the 54 PRO areas.⁸ Each PRO

⁵These organizations must have letters of support (written by other physicians in the area) establishing that they are representative of the specialty, as it is practiced in the PRO area (83).

⁶As of January 1988, the only PRO with a contract held by a third-party payer was the Hawaii PRO.

⁷The Omnibus Budget Reconciliation Act of 1987 (OBRA-87)(Public Law 100-203) mandates that PRO contracts in the next set are to be renegotiated every 3 years.

⁸The PRO contracts for Maryland, New Jersey, the Virgin Islands, Guam, American Samoa, and in the North Mariana Islands have differed with regard to specific objectives, because in these areas, Medicare does not pay for beneficiary inpatient care on the basis of DRGs; these areas have held waivers from the national Medicare program and have been regulated by alternative payment systems (630).

is required by HCFA to propose area-specific objectives, used as measurable targets to be reached during the 2-year contracts. A PRO's performance is evaluated by HCFA regional offices and the HCFA central office on the basis of how successfully the PRO has met its stated objectives (429). HCFA'S evaluations are also used for determining PRO contracts for the following cycle. Although PRO contracts are applicable only to the review of Medicare patients, PROS are encouraged to enter into similar contracts with Medicaid and other third-party payers.⁹

The first round PRO contracts, which became effective between July and November 1984, covered the 2-year period 1984-86. These contracts focused primarily on the detection by PROS of inappropriate utilization and payment patterns. Specifically, PROS were expected to reduce unnecessary hospital admissions, to ensure that Medicare payment rates were based on diagnostic and procedural information contained in patient records, and to ensure that Medicare patients were not readmitted within 7 days of discharge as a result of premature release from the hospital (535). The PRO contracts for 1984-86 were also to include area-specific admission¹⁰ and quality objectives (see table D-3). PRO were allowed to choose the procedures and conditions on which to focus both admission and quality objectives.

The second round of PRO reviews, beginning in July 1986 and covering a 2-year period through 1988,¹¹ have been more focused on quality-of-care issues (535). Provisions of the Omnibus Budget Reconciliation Act of 1986 (OBRA-86) (Public Law 99-509) required PROS to review health care provided to Medicare beneficiaries enrolled in health maintenance organizations (HMOS) and competitive medical plans (CMPS), but these provisions were not reflected in the 1986-88 PRO contracts; contracts used to implement HMO/CMP review by PROS were implemented in mid-1987 (see discussion below).

Table D-4 compares PROS' 1984-86 and 1986-88 scopes of work. As in the first contract period, the medical records reviewed by the PROS in the second contract period are obtained from the fiscal intermediary payment claims for inpatient hospital care. The

⁹If State Medicaid programs contract with the local PRO for the review of medical care provided to Medicaid beneficiaries, they receive a 75-percent Federal reimbursement, as opposed to a 50-percent reimbursement for contracting with an outside organization (83).

¹⁰A review of the PRO contract objectives revealed large differences in the proposed reduction targets. Although the PRO contracts for Florida, Georgia, and Iowa each specified a reduction in hospital admissions for lens procedures, Florida targeted its reduction rate at 76 percent, Georgia specified a 25-percent decrease, and Iowa proposed only a 10-percent reduction (474).

¹¹The termination dates for the PRO contracts in 1988 differ because of the range in contract initiation dates in 1986.

Table D-3.—Admissions and Quality Objectives for PROS in the 1984-86 PRO Contracts

Admissions and quality-related objectives in the 1984-88 PRO contracts were as follows:

Admissions objectives

1. To reduce admissions for procedures that could be performed safely and effectively on an ambulatory basis.
2. To reduce inappropriate or unnecessary admissions or reducing invasive procedures for specific DRGs, practitioners, or hospitals.

Quality objectives

1. Reduce unnecessary hospital readmission resulting from substandard care provided during the prior admission.
2. Assure the provision of medical services which, when not performed, have significant potential for causing serious patient complications.
3. Reduce avoidable deaths.
4. Reduce unnecessary surgery or other invasive procedures.
5. Reduce avoidable postoperative or other complications.

SOURCE: P.E. Dans, J.P. Weiner, and S.E. Otter, "Peer Review Organizations: Promises and Pitfalls," *New England Journal of Medicine* 31 3(18):1 131-1137, 1985.

criteria and specified percentages of cases to be reviewed, however, have been changed in the more recent contracts to reflect the new quality-of-care focus. The PRO scope of work for the 1986-88 contract period includes several new review requirements (659):

- apply generic quality screens to all inpatient cases reviewed in order to identify potential quality problems; ¹²
- review hospitals identified because of unexplained statistical outliers in the HCFA data on high mortality rates or utilization patterns;
- review each case selected by the PRO for retrospective review for the appropriateness of discharge;
- develop and implement a community outreach program to educate beneficiaries about PRO review and Medicare rights.

The 1986-88 contracts have included national objectives, which are established by HCFA, and area-specific objectives, which are proposed by each PRO under guidelines specified by HCFA. All objectives are physician or hospital specific. PROS' 1986-88 scope of work stipulates that the following cases are to be reviewed retrospectively:

a 3-percent random sample of all discharges per hospital;

¹²The following six categories of screens are applied to every case reviewed in order to identify potential quality problems: 1) adequacy of discharge planning, 2) medical stability of patient at discharge, 3) deaths that may indicate poor-quality care, 4) nosocomial infections, 5) unscheduled return to surgery, and 6) trauma suffered in the hospital (see ch. 5 for more details on generic screens).

Table D-4.—Comparison of PROS' 1984-86 Scope of Work and PROS' 1986-88 Scope of Work

| Category | 1984-86 Scope of work | 1986-88 Scope of work |
|--|---|---|
| Objectives | Three admissions objectives with five quality objectives, all proposed and validated by PROS; very limited areas for focusing objectives | Five objectives based on PRO data from first 90 days of generic quality screen review. ^a HCFA-identified mortality and utilization outliers, Broader objectives |
| Random samples | Review a 5-percent sample of all hospital admissions; 3-percent to 100-percent sample of inpatient hospital records for DRG validation (based on number of hospital discharges) | Review a 3-percent random sample of all prospective payment hospital discharges (including, for the first 6 months of PRO contract, all cases with a 1- or 2- day hospital stay) |
| Preadmission review | Review cases involving any of five procedures proposed by PRO | Review cases involving cardiac pacemaker implants or reimplants plus four procedures proposed by PRO |
| Cases involving cardiac pacemaker implants or reimplants | Review 100 percent of cases retrospectively | Review 100 percent of cases preadmission (see above) |
| Transfers | Review all transfers from a prospective payment hospital to another hospital exempt unit or swing bed | Same, but lower percentage of cases are reviewed |
| Readmission | Review all readmission within 7 days of discharge from a PPS hospital | Review all readmission within 15 days of discharge from a PPS hospital |
| Medicare code editor | Review 100 percent of nine diagnoses specified by HCFA | Same |
| Review cases in specific DRGs | Review all cases in DRG 468 (unrelated operating room procedure); DRG 462 (rehabilitation) was added during the contract period | All cases in DRG 468 (unrelated operating room procedure), DRG 462 (rehabilitation), and DRG 088 (chronic obstructive pulmonary disease) |
| Day and cost outliers ^b | Review 100 percent (reduced to 50 percent during the contract period) | Review a 50-percent sample |
| Cases involving percutaneous lithotripsy | Not in contracts | Review all claims for percutaneous lithotripsy in hospitals that have an extracorporeal shock wave lithotripter |
| Validation of objectives | Not in contracts | Review a sample of discharges within a 3-month period to validate PRO's individually negotiated performance objectives |
| Hospital notices of non-coverage to beneficiaries | Review 100 percent where patient disagrees. 100 percent where patient is liable for charges for services rendered after notification of noncoverage. 10 percent of remaining. | Same |
| Specialty hospital review | Proposed by each PRO | Review 15 percent of discharges |
| Admission pattern monitoring | Discontinued during contract | Not in scope of work |
| Intensified review ^c | Trigger: 2.5 percent of cases reviewed or three cases per hospital (whichever is greater) | If denial associated with 1 department or physician, review increased to 100 percent. Trigger: 5 percent of cases reviewed or six cases (whichever is greater). If denial associated with one department or physician, review increased to 50 percent (first quarter) or 100 percent (two or more consecutive quarters) |
| Community outreach | Not in contracts | All PROS to c)roDose Droaram |

^aEach PRO determines its own specific targets for these objectives according to potential problems of quality of care revealed from the first 90 days of generic quality screen review

^bDay outlier is a case in which a hospital seeks payment for days in the hospital exceeding, by a specified amount, the average length of stay paid under Medicare's prospective payment system (PPS). A cost outlier is a case in which a hospital seeks payment for medical care expenses exceeding, by a specified dollar amount, the average level of payment paid for that DRG.

^cThis is more focused review triggered by a certain percentage of denials for a specific physician or hospital department (often revealed by Physician and Hospital Profiles)

SOURCE: U.S. Department of Health and Human Services, Office of the Inspector General, Office of Analysis and Inspections, "The Utilization and Quality Control Peer Review Organization (PRO) Program," draft report, Control No. OAI-01-88-00570, Washington, DC, February 1988.

- all readmission within 15 days of discharge from a prospective payment hospital;
- all transfers from one PPS hospital to another. A sample of transfers from a PPS hospital to PPS exempt swing beds, alcohol/drug abuse units, psychiatric units, and rehabilitation units;
- a 50-percent sample of day outliers and cost outliers;
- all cases with DRG assignment for rehabilitation (DRG 462), unrelated operating room procedure (DRG 468), and chronic obstructive pulmonary disease (DRG 088).¹³
- all cases in which the patient disagrees with a notice of non-Medicare coverage by a hospital or in which the patient is liable for the charges for non-Medicare coverage. All cases in which the physician disagrees with hospital notice of non-Medicare coverage. The PRO also reviews 10 percent of all other cases where notices of non-Medicare coverage have been issued.
- a random sample of 15 percent of discharges from PPS-exempt hospitals.
- all cases for percutaneous lithotripsy in hospitals with an extracorporeal shockwave lithotripter and cardiac pacemaker implants or reimplants.
- all cases in which a covered level of care occurs during a hospital admission that the hospital had determined originally to be a noncovered hospital stay.
- all cases that the fiscal intermediary refers to the PRO for a medical necessity determination.

HCFA also requires in the 1986-88 contracts that PROS review cases involving nine specified diagnoses before Medicare payment is provided. " In addition, PROS are to perform preadmission review for five procedures, a review for all cases involving the implantation or reimplantation of cardiac pacemakers and four other procedures chosen by each PRO. The four PRO-selected procedures are based on criteria delineated by HCFA and have been designated in the PRO contract. PROS will be required to perform 100-percent preadmission and preprocedure review for 10 different elective surgical procedures, a provision under the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Public Law 99-272). Guidelines for this provision have not yet been implemented (83).

Each PRO must also develop specific goals based on the following objectives (83):

1. Eliminate adverse outcomes (including premature discharges) by focusing on providers and/or practitioners and by focusing on DRGs;
2. Reduce unnecessary admissions and/or procedures by provider 'and/or practitioner aid by focusing on DRGs.

Each PRO has determined its own specific targets for these objectives according to potential problems of quality of care revealed from the first 90 days of generic quality screen review, HCFA-identified outliers, 5 or other identified problem areas. Altogether, the cases selected for PRO review have included approximately 25 percent of all hospital discharges for Medicare.

Additional PRO duties have been mandated under COBRA and OBRA-86, but they have not yet been incorporated into the 1986-88 PRO contracts. COBRA allows PROS to deny payment for care of substandard quality as identified through criteria developed under HCFA guidelines. As part of the preadmission review for specific elective surgeries, COBRA also allows PROS to require second opinions if warranted.

PROS' 1988-90 scope of work includes the new requirements mandated in OBRA-86 and in the Omnibus Budget Reconciliation Act of 1987 (OBRA-87) (Public-Law 100-203). Rather than concentrating solely on inpatient hospital care, the 1988-90 scope of work focuses on the continuum of patient care. The third round of PRO contracts will include a requirement that PROS review all hospital readmission within 31 days of discharge. PROS will also be required to review the intervening care delivered to a percentage of Medicare beneficiaries with hospital readmission. HCFA'S proposed generic quality screens used by PROS for reviewing inpatient hospital records have been revised for the third scope of work (table D-5).¹⁶ The new generic quality screens include a 7-page *Generic Quality Screens Guideline* to clarify the criteria for determining potential quality-of-care problems (see ch. 5).

PROS' 1988-90 scope of work also contains a requirement that PROS review the quality of services among a variety of alternative settings, including ambulatory surgical centers,¹⁷ hospital outpatient departments,¹⁸ and nursing homes, PRO reviews will include

¹³These DRGs have a high level of payment and tend to be miscoded or abused by hospitals (83).

¹⁴These diagnoses include diabetes mellitus, noninsulin-dependent and insulin dependent; impacted cerumen; benign hypertension; left bundle branch hemiblock; other left bundle branch block; right bundle branch block; elevated blood pressure without diagnosis of hypertension; and other unspecified complications of medical care not elsewhere classified (651).

¹⁵HCFA provides each PRO with lists of hospitals in the PRO's area that have been identified as having mortality rates that vary significantly from national norms. The PROS were required to evaluate the outliers in their area determined by 1986-87 data. They are not required to perform any focused reviews of outliers revealed in the 1987-88 data.

¹⁶These new generic quality screens may undergo additional revisions before final implementation.

¹⁷The review of medical services provided in ambulatory surgical centers and outpatient surgery hospital departments will be incorporated into PRO contracts for those contracts entered into or renewed before January 1, 1987. As of February 1988, Pennsylvania and Massachusetts are the only States that are reviewing these ambulatory settings (83).

¹⁸Tentatively, PRO reviews of hospital outpatient departments and nursing homes will begin towards the end of 1988 (83).

all written complaints by Medicare beneficiaries about the quality of services provided in skilled nursing facilities, home health agencies, and hospital outpatient

Table D-5.—HCFA'S Proposed Generic Quality Screens for Reviewing Inpatient Hospital Records^a

17 Adequacy of discharge planning

No documentation of discharge planning or appropriate follow up care with consideration of physical, emotional, and mental status needs at time of discharge.

2. Medical stability of the patient

- a. Blood pressure within 24 hours of discharge (systolic less than 85 or greater than 180; diastolic less than 50 or greater than 110)
- b. Temperature within 24 hours of discharge greater than 101° F (38.3° C) oral, greater than 102° F (38.9° C) rectal
- c. Pulse less than 50 (or 45 if the patient is on a beta blocker), or greater than 120 within 24 hours of discharge
- d. Abnormal diagnostic findings which are not addressed and resolved or **where the record does not explain why they are not resolved**
- e. **Intravenous fluids or drugs after 12 midnight OR day of discharge**
- f. **Purulent or bloody drainage of wound or open area** within 24 hours prior to discharge

3. Deaths

- a. During or following any surgery performed during the current admission
- b. Following return to intensive care unit, coronary care unit, or other special care unit within 24 hours of being transferred out
- c. Other expected death

4. Nosocomial (hospital-acquired) infection

5. Unscheduled return to surge~
Within same admission for same condition as previous surgery or to correct operative problem

6. Trauma suffered in the hospital

- a. Unplanned surgery which includes, but is not limited to, removal or repair of a normal organ or body part (i.e., surgery not addressed specifically in the operative consent)
- b. Fall
- c. Serious complications of anesthesia
- d. Any transfusion error or serious transfusion reaction
- e. Hospital-acquired decubitus ulcer and/or deterioration of an existing decubitus
- f. Medication error or adverse drug reaction (1) with serious potential for harm or (2) resulting in measures to correct
- g. Care or lack of care resulting in serious or potentially serious complications

"Optional Screen"

Medication or treatment changes (including discontinuation) within 24 hours of discharge without adequate observation

^aThe PRO scope of work for 1988-90 includes a scoring system to reflect differences in severity of potential quality problems. For items marked with an asterisk in this table, the PRO reviewer is to record the failure of the screen, but need not refer potential severity Level I quality problems to a physician reviewer until a pattern emerges

SOURCE: U. S. Department of Health and Human Services, Health Care Financing Administration, Health Standards and Quality Bureau, 1988-19. "PRO Scope of Work (Baltimore, MD: Apr. 1, 1988)

areas.¹⁹ pilot studies for reviewing the quality of services delivered in physicians' offices is scheduled to begin in January 1989 (83).

Reviews of Health Maintenance Organizations and Competitive Medical Plans

Contracts for the review of HMOS and CMPS, mandated in COBRA, were implemented between June and November 1987.²⁰ All but one HMO/CMP contract have been awarded to existing PROS (428). These contracts require the review of the quality of care delivered to Medicare beneficiaries in HMOS and CMPS. The criteria delineated in the contracts for HMO/CMP review, however, are somewhat different from the objectives contained in the PRO contracts for inpatient hospital review. Each case picked for HMO/CMP review may undergo inpatient review, ambulatory review, and/or post-hospital review (644). The selection of cases for HMO/CMP review is based on the following elements:

- Random sample of 13 conditions, determined by HCFA to be conditions that when leading to inpatient hospital care may be indicative of poor-quality ambulatory care;
- Focused review of ambulatory care services (to begin after the first 6 months of the contract);
- 3- to 6-percent random sample of hospital discharges;
- readmission within 30 days of discharge from an acute care hospital;
- patient transfers to other hospitals; and
- nontrauma deaths.

An initial analysis of an HMO/CMP's internal quality assurance system determines whether an HMO/CMP will undergo limited or basic review of these elements. When poor review findings exceed certain threshold levels, an HMO/CMP is reassigned to an intensified level of review. Each level of review evaluates cases according to the same criteria. However, the limited review plan evaluates a lower percentage of cases than the basic plan, and the intensified plan analyzes the highest percentage of cases (644).

¹⁹The review of beneficial complaints was implemented via modification to the 1986-88 PRO contracts (83).

²⁰COBRA initially authorized PROS to review the services provided by HMOS and CMPS. This legislation, however, was amended by provisions in OBRA-86. OBRA-86 allowed HCFA to contract for reviews of HMO and CMP services with entities other than PROS on a competitive basis, but these contracts were limited to no more than half of the States, covering no more than half the Medicare HMO or CMP enrollment (627).

²¹The contractor has 6 months from the effective date of the contract to develop and submit a methodology for performing focused review (e.g., by provider, by medical condition) of ambulatory care.

The PRO Review Process

The patient records needed for retrospective review by PROS are identified from Medicare hospital claims submitted to a fiscal intermediary for payment. The fiscal intermediary sends the PRO the data tape for all claims made within a specific time period, usually a month. The PRO analyzes this information with a computer program that flags the specific cases to be reviewed, according to the criteria and specified percentages of cases described above. To obtain the patient records that correspond to the flagged claims, the PRO requests copies of the records (within 30 days) from the hospital, or PRO personnel may go to the hospital to review the records on-site. Physicians are required to notify the PROS of the cases that require preprocedure review (83).

Each record identified for review undergoes five different basic reviews by PRO nurse reviewers. These initial reviews include generic quality screen reviews, admissions reviews, discharge reviews, DRG validation, and items/services coverage reviews. Nurse reviewers use explicit criteria, developed by the PRO, to determine potential quality-related or utilization problems. Should one of these reviews detect a potential problem, the records are referred to a PRO physician adviser for further review (199). Potential quality problems not detected by one of the five reviews, e.g., mismanagement of the case, may be discovered by the initial nurse reviewer based on his or her medical judgment. In this case, the medical record would also be referred to a physician adviser. If the initial reviewer can determine that a case failing one of the generic quality screens is not actually a quality problem, the case is not referred to a physician adviser (627).

A physician reviewer will conduct a more indepth examination of the medical record, based on his or her clinical judgment, to determine whether there actually is a problem. The review process also allows the attending physician and hospital an opportunity to discuss the specifics of the case in question. These discussions often reveal unique characteristics of the case that explain why it may have failed the initial screens. Most cases of potential problems are resolved this way (164).

If the physician reviewer determines after the discussions that the care provided was not medically necessary or that it should have been provided in another setting, a payment denial notice is sent by the PRO to the beneficiary, physician, provider, and fiscal intermediary. If the physician reviewer identifies a quality-of-care problem that is not cleared up after discussing the case with the patient's physician, the PRO

will initiate appropriate interventions.²² These interventions may include physician education through a continuing medical education program, a corrective action plan, intensified review of the physician and hospital, or the initiation of a sanction review (627).

The sanction review process is initiated if other interventions have not corrected the problem or if the quality problem has been determined to be a substantial or a gross and flagrant violation.²³ This sanction process may result in exclusion from the Medicare program or the imposition of monetary penalties (360) (see ch. 6 for a further description of the PRO sanction process).

PROS review the care provided by nearly 7,000 hospitals and 450,000 physicians (164). During the 1986-88 scope of work, PROS took some form of quality intervention, short of initiating the sanction process, against 16,823 physicians and 1,376 hospitals (535). From 1985 through September 1987, 79 sanctions were imposed by the Office of the Inspector General as a result of PRO recommendations: 53 physicians and 1 hospital were excluded from the Medicare program, and civil monetary penalties were imposed on 24 physicians and one hospital (164).

Physician and Hospital Profiles Produced by PROS

PROS also use the data collected from medical record reviews to produce physician and hospital profiles. These profiles include data on denial rates, mortality rates, and review findings on quality and admissions objectives. The PROS analyze these profiles to compare patterns of care by similar providers and current patterns with previous patterns. In addition, the profiles are used to identify patterns of care among physicians and hospitals that deviate from established criteria and standards (627). The identification of an aberrant pattern of care may trigger a PRO's evaluation of a larger sampling of records from the physician or hospital in question.

²²COBRA allows PROs to issue denial notices for substandard quality of care, but HCFA, as noted earlier, has not yet implemented regulations regarding these types of denial notices.

²³As noted in ch. 6, a substantial violation refers to a pattern of care that is inappropriate, unnecessary, or does not meet recognized professional standards of care, or is not supported by the necessary documentation of care, as required by the PRO (42 CFR 1004.1b). A gross and flagrant violation entails a violation of an obligation in one or more instances which presents an imminent danger to the health, safety, or well-being of a Medicare beneficiary or places the beneficiary in high-risk situations (42 CFR 1004.1b).

The SuperPRO

In June 1985, HCFA contracted with Systemetrics, Inc. to evaluate the PRO program. Every 6 months, this organization, also known as the SuperPRO, re-reviews a random sample of 400 medical records from each of the 54 PROS' random sample of reviews (199). The purposes of the SuperPRO's reviews are as follows:

- to validate the determinations made by PROS, specifically on admission review, discharge review, and DRG validations;
- to validate the medical review criteria used by nonphysician reviewers for admission reviews;
- to verify that nonphysicians are properly applying the PROS' criteria for referring cases to physicians for review; and
- to identify quality issues that should have been addressed by the PRO (use of screening criteria) (637).

The SuperPRO submits the reports generated for each PRO to HCFA. Problems identified by the SuperPRO are also submitted to the individual PRO. The PRO may appeal the SuperPRO's findings with additional data or explanations. If PRO appeals do not lead to a reversal of the initial SuperPRO findings, HCFA reviews the SuperPRO findings and initiates appropriate actions to correct any problems. HCFA is responsible for any final determinations (637).

The SuperPRO review process is mostly educational for the PROS. The SuperPRO's record review may detect an aberrant pattern of care not recognized by the PRO's initial review. Thus, PROS are made aware of the types of cases that should be addressed differently.

Similar to the PRO review process, the SuperPRO has a team of chart reviewers that initially evaluates the hospital records (without benefit of the PRO's reviewer findings).²⁴ A subcontractor has recruited physicians from across the country (providing a representative sampling of medical specialties and geographical regions), and they make the ultimate decisions on the medical necessity of the admission, DRG validation, appropriateness of discharge, and quality of care (83). The SuperPRO uses the same basic screens in its review that each individual PRO used for the initial review.

HCFA conducts its own review of PRO activities through an internal PRO Monitoring Protocol and Tracking System. This system evaluates how well PROS have fulfilled their contractual obligations. If the PRO data reveal that a PRO is not performing adequately,²⁵ a corrective action plan may be instigated by HCFA regional offices. Deficiencies in areas such as the use of generic screens, physician profiles, or timeliness of reviews may warrant a corrective action plan. Although data from each PRO are collected by HCFA regional offices every 9 months, a final evaluation of a PRO's contractual performance is not conducted until 90 days before the PRO contract's expiration date (429).

²⁴The records reviewed by the SuperPRO are copies of the hospital records used by the PRO in the initial review process. The PRO must copy the medical records as requested and send them to the SuperPRO.

²⁵HCFA regional offices record the frequencies and the percentage of cases for which they disagreed with initial PRO determinations