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THE CHANGING FOCUS OF PEER REVIEW UNDER MEDICARE

*Peter M. Mellette**

I. AN INTRODUCTION TO THE ROLE OF PEER REVIEW IN HEALTH CARE FINANCING

Consumers today rely on both physicians and the federal government for health care services. A consumer/patient's visit to a physician is the usual method of access to such services. After examining the patient, the physician will typically send the patient home with a prescription for medication or refer the patient for admission to an appropriate health care provider, such as a hospital. In either instance, the patient incurs medical bills. If the patient is age sixty-five or older, the federal government probably pays for most of those bills through the Medicare program.¹

As a method of controlling Medicare costs and reducing unnecessary medical care, Congress created several peer review systems to review physician and hospital treatment practices. This article will review the growing federal involvement in professional peer review and will analyze the goals and results of peer review legislation. The article will also examine how physician and provider groups have responded to federal peer review efforts. Finally, the article will suggest how the Medicare prospective payment system and current peer review efforts will increase the conflicts between cost and quality of care concerns for physicians and other health care providers.

A. *Effects of Treatment Patterns and Public Financing*

1. How Physicians Ration Health Care Resources

The above scenario repeats itself daily. The typical consumer's involvement in health care decisions is minimal, especially after the initial decision to seek care.² The consumer-patient usually

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1. See 42 U.S.C. §§ 1395a-1395xx (1982 & Supp. I 1983).

2. The decision to seek medical care depends on a number of interrelated factors: (1) the

lacks sufficient information to weigh the costs and the benefits, both to himself and to others, of additional increments of medical services. Accordingly, the patient typically delegates both diagnostic and treatment authority to the professionally trained physician and his staff.³

Although the modern physician maintains a dominant role in treatment decisions, the physician relies heavily on the participation of hospitals and third-party payors during patient treatment.⁴ The hospital provides the physician with an array of diagnostic and treatment devices for patient care, and the payor, usually the federal government or a commercial insurer, guarantees payment to the physician and hospital for such care. In this way, both the hospital and the payor help consumers gain access to needed health care services. However, neither the hospital nor the payor is in a position to participate in treatment decisions on an equal basis with the physician.

A hospital can exercise only limited control over treatment decisions because its financial survival depends upon its continued access to the physician's skill and his patient clientele. By law and custom, a hospital's non-physician staff cannot make major treatment decisions without the physician's assistance and oversight.⁵ Without the physician's patient referral many hospital beds would remain empty, adversely affecting the hospital's cash flow. In light of these concerns, hospitals have allowed physicians to exercise broad discretion in patient treatment.⁶

individual's underlying state of health; (2) his or her perception of need; and (3) the availability (access and cost) of such care. Lave & Lave, *Medical Care and Its Delivery: An Economic Appraisal*, 35 LAW & CONTEMP. PROBS. 252, 258 (1970). The development of third-party insurance (including government expenditures through Medicare and Medicaid) and the broadening of employee health benefits have virtually eliminated cost as a major factor in individual decisionmaking. See *infra* note 13.

3. The health care consumer has the dual characteristics of being ignorant about medicine and of loathing to take risks concerning his or her health. See Lave & Lave, *supra* note 2, at 259; see also Note, *Restructuring Informed Consent: Legal Therapy For the Doctor-Patient Relationship*, 79 YALE L.J. 1533, 1533-41 (1970) (emphasizing the physician's control over treatment decisions and the patient's passivity under the circumstances).

4. See *infra* notes 6, 13 & 39.

5. Most states limit the role of non-physicians in treatment decisions. See, e.g., VA. CODE ANN. §§ 54-274 to -281.4 (Cum. Supp. 1985) (licensing and delegation); see also 42 U.S.C. § 1395x(e) (1982) (Medicare requirement).

6. The advantages of physician proximity to the expensive medical equipment that a hospital can offer prompted independent practitioners in the early twentieth century to join hospital medical staffs. The hospital, dependent upon the skill and patient clientele of physicians, allowed physicians to extend their professional dominance into the hospital setting.

A third-party payor has some financial control over general physician practices, but is not present when physicians weigh the costs and benefits of particular treatment decisions. A payor typically reviews a physician's treatment decision weeks after the patient has received care. At that point, the payor is under pressure to approve payment of the attendant medical bills. If the patient completely recovers from his or her illness, a payor then has difficulty denying the payment request, even if the physician's treatment decisions were suspect.⁷

Physicians tend to ignore treatment advice from hospitals and payors. Where a payor denies payment for care, the affected physician may not even notice the denial; instead, the physician's billing office may merely seek reimbursement from the patient.⁸ If the physician does note the payment denial, he may nonetheless elect to follow the same treatment pattern with subsequent patients because of his understanding of the medical literature and his knowledge of how fellow practitioners treat similar patients.⁹ Rising con-

See Scott, *Managing Professional Work: Three Models of Control for Health Organizations*, in ORGANIZATION AND CHANGE IN HEALTH CARE QUALITY ASSURANCE 41, 44-45 (R. Luke, J. Krueger & R. Modrow eds. 1983).

7. See *infra* note 9.

8. See 42 U.S.C. § 1395u(b)(3) (1982); see also *id.* § 1395n(c) (provider right to seek reimbursement from patient for inpatient care).

9. The community's standard of care can be thought of as the average choice of therapy for a group that encompasses the individual treatment decisions of similarly situated physicians, namely physicians who have similar specialty training, if any, and who care for the same type of patient complaint. The standard thereby varies, depending on the patient diagnosis and the physician's measurable specialty training. The standard also will vary from community to community, as shown by epidemiological studies. See, e.g., Wennberg & Git-telsohn, *Small Area Variations in Health Care Delivery*, 182 SCIENCE 1102 (1973).

In reviewing the diagnosis-specific treatment variations in New England communities, Professor Wennberg found that

[t]he [treatment] procedures exhibiting the most variation are often for conditions that are part of the aging process. The controversies [concerning the value of specific treatments] arise because for such conditions the natural history of the untreated or conservatively treated case is often poorly understood As a consequence, the opinions of individual doctors can vary substantially, based upon subjective experience

. . . .
 . . . By contrast, the low-variation procedures derive from quite specific conditions for which there is a professional consensus on the preferred place or style of treatment For these conditions, practice style, at least in the United States, only plays a small part in affecting demand.

Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, HEALTH AFF. 6, 9 (1984) [hereinafter cited as *A Proposal for Action*]. Wennberg's findings suggest that treatment norms for Medicare patients may be difficult to determine. Many Medicare patients have diagnoses that show high variations because their complaints are related to the

sumer expectations and the threat of malpractice claims also affect the physician's choice of treatment.¹⁰ The use of additional and more sophisticated treatment techniques provides physicians with protection against lawsuits, even if the treatment approach runs counter to payor preferences. This lack of effective feedback to physicians regarding appropriate treatment decisions and the threat of malpractice claims lead many physicians to make the same decisions, even if experience shows these decisions to be inappropriate.¹¹

Patients generally benefit from physician treatment decisions, even if the particular decision was inappropriate and costly. Moreover, a patient without medical knowledge is in no position to question such decisions, particularly in a life-saving context. With the unbridled discretion and authority to choose the type of treatment in most instances, a physician may select a course of treatment with only marginal diagnostic or therapeutic benefit but which costs the patient and the payor considerably more money.¹² The prospect of such choices has made increasing health care costs for individuals and for society all the more likely.¹³

aging process.

As Wennberg suggests, there is no effective professional consensus on the value of particular therapies for many diagnoses. Very often, physicians disagree about the diagnosis. These complications limit a payor's opportunity for promoting consistent treatment decisions by physicians. In the past, these limitations have hindered payor efforts to control the utilization of health care resources and the overall cost of health care. Wennberg, McPherson & Caper, *Will Payment Based on Diagnosis-Related Groups Control Hospital Costs?*, 311 NEW ENG. J. MED. 295, 298-99 (1984). However, continued efforts by payors and others to inform physicians that existing variations in treatment practices have no effect on patient recovery may improve the consistency of physician treatment for many diagnoses. See *A Proposal for Action*, *supra* this note, at 21-25.

10. Much has been written on the subject of "defensive medicine," but the topic is beyond the scope of this article. See generally Grad, *Medical Malpractice and Its Implications for Public Health*, in LEGAL ASPECTS OF HEALTH POLICY: ISSUES AND TRENDS 397 (R. Roemer & G. McKray eds. 1980); Report of the Secretary's Commission on Medical Malpractice, U.S. Dep't of Health, Educ. & Welfare (1973).

11. See *supra* note 9.

12. Havighurst & Blumstein, *Coping with Quality/Cost Trade-Offs in Medical Care: The Role of PSROs*, 70 NW. U.L. REV. 6, 12 (1975).

13. Havighurst and Blumstein state:

[T]he need for particular health services is frequently not an all-or-nothing proposition but is, instead, heavily dependent upon the financial resources available.

. . . Ever since World War II, labor bargaining and the favorable tax treatment of group health insurance premiums have helped to induce a steady increase in insurance coverage. While the Medicare and Medicaid programs enacted in 1965 [provided] the most dramatic infusion of new demand and have been widely blamed for the cost escalation, they were only part of a larger trend toward third-party payment which was also attended by a steady cost rise. As insurance and government financing

2. The Effect of Public Funding on the Payor Rationing Process

In 1965, Congress created the Medicare program,¹⁴ seeking to improve the elderly population's access to quality health care services.¹⁵ Pursuant to congressional mandate, the federal government became a third-party payor. Under Medicare Part A, the federal Medicare program reimbursed institutional providers such as hospitals for the reasonable costs of providing care to Medicare beneficiaries.¹⁶ Congress limited Medicare's beneficiary population almost exclusively to persons over the age of sixty-five. In addition, Congress gave the elderly the option to participate in a complementary health insurance program, known as Medicare Part B, for payment of physician services to beneficiaries.¹⁷

The enactment of Medicare contributed to a general expansion of third-party insurance coverage for all age groups.¹⁸ The federal government's growing role as a payor of health care services under both Medicare and Medicaid¹⁹ reduced consumer concerns over access to, equity of, and cost of care. Meanwhile, physicians and hospitals enjoyed the prosperity created by federal involvement. Physicians used their treatment authority to obtain the benefits of new

reduced or eliminated the patient's concern about the cost of care, the physician came to see himself less as a fiduciary with a responsibility for the patient's pocket-book as well as his health and more as a technician freed by insurance to pursue medical results without regard to cost.

Id. at 13-14 (footnotes omitted).

14. See 42 U.S.C. §§ 1395a- 1395xx (1982 & Supp. I 1983).

15. See Zubkoff & Blumstein, *The Medical Marketplace: Health Policy Formulation in Consideration of Economic Structure*, in 2 NATIONAL COMMISSION ON THE COST OF MEDICAL CARE 1976-1977, at 73, 91 (1977) [hereinafter cited as *Medical Marketplace*].

16. See 42 U.S.C. § 1395x(r) (1982 & Supp. I 1983) (statutory definition of reasonable cost). The working definition of what is "reasonable" has changed considerably over the years as both Congress and the Health Care Financing Administration (HCFA) have sought to contain rising program costs. See Lave, *Hospital Reimbursement Under Medicare*, 62 MILBANK MEMORIAL FUND Q. 251, 252-53 (1984).

17. See 42 U.S.C. § 1395j (1982). The method of physician payment, like that for hospitals, has received considerable attention in recent years. For more information, see *Medicare: Physician Payment Options, Hearing Before the Senate Special Comm. on Aging*, 98th Cong., 2d Sess. (1984).

18. See *supra* note 13.

19. Title XIX of the Social Security Act covers the Medicaid program. Congress enacted Medicaid in order to improve the access of low income Americans to health care services. See 42 U.S.C. §§ 1396-1396p (1982). Medicaid payments to nursing homes and hospitals are now based on the costs of efficiently and economically operated facilities. See 42 U.S.C. § 1396a(a)(13)(A) (1982). Congress included both this provision and a provision which made permissive state Medicaid agency contracts with local PSROs for peer review in the Omnibus Budget Reconciliation Act of 1981 (OBRA), Pub. L. No. 97-35, 95 Stat. 794 (codified in pertinent part in scattered sections of 42 U.S.C.).

technologies and therapies covered by third-party payment.²⁰ Hospitals, once a business left to charitable institutions, began to realize profits, making hospital development and expansion more feasible.²¹ Consumers were happy because they received better treatment at lower out-of-pocket costs. However, payors such as the federal government were alarmed by the substantial increases in ordered services and hospital capital costs.²² The resulting increase in Medicare program costs prompted Congress to seek greater control over cost-inflation and over-utilization of Medicare-covered services.

20. Many studies have shown that the mere availability of medical equipment creates a demand for its use. See, e.g., Klarman, *Approaches to Moderating the Increases in Medical Care Costs*, 7 MED. CARE 175 (1969). Federal efforts at developing standards for the planned introduction and use of new technologies include the Health Services Research, Health Statistics, and Health Care Technology Act of 1978, PUB. L. No. 95-623, 92 Stat. 3443 (codified in scattered sections of 42 U.S.C.). Section 309 of the Act authorized federal funding for technology assessment and established a mechanism for development and promulgation of standards, norms and criteria for the use of new technology.

21. Due to public concern over the effect of hospital development on health care costs, capital expenditures by health care facilities are currently regulated by federal and state administrative agencies. See The National Health Planning and Resources Development Act of 1974, PUB. L. No. 93-641, 88 Stat. 2225 (1975) (codified as amended at 42 U.S.C. §§ 300m-1 to 300n (1982)).

The 1974 Act encouraged states to develop mandatory bed and health service laws and standards. These state laws limited hospital growth by requiring all health care facilities to receive state certification that a need existed in the facility's service area before a facility could add new beds or equipment. See, e.g., VA. CODE ANN. §§ 32.1-102.1 to -102.11 (Repl. Vol. 1985).

Title XVIII of the Social Security Act (the Medicare provisions) also includes a review of capital expenditures under § 1122. However, § 1122 applies only to reimbursement for those capital expenditures allocable to Medicare patients. The § 1122 program does not control the acquisition of equipment or services with an initial cost that was insignificant or recoverable from other third-party payors.

Although beyond the scope of this article, many evaluations of health planning activities at the state and federal level are available. For more information, see Klarman, *Health Planning: Progress, Prospects, And Issues*, 56 MILBANK MEMORIAL FUND Q. 78 (1978) (economic appraisal); Payton & Powmer, *Regulation Through The Looking Glass: Hospitals, Blue Cross, and Certificate-of-Need*, 79 MICH. L. REV. 203 (1980) (historical perspective); Sloan & Steinwald, *Effects of Regulation on Hospital Costs and Input Use*, 23 J. L. & ECON. 81 (1980) (same). The history of health planning law reveals the piecemeal approach taken to date in meeting quality-assurance and cost-containment goals. See generally Fielding, *PSROs and HSAs—Shall the Twain Meet?*, in P.S.R.O.: THE PROMISE, PERSPECTIVE, AND POTENTIAL 317 (J. Bussman & S. Davidson eds. 1981) [hereinafter cited as P.S.R.O. PROMISE].

22. The statistics are particularly revealing: between fiscal years 1965 and 1975, public expenditures for health care costs rose from 21% to 42% of total personal health expenditures. Over the same period, the proportion of the gross national product (GNP) spent in the health sector rose from 5.9% to 8.4%. Gibson & Mueller, *National Health Expenditures, Fiscal Year 1976*, 40 SOC. SECURITY BULL. 3, 4, 18 (1977). Current estimates show that health sector expenditures have increased to over 10% of the GNP for fiscal year 1984.

B. Congressional Responses to Medicare Cost Increases

1. Changes in Hospital Payment

From 1965 to 1982, the Medicare program reimbursed participating hospitals²³ for care to beneficiaries on a "reasonable cost" basis.²⁴ The Medicare provisions in the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA)²⁵ shifted the focus of hospital reimbursement from a cost per diem system to a diagnosis-related group (DRG) system.²⁶ The Medicare program now pays a predetermined price per patient admission, according to the patient's diagnosis at discharge.²⁷ Each DRG rate includes all of the typical ancillary costs for patients with that particular diagnosis as well as the patient's room and board costs for typical hospital stays.

Congress adopted the DRG system following a year of administrative development. TEFRA directed the Secretary of Health and Human Services (HHS) to develop the prospective payment system based on typical provider payments for each diagnosis.²⁸ Con-

23. A participating hospital negotiates an agreement with the Medicare program to provide care to eligible beneficiaries and is thereby subject to the conditions of participation in the program, one of which is peer review. See 42 C.F.R. § 405.1035 (1984).

24. See *supra* note 16 and accompanying text.

25. PUB. L. No. 97-248, 96 Stat. 324, 331 (1982) (codified as amended in scattered sections of 42 U.S.C.).

26. Prior to the implementation of the DRG system, hospitals received payment from Medicare for each day the patient remained in the hospital and for each service the patient received, as long as the hospital stay and service were "medically necessary" and the costs were reasonable. Hospitals had no incentive to keep these costs to a minimum because more services ordered by physicians and delivered by hospitals led to more reimbursement received by both hospitals and physicians. Under the DRG system, a hospital receives a fixed sum for each patient admission, based on the patient's diagnosis. See, e.g., *New Jersey's Hospital Reimbursement System: Hearing Before the House Select Comm. on Aging*, 98th Cong., 1st Sess. 33 (1983) (statement of Dennis J. Duffy, Executive Vice-President, Suburban Medical Review Organization) [hereinafter cited as *The New Jersey DRG Experience*]; see also Lave, *supra* note 16, at 253. New Jersey received a HCFA demonstration project waiver in 1980, and established the first large-scale DRG experiment in the country. The demonstration project was reportedly successful in reducing patient lengths of stay and hospital operating expenses, although the number of patient admissions rose slightly at DRG-funded hospitals. The New Jersey all-payor DRG system differs in two major respects from the nationwide program that Congress approved: (1) the nationwide system covers payment for Medicare beneficiaries only; and (2) the New Jersey DRG rates are hospital-specific, while the Medicare rates are gradually becoming fixed for each case regardless of hospital location. See *The New Jersey DRG Experience*, *supra* this note, at 3-6 (statement of J. Richard Goldstein, M.D., Commissioner, New Jersey Department of Health). Dr. Goldstein identified five other differences between the state and national DRG programs which go beyond the scope of this article.

27. See Wennberg, McPherson & Caper, *supra* note 9, at 295.

28. PUB. L. No. 97-248, tit. I, § 101(b)(3), 96 Stat. 324, 335 (1982) (codified as amended at

gress sought a payment system that would eliminate the incentive among hospitals and physicians to keep patients in the hospital longer or provide them with more ancillary services in order to obtain more money.²⁹

In the Social Security Amendments of 1983,³⁰ Congress relied on HHS Secretary's recommendation that Congress base the Medicare prospective payment system for participating hospitals on the New Jersey DRG demonstration project.³¹ The congressional initiatives of 1982 and 1983 now limit the Medicare program funds available for each hospital admission. With a fixed payment level per diagnosis, hospitals can suffer an immediate cash shortfall if a patient's length of stay or ancillary studies exceed those of a typical patient with the same diagnosis. Health care policy experts anticipate that these financing provisions will give hospitals an incentive to promote early patient discharge and lower utilization of hospital services.³² In theory, the new financing mechanism will indirectly force admitting physicians to discharge patients earlier

42 U.S.C. § 1326b-5 (1982)); see also J. O'SULLIVAN & G. MARKUS, *MEDICARE AND MEDICAID PROVISIONS OF THE "TAX EQUITY AND FISCAL RESPONSIBILITY ACT OF 1982"* (P.L. 97-248) (1982).

29. See Lave, *supra* note 16, at 252, 260-61.

30. PUB. L. No. 98-21, 97 Stat. 141, 149 (1983) (codified as amended in scattered sections of 42 U.S.C.).

31. For a discussion of the New Jersey program, see *The New Jersey DRG Experience*, *supra* note 26.

The basic features of the prospective payment system that Congress approved are:

1. all Medicare patients are classified as falling into one of 468 DRGs;
2. with the exception of a limited number of "outlier" patients which have medically necessary but atypically long lengths of patient stay ("day" outliers) or atypically expensive treatments ("cost" outliers), each hospital will receive a fixed payment per DRG to cover operating costs;
3. each hospital's DRG payment will include allowances for variations in area wages, urban versus rural population mix, and the number of full-time interns and residents on the hospital staff;
4. capital costs and direct educational costs are to be paid separately ("passed through") until such time as the HHS Secretary can propose a method acceptable to Congress for including these costs in the prospective DRG rates; and
5. nationwide DRG rates (plus allowances) will gradually replace each hospital's reasonable cost-based rates for each DRG over a three-year phase-in period.

See Lave, *supra* note 16, at 253. The DRG system reduces the conflict between peer review organization efforts to control use of costly services where less expensive alternatives are available and the contrary incentives of cost-based reimbursement to use the most sophisticated services available. See *supra* notes 12-13 and accompanying text.

32. See Wennberg, McPherson & Caper, *supra* note 9, at 297-99. In addition, note that DRG payments may also cause higher health care costs in the absence of effective utilization controls due to increased hospital admissions. *Id.*

and to perform fewer ancillary studies during each hospital stay.³³

2. Development of Peer Review Systems

In creating the Medicare program, Congress looked for some method of direct control over the quality, cost, and utilization of health care services by Medicare beneficiaries. Because of physician control over the treatment method and location of care, the physician's treatment decisions became the ultimate target for cost control efforts. Congress' first cost control measure was the Utilization Review (UR) program, a part of the original Medicare legislation.³⁴ The Medicare UR provisions still exist; however, the provisions have not been applied since 1972 to those hospitals in areas where an active Professional Standards Review Organization (PSRO)³⁵ or Utilization and Quality Control Peer Review Organization (PRO) program³⁶ exists.³⁷ The development of each of these three programs is discussed in the remainder of this article. In each case, the program's ability to balance cost and quality concerns³⁸ in the context of Medicare payment methods has been determinative of continued congressional support.

33. See, e.g., Zaslow, *Life After Legislation: Effects of TEFRA and DRG on Physician-Hospital Relationships*, 12 *LEGAL ASP. OF MED. PRAC.* 1, 1-2 (Jan. 1984).

34. See 42 U.S.C. § 1395x(k) (1982) (utilization review provisions in current Medicare Act).

35. See PUB. L. No. 92-603, tit. II, § 249(F), 86 Stat. 1429 (1972) (superseded by PUB. L. No. 97-248, tit. I, § 143, 96 Stat. 382 (1982)) (current version at 42 U.S.C. §§ 1320c to c-12 (1982)).

36. See PUB. L. No. 97-248, tit. I, § 143, 96 Stat. 382 (1982) (codified as amended at 42 U.S.C. §§ 1320c to 1320c-12 (1982)).

37. See 42 C.F.R. § 405.1035(m) (1984) (PRO and PSRO review in lieu of UR requirement).

38. See, e.g., Havighurst & Blumstein, *supra* note 12, at 15-21, 62-68. The authors present an illustration of how one might determine an optimal level of health care spending based upon the relationship between health care "benefits" and "costs." Beyond the optimal point there exists a "quality/cost no man's land" that reflects distortions created by physician control over demand and the inability of third-party payors or providers to impose limits on the provision of care falling in this range. Another figure illustrates how the infusion of government spending and private insurance coverage can prevent optimal health care spending decisions by reducing consumer cost barriers. Although total cost remains the same, the individual may be encouraged to seek out additional care. *Id.* at 17-18.

II. DEVELOPMENT OF PEER REVIEW

A. *Beginnings: Hospital-Based Utilization Review Committees and the Kaiser Plan*

Peer review was not a new idea when Congress first adopted it in 1965. Before Congress enacted the Medicare program, physician peer review committees on hospital medical staffs reviewed individual treatment decisions. These hospital medical staff committees, also known as utilization review committees, gave physicians an opportunity to observe and correct one another.³⁹ The quality of patient care,⁴⁰ rather than its cost, was the major consideration of the pre-Medicare utilization review committees.⁴¹ These early review committees looked at a patient's response to treatment and decided, based on their knowledge of common treatment practices, if the physician had acted properly and competently.⁴²

The hospital staff committees found that treatment outcomes were easy to measure—either the patient's condition improved or it worsened. However, these outcome studies could not direct phy-

39. See, e.g., G. SILVER, *A SPY IN THE HOUSE OF MEDICINE 177-80* (1976) (emphasizing the medieval guild beginnings of medicine and the traditional delegation of professional standards and quality control to the profession). The "guild spirit" remains strong among many physicians who vehemently oppose all government intervention in the health sector. A recent example of this view was expressed by Rep. Ron Paul, M.D. who stated, "Federal intervention can in no way improve medical care, but it can impose higher costs and make it much harder for physicians to do their real job—that is, to care for patients. . . . But even more disturbing than the cost in dollars of an increased PSRO presence is the cost in terms of human freedom. PSROs, in frank terms, represent our nation's distressing creep toward state control of medicine." *PSRO Proposals: Hearing on S. 1250 and S. 2142 Before the Subcomm. on Health of the Senate Comm. on Finance, 97th Cong., 2d Sess. 54, 56-60* (1982) [hereinafter cited as *PSRO Proposals*].

The development of peer review in the hospital setting has occurred in the last century. Prior to the 20th century, hospitals were viewed as a place of last resort—a place to die. It is only with the advent of drug therapies, such as antibiotics, and modern diagnostic technology that hospitals have become a center for curative treatment:

In my father's time, talking with the patient was the biggest part of medicine, for it was almost all there was to do. . . . Many patients [today] go home speedily, in good health, cured of their diseases. In my father's day this happened much less often, and when it did, it was a matter of good luck or a strong constitution. When it happens today, it is more frequently due to technology.

L. THOMAS, *THE YOUNGEST SCIENCE: NOTES OF A MEDICINE WATCHER 59* (1983).

40. Quality of care is the traditional goal of peer review. A useful measure of quality, like that of "health," is difficult to define. See, e.g., Lave & Lave, *supra* note 2, at 256 (describing quality of care as an "amorphous concept" composed of two dimensions: (1) the subjective perception of the patient; and (2) objective medical efficacy).

41. Scott, *supra* note 6, at 45.

42. G. SILVER, *supra* note 39, at 179-80.

sicians to utilize more appropriate treatment methods. A poor outcome, such as a patient death, was in many ways inconclusive because of the myriad potential causes. It did not necessarily mean that the physician's treatment decisions were in error.⁴³

The potential for inconsistent results with patient outcome analyses led utilization review committees to develop other measures to gauge the quality of a physician's treatment decisions.⁴⁴ Over time, the committees began to use more sensitive criteria in reviewing physician behavior. These "process assessments" looked at whether a physician's treatment decisions were necessarily for the good of the patient and whether a physician followed community standards of care in treating his patients.⁴⁵

Hospital-based utilization committee reviews using process assessments encouraged competent physician behavior, and a committee's policy of confidentiality prompted physician participation and eased physician resistance. If some corrective action, such as revocation of hospital staff privileges, proved necessary for repeated use of improper treatment methods, then the review committee would inform the hospital administration and the executive committee of the medical staff.⁴⁶

In the 1940's and 1950's, Kaiser-Permanente⁴⁷ began to use peer review to control costs and improve the quality of care for its beneficiaries. Kaiser's Foundation for Medical Care of San Joaquin County offered, at minimal extra cost, a prepaid insurance plan for physician office visits. As part of their contracts with Kaiser, participating physicians had to accept inpatient review by a hospital

43. *Id.* at 175.

44. Havighurst & Blumstein, *supra* note 12, at 28. The authors go on to state that outcome assessment may be more appropriate where process standards, mandated on a large scale, could increase the cost of care dramatically without significant improvements in a patient's health. Ideally, professional process standards may narrow the margin for error; however, they have great costs as perfection is approached. Further, such standards may not exist, as there often is no professional consensus on which therapeutic measures lead to good outcomes. *Id.* at 29.

45. G. SILVER, *supra* note 39, at 175; *see also supra* note 9 (discussing community standards of care).

46. G. SILVER, *supra* note 39, at 180. The intricacies of medical staff organizations and the due process questions surrounding the grant and revocation of medical staff privileges are beyond the scope of this article. For further information, see Ludlam, *Physician-Hospital Relations: The Role of Staff Privileges*, 35 LAW & CONTEMP. PROBS. 879 (1970).

47. Kaiser-Permanente owns a number of hospitals, primarily in the Western United States. Kaiser is well known for its pioneering efforts in health care financing. *See generally* Harrington, *Foundations for Medical Care: A Stepping Stone to PSRO*, in PSRO PROMISE, *supra* note 21, at 17 (history of the Kaiser peer review program).

utilization review committee. Kaiser designed its plan to minimize hospital bed use and maximize patient reliance on office-based medical care.⁴⁸ By the 1960's, most hospitals had also developed utilization review committees for quality of care reviews. Such hospital committees were a condition of continued accreditation.⁴⁹

B. *The Utilization Review Program*

In 1965, Congress adopted its first peer review program in Title XVIII of the Social Security Act.⁵⁰ UR program requirements included measurement of the lengths of stay and the use of ancillary services by patients in the hospital.⁵¹ If Medicare-funded patients stayed longer or used more hospital services than the norm, the UR program required physicians to justify the additional patient-days or services to a hospital utilization review committee.⁵² If the committee decided the excess was not justified, then it was supposed to report its findings to the Medicare fiscal intermediary ("intermediary").⁵³ The intermediary could then deny hospital payment for the excess days of care.

The UR program had shortcomings from a cost control standpoint. First, Congress gave physicians on participating hospital utilization review committees considerable discretion in carrying out UR reviews. Physician committees were allowed to develop their own review procedures and standards.⁵⁴ Trained to respect and rely upon professional control of treatment decisions, these physician committees were reluctant to inform the intermediary of

48. See S. PALMER & D. GILL, PUBLIC ACCOUNTABILITY AND PEER REVIEW IN HEALTH CARE DELIVERY IN THE UNITED STATES AND THE UNITED KINGDOM 10-11, HEW PUB. NO. 77-1429 (1977).

49. See Scott, *supra* note 6, at 46-47.

50. PUB. L. No. 89-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. §§ 1395 to 1395xx (1982 & Supp. I 1983)).

51. See 42 C.F.R. § 405.1035j (1984) (describing medical care evaluation studies).

52. See *id.* § 405.1035g (extended stay review).

53. The fiscal intermediary (FI) is a regional or statewide organization, such as Blue Cross, which contracts with the Medicare program to review beneficiary claims and disburse funds for approved claims. See 42 U.S.C. §§ 1395h(a), 1395u(a)(1) (1982).

54. See 20 C.F.R. § 405.1035(b)(1) (1969) (conformance with statute met by submission of a hospital review plan and by certification that plan was in effect). The Senate Finance Committee found, *inter alia*, the following reasons for ineffective utilization review: deficient regulations, laxity both by intermediaries and by the Social Security Administration, conflicts of interest in institutions, insufficient professional participation, and the absence of norms. See Havighurst & Blumstein, *supra* note 12, at 38-39 & n.112 (citing STAFF OF THE SENATE COMM. ON FINANCE, 91ST CONG., 1ST SESS., MEDICARE AND MEDICAID: PROBLEMS, ISSUES, AND ALTERNATIVES 3-27 (Comm. Print 1970)).

any overuse of hospital services by their colleagues. A second problem was that physicians holding a financial interest in the hospital often participated on hospital utilization review committees. Putting such physicians in a position to approve or deny payment for hospital care created a conflict of interest.⁵⁵ Finally, hospital utilization review committees were often reluctant to tell a physician how to practice medicine, at least where the physician was not grossly incompetent.⁵⁶ By the 1970's, Congress became alarmed by the cost overruns in the Medicare program and set out to develop a new approach.

C. *The Professional Standards Review Organization Program*

1. Legislative History

In 1971, Senator Bennett proposed legislation, which Congress adopted during the 1972 session, to create a nationwide network of PSROs.⁵⁷ Congress' intent in enacting the PSRO program was to control costs and improve the quality of patient care through reductions in unnecessary utilization. The declared congressional purpose was

to assure, through the application of *suitable* procedures of professional standards review, that the services for which payment may be made under this chapter *will conform to appropriate* professional standards for the provision of health care and that payment for such services will be made—

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

(2) in the case of services provided by a hospital or other health

55. See 20 C.F.R. § 405.1035(d)(2)(iii) (1969) (compliance with statute met by a review committee that was broadly representative of the medical staff and that had *at least* one member without financial interest in the hospital). In addition to conflict situations, there was also a series of articles in the Chicago Sun-Times that revealed many improprieties in the use of Medicare funds by physicians on the staff of the Cook County Hospital. These reported abuses led to a Finance Committee hearing that resulted in the 1972 amendments. See Bennett, *The History of the Bennett Amendment*, in PSRO PROMISE, *supra* note 21, at 4-5.

56. Scott refers to this trait as the "ethic of professional courtesy." Scott, *supra* note 6, at 48-49.

57. Bennett, *supra* note 55, at 6. The PSRO Act, Pub. L. No. 92-603, § 249F, 86 Stat. 1429 (1972) (superseded by Pub. L. No. 97-248, tit I, § 143, 96 Stat. 382 (1982)) makes up Part B of Title XI of the Social Security Act. The statute was replaced by the PRO program in 1982. See 42 U.S.C. §§ 1320c to 1320c-12 (1982).

care facility on an inpatient basis, only when and for such period as such services cannot, consistent with *professionally recognized* health care standards, *effectively* be provided on an outpatient basis *or more economically* in an inpatient health care facility of a different type, as determined *in the exercise of reasonable limits of professional discretion*.⁵⁸

The emphasis on cost control is readily apparent from the statement of purpose; however, the prefatory language maintained much of the UR program's emphasis on physician discretion in establishing and enforcing standards of practice.⁵⁹ The PSRO program differed from the UR program because the PSROs, designated by the Secretary of Health, Education & Welfare (HEW), now had the power to perform their own reviews if the hospital review committees failed to do so.⁶⁰

2. PSRO Operation

The PSRO Act instructed the Secretary of HEW to designate PSRO areas on a nationwide basis by January 1, 1974.⁶¹ These areas ranged in size from part of a city to entire states, depending on the number of physicians residing in the area.⁶² PSRO proponents in Congress anticipated that local medical societies would apply for and receive PSRO designation.⁶³ The PSRO Act required the Sec-

58. The PSRO Act, PUB. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1429-30 (1972) (emphasis added).

59. See *supra* notes 50-56 and accompanying text.

60. See The PSRO Act, PUB. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1435 (1972).

61. *Id.*, 86 Stat. at 1430. Two hundred and three PSRO areas were designated in March 1974 although not every area became fully operational, if at all, until much later. See A. GOSFIELD, *PSROS: THE LAW AND THE HEALTH CONSUMER* 8 & n.35 (1975). The number of PSROs peaked at 187 in 1981. *PSRO Proposals*, *supra* note 39, at 4 (statement of Sen. Baucus).

One of the differences between the PSRO and PRO programs is in the designation of review areas. The Secretary of HHS now must use states as geographic areas unless the Secretary determines that a local or regional area meets certain criteria based on hospital admissions and availability of services. See The Peer Review Improvement Act of 1982, PUB. L. No. 97-248, tit. I, § 143, 96 Stat. 381, 382 (1982) (codified as amended at 42 U.S.C. § 1320c-2 (a) (1982)). The redefinition of a peer review area reflects the growing trend towards national peer review standards.

62. See 42 C.F.R. § 460.2 (1984).

63. The PSRO Act reflected this view by directing HEW to approve all physician-run "qualified organizations" as the local PSRO before contracting with payor organizations. See The PSRO Act, PUB. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1431 (1972). The PSRO Act, unlike the PRO Act, also gave local physicians the power to object to and to veto HEW agreements with payor organizations. See *id.*, 86 Stat. at 1431-32.

retary to enter into a PSRO agreement with a qualified organization that included a substantial proportion of the area's licensed physicians.⁶⁴ However, the statute allowed the Secretary to appoint non-physician review organizations, such as Medicare intermediaries, as PSROs in areas where local physicians opposed participation in the PSRO program.⁶⁵

The Secretary's appointment of a non-physician review organization, such as an intermediary, as the local PSRO did not change the scope of PSRO review because of two statutory requirements. First, only physicians, albeit disinterested ones, could evaluate their peers.⁶⁶ This guaranteed that PSRO reviews would rely on physician expertise in review decisions and prevented non-physician, intermediary-run PSROs from focusing on Medicare program costs and ignoring the medical benefits of particular treatment decisions. Second, the statute required the PSRO to accept the findings of hospital utilization review committees in all cases once the PSRO had determined that a hospital's in-house review was effective.⁶⁷ This became important when the PSRO delegated review responsibilities to hospital committees. A physician or non-physician PSRO was often willing to share review responsibilities when it led to improved relations with provider groups. Further, a refusal to delegate meant only that the PSRO had to perform the review function itself.⁶⁸

64. A proposed PSRO had to have the support of at least 25% of the physicians in the PSRO area before the Secretary could approve it.

65. The PSRO Act, PUB. L. No. 92-603, § 249F(b), 86 Stat. at 1430-31 (1972). Again, the PRO Act increases the power of the Secretary to negotiate agreements with profit-making, non-physician groups, including third-party payors with sufficient numbers of physicians available to perform review. 42 U.S.C. § 1320c-1 (1982). One commentator has suggested that the association of peer review and payment authority within the same organization poses antitrust problems. See Hastings, *Legal Issues Raised by Private Review Activities of Medical Peer-Review Organizations*, 8 J. HEALTH POL. POL'Y & L. 293, 308-10 (1983).

66. See The PSRO Act, PUB. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1433-34 (1972). The provisions prohibiting on-site review by physicians with a financial interest in an institution and limiting hospital peer responsibilities of physicians with active staff privileges corrected a conflict of interest problem present in the Utilization Review program. See *supra* notes 54-55 and accompanying text.

67. The PSRO Act, PUB. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1435 (1972).

68. A. GOSFIELD, *supra* note 61, at 73. The PSRO, once operational, was required to perform three types of patient admission review in short-stay general hospitals. The review had to include: (1) a certification of the necessity and appropriateness of patient admissions to the hospital (admission certification); (2) an assessment of the patient's need for continued hospitalization (continued stay review); and (3) retrospective studies of specific problems or diagnoses at a health care facility (medical care evaluation studies). PSROs were also required to develop, over time, an analysis of the utilization patterns of patients, practitioners and providers on an individual and/or aggregate basis (profile reviews). See Price, *Health*

Congress gave the PSROs general objectives and guidelines for conducting peer reviews. The PSRO law made PSROs responsible for determining whether the health care services and items paid for by Medicare and Medicaid were "medically necessary," "of professionally recognized standards of health care" quality, and provided in the most effective and economical setting.⁶⁹ The admitting physician and the hospital had parallel statutory duties of assuring medical necessity and quality of care before treating Medicare beneficiaries.⁷⁰ The physician and the hospital also had to provide evidence, at the PSRO's request, that the particular health care services and items satisfied the medical necessity and quality of care tests.⁷¹ Finally, the PSRO Act instructed each physician and hospital to authorize *inpatient* care only when medically necessary and when a patient could not receive care in a more economical setting.⁷²

A PSRO's means of measuring "medical necessity" became the critical variable in its peer review activities. Congress included a section in the PSRO Act on "norms of health care services,"⁷³ described as "the principal point of [PSRO] evaluation and review."⁷⁴ The PSRO law referred to lengths of patient stays in hospitals and thereby defined a norm as a typical pattern of patient care for each diagnosis and by each age group within a region.⁷⁵ The Secretary of HEW, through enabling regulations collected in

Systems Agencies and Peer Review Organizations: Experiments in Regulating the Delivery of Health Care, in LEGAL ASPECTS OF HEALTH POLICY: ISSUES AND TRENDS 359, 384 (R. Roemer & G. McKray eds. 1980); P.S.R.O. PROGRAM MANUAL, OFFICE OF PROFESSIONAL STANDARDS REVIEW, DEP'T OF HEALTH, EDUC. & WELFARE 3 (1974) [hereinafter cited as PSRO PROGRAM MANUAL]. The physician profiles were designed, in part, to address the growing concerns over area-wide variations in health care delivery and supplier-induced demand. See *supra* note 9. For more information on the development of these review mechanisms in practice, see generally PSRO PROMISE, *supra* note 21.

69. See The PSRO Act, Pub. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1433 (1972). Note that this language parallels the congressional declaration of purpose. See *supra* note 58 and accompanying text. The PSRO program initially had review authority over both Medicare and Medicaid payment. The Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-25, 95 Stat. 357 (1981), limited mandatory PSRO review to the Medicare program.

70. The PSRO Act, Pub. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1438-39 (1972). The PSRO Act specifically exempted physicians who exercised due care in treating patients by using PSRO norms and criteria from malpractice liability. See *id.*, 86 Stat. at 1444.

71. *Id.*, 86 Stat. at 1438.

72. *Id.*, 86 Stat. at 1438-39.

73. See *id.*, 86 Stat. at 1435-36.

74. *Id.*, 86 Stat. at 1436.

75. *Id.*, 86 Stat. at 1435-36.

the PSRO Program Manual,⁷⁶ instructed each PSRO to develop its own regional norms by measuring quantifiable items such as average length of patient stay for a particular diagnosis.⁷⁷ The PSROs then used regional treatment norms as a benchmark for subsequent reviews of the same diagnosis.

An average figure, such as a norm, could not reflect the range of acceptable treatment practices. Many patients required longer hospitalizations or more services than the norms would suggest. The Secretary of HEW therefore directed each PSRO to use norms flexibly and to allow physicians and hospitals some discretion in treatment decisions according to varying patient needs. The Secretary authorized the PSROs to develop patient care "standards," which were defined as "professionally developed expressions of the range of acceptable variation from a norm or criterion."⁷⁸ The standards measured the acceptable range of treatments for a particular diagnosis. The "criteria," also defined in the Manual,⁷⁹ consisted of professional assessments of the services and items needed for the optimal treatment of each patient's diagnosis.⁸⁰

Many health care providers were concerned about the PSRO's discretion to use these norms, standards and criteria as a reason to deny federal payment for health care services. The PSRO Act gave PSROs the authority to disapprove Medicare and Medicaid payment for medical care services and items that the PSRO found medically unnecessary or inappropriate in its review of a patient's

76. See PSRO PROGRAM MANUAL, *supra* note 68. The Manual defined "norms" as "numerical and statistical measures of usual observed performance." *Id.* at 16.

77. See A. GOSFIELD, *supra* note 61, at 35. The PSRO Act specified that the National Professional Standards Review Council would have responsibility for developing norms. In practice, the Council merely provided a sample set of norms and criteria. The PSROs were then free to adopt the Council's recommendations or develop alternative norms and criteria acceptable to the Council. *Id.*; see also The PSRO Act, PUB. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1436 (1972).

78. See PSRO PROGRAM MANUAL, *supra* note 68, at 16.

79. *Id.*

80. See A. GOSFIELD, *supra* note 61, at 36. As the author notes, the PSRO program awarded millions of dollars in contracts to professional organizations, such as the American Medical Association, to develop PSRO criteria. *Id.* at 36 n.72.

A typical PSRO's review of the treatment of a heart attack patient exemplifies how PSROs applied norms, standards and criteria. A PSRO would first look at the patient's length of hospitalization and services received; it would then decide if the length of the patient's hospital stay was within the PSRO standards for heart attack patients and if the ordered services met the treatment criteria. If the patient's treatment was close enough to the PSRO norms and it met both tests, then the physician and the provider would receive Medicare reimbursement.

claim.⁸¹ Congress, however, did not give the PSROs unreviewable authority. Before an adverse determination could take effect, the PSRO or its delegate (the hospital review committee) had to notify the affected physician or provider of the adverse determination and give its reasons for the payment denial. An affected party then had the opportunity to review the matter with the PSRO.⁸²

The informal review of the PSRO's adverse determination gave physicians and providers an opportunity to show that the PSRO's determination was incorrect and not in accord with appropriate standards. A physician or provider could also prove that it was without fault in providing such services.⁸³ If informal discussions did not result in a reversal of the adverse determination, the PSRO Act instructed each PSRO to notify the patient, the physician, the provider, and the payor organization in writing regarding the denial of the claim.⁸⁴ The Medicare intermediary or state Medicaid agency, as payor, would then withhold payment unless a party requested reconsideration.

The PSRO's reconsideration of an adverse determination, like the informal review, did not have to follow a particular administrative format and could be done informally.⁸⁵ If the reimbursement claim for PSRO reconsideration was for less than one hundred dollars, the PSRO's determination following reconsideration was final.⁸⁶ If the contested claim equaled or exceeded one hundred dollars, then the dissatisfied beneficiary, physician or provider could appeal the PSRO's reconsideration decision to the Statewide Professional Standards Review Council (SPSRC) in states which had such a council.⁸⁷ The SPSRC's review was, in most cases, the final

81. The PSRO Act, PUB. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1437 (1972).

82. *Id.*, 86 Stat. at 1440.

83. *Id.*, 86 Stat. at 1437; see also A. GOSFIELD, *supra* note 61, at 145. The "without fault" test, known as the waiver of liability provision, prevented the PSRO from denying payment for medical care services where the physician was unaware of the applicable PSRO norms and criteria. In practice, the PSROs used this provision to hold the beneficiary harmless for the care received and to give physicians and providers a "second chance" to comply with PSRO norms and criteria. Whenever the PSRO waived liability for medically unnecessary care, it also sent a notice of non-coverage to the physician, the provider, and the beneficiary. In future similar situations the physician, the provider, and the beneficiary all had notice of the PSRO-approved treatment practice and could not rely on the waiver of liability provision for payment. A. GOSFIELD, *supra* note 61.

84. The PSRO Act, PUB. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1437 (1972).

85. Price, *supra* note 68, at 386.

86. The PSRO Act, PUB. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1437-38 (1972).

87. *Id.* The SPSRC consisted of a representative from each local PSRO, four other physicians designated by the state medical society and state hospital association, and four per-

appeal for denial of payment of claims.⁸⁸

In addition to individual denial of payment for claims, a PSRO could recommend that the Secretary of HEW apply specific sanctions against a physician or provider for failure to comply with PSRO obligations.⁸⁹ Violations that could lead to sanctions included gross or continued overuse of services, use of services in an unnecessarily costly manner, or inadequate assurance of the quality of services.⁹⁰ After reasonable notice and opportunity for discussions between the physician or provider and the PSRO, the PSRO would submit a report identifying program violations and recommend sanctions to the Secretary through the SPSRC.⁹¹

The Secretary or his designee reviewed the PSRO recommendations. If he found that the physician's or provider's violations demonstrated an unwillingness or lack of ability to substantially comply with PSRO obligations, he could then impose one of the following sanctions: (1) termination of participation in the Medicare or Medicaid programs; (2) suspension of participation until the Secretary found that the basis for the sanction had been removed and would not recur; or (3) reimbursement to the government for the cost, up to five thousand dollars, of the medically unnecessary or inappropriate services.⁹²

If a physician or provider wanted to challenge a proposed sanction, that party was entitled to notice and an opportunity for a hearing before the Secretary.⁹³ Judicial review of the Secretary's

sons knowledgeable in health care matters from that state and selected by the Secretary of HEW. The SPSRC was responsible for data collection and dissemination along with review of adverse determinations and general PSRO oversight. *Id.*, 86 Stat. at 1440-41. Only six states had SPSRCs during the PSRO program, in part because of funding, but also because several states had only one PSRO and thus did not need to oversee multiple PSROs. Interview with John Di Nardi, Assistant Director, Medical Society of Virginia Peer Review Organization (Feb. 26, 1985).

88. While a physician and a provider were precluded from further review, a beneficiary could appeal the SPSRC decision to the Secretary of HEW for further administrative review. *See* The PSRO Act, Pub. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1438 (1972). For beneficiary claims less than \$1,000, the Secretary's decision was final. For amounts in controversy of \$1,000 or more, the beneficiary also could seek judicial review following final agency action by the Secretary denying the claim. *See* 42 U.S.C. § 405(g) (1982) (judicial review provisions).

89. *See* The PSRO Act, Pub. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1439-40 (1972).

90. *Id.*; *see* Price, *supra* note 68, at 386.

91. The PSRO Act, Pub. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1439 (1972).

92. *Id.*

93. *Id.*, 86 Stat. at 1440.

final decision was also available.⁹⁴ If the Secretary elected to exclude the affected party from participation in the Medicare or Medicaid program, the exclusion became effective after reasonable notice to either the provider or the physician and to the public.⁹⁵ The imposition of a fine did not require notice to the public, and the Secretary could instruct the Medicare intermediary to deduct the fine from any sums due the party for subsequent Medicare- and Medicaid-funded care to program beneficiaries.⁹⁶ The imposition of PSRO sanctions did not preempt other legal sanctions against the physician or provider.⁹⁷

3. Problems with the PSRO Approach

By creating the PSRO program, Congress tried to establish uniform professional standards for medical treatment. It also attempted to impose cost consciousness and a uniform self-regulatory mechanism on a professional group highly resistant to outside interference.⁹⁸ As the traditional independence of the physician in making treatment decisions became subject to government scrutiny through PSROs, administrative and judicial conflicts resulted.

The PSRO program faced a number of organizational hurdles that Congress failed to anticipate. The design of the PSRO program clearly depended upon broad physician commitment and participation in each PSRO area.⁹⁹ In order to overcome physician resistance to PSROs and obtain enough professional support to operate the program, HEW representatives stressed the PSRO program's quality assurance role in their communications with physician groups.¹⁰⁰ This "campaign" down-played the cost control

94. *Id.*; see also 42 U.S.C. § 405(g)(1982) (judicial review provisions).

95. The PSRO Act, Pub. L. No. 92-603, § 249F(b), 86 Stat. 1429, 1439 (1972).

96. *Id.*

97. *Id.* Gosfield suggests that other possible actions included criminal penalties for Medicare and Medicaid fraud and abuse, see 42 U.S.C. §§ 1395nn, 1396h (1982); state medical and malpractice damage claims; and professional continuing education requirements as established by regulations. See A. GOSFIELD, *supra* note 61, at 233 & n.28.

98. The Secretary of HEW started the PSRO program amidst an atmosphere of active physician opposition and hostility. Individual hospitals also resisted the PSROs by using delay tactics in negotiating memoranda of understanding and by refusing to cooperate at all. See, e.g., Goran, Moga & Siebert, *From Development to Performance: A Federal View of PSROs*, in PSRO PROMISE, *supra* note 21, at 8, 9.

99. See Bennett, *supra* note 55, at 8.

100. See, e.g., Havighurst & Blumstein, *supra* note 12, at 41-45. The authors point out many instances of rhetoric by HEW officials during the selling effort. On many occasions, the official HEW positions were in direct contravention to the congressional cost control

directive in the PSRO statute¹⁰¹ and helped the PSRO program obtain the necessary physician support for program implementation. However, HEW's early emphasis on quality assurance made it difficult for the PSRO program to shift its emphasis to cost control later.¹⁰²

Another problem that HEW experienced in implementing the PSRO program was deciding which HEW branch would administer the program. The control issue focused again on the cost control and quality assurance goals of the program.¹⁰³ HEW's decision to give the program development responsibilities to the Office of the Assistant Secretary for Health (ASH) instead of the Social Security Administration (SSA) marked a conciliatory gesture toward physician groups.¹⁰⁴ PSRO reviews were thereby insulated from the cost control concerns of SSA, the paying agent for the Medicare program.¹⁰⁵ The internal bureaucratic resistance¹⁰⁶ to HEW's scheme probably contributed to the reluctance of state Medicaid agencies to cooperate with the physician-run PSROs.¹⁰⁷

Several issues related to the PSRO program also underwent judicial scrutiny. Court challenges arose based on claims of a patient's right to treatment and a physician's right to practice his or her profession. Physician groups filed suit on behalf of patients and physicians on several occasions, most notably in *Association of American Physicians and Surgeons v. Weinberger (AAPS)*¹⁰⁸ and in *American Medical Association v. Weinberger (AMA)*.¹⁰⁹ The AAPS lawsuit included fourteen separate claims for relief¹¹⁰ upon

intent. *Id.* at 42.

101. See *supra* notes 58-59 and accompanying text.

102. See Havighurst & Blumstein, *supra* note 12, at 44-45.

103. *Id.* at 41.

104. *Id.* Havighurst and Blumstein also note that the ASH has been an office traditionally filled by a physician acceptable to organized medicine. *Id.*

105. *Id.*

106. Political scientists have devoted much attention in recent years to the effects of bureaucratic organization and development in carrying forth legislative intent. See, e.g., J. MASHAW, *BUREAUCRATIC JUSTICE: MANAGING SOCIAL SECURITY DISABILITY CLAIMS* (1983).

107. Goran, Moga & Siebert, *supra* note 98, at 9-10.

108. 395 F. Supp. 125 (N.D. Ill. 1975).

109. 395 F. Supp. 515 (N.D. Ill.), *aff'd*, 522 F.2d 921 (7th Cir. 1975).

110. One commentator organized these grounds into seven basic allegations for analysis purposes. These allegations included claims that the PSRO law:

1) unconstitutionally limited or deprived physicians of their right to practice their profession (argued as a fifth amendment due process right);

2) unconstitutionally deprived patients of their right to treatment through application of PSRO norms that failed to allow for regional variations in treatment choice

which the court found that the plaintiffs either lacked standing¹¹¹ or that the challenged statute struck a reasonable balance between the physician's rights and the government's interest in maintaining proper health care in an economical manner.¹¹² The court summarily dismissed as without merit the plaintiff's fifth amendment claim of a property right in the practice of medicine.¹¹³

The *AMA* suit challenged the enforcement of certain sections of the Medicare and Medicaid Utilization Review regulations.¹¹⁴ Although the factual context of the *AMA* suit did not pertain to the PSRO law, the constitutional issues of interference with the physician's right to practice and the patient's right to receive medical treatment were similar to the first two issues raised in *AAPS*.¹¹⁵ The *AMA* persuaded the district court to look beyond the terms of the regulations and to examine their practical effect on patient access to medical care services.¹¹⁶ The district court issued a prelimi-

(again argued on fifth amendment grounds);

3) unconstitutionally required disclosure of confidential information obtained through the physician-patient relationship (argued on first and fourth amendment grounds);

4) was arbitrary, overbroad, and not justified by any compelling state interest (argued on fifth amendment procedural due process and equal protection grounds);

5) set unconstitutionally vague duties for physicians and similarly made sanctioning procedures so vague as to constitute a denial of procedural due process;

6) unconstitutionally delegated peer review authority to potentially biased private organizations; and

7) purported to change state medical malpractice law by granting physicians immunity for compliance with PSRO norms and criteria (argued as a source of physician liability without due process should the state law prevail).

J. BLUM, P. GERTMAN & J. RABINOW, *PSROs AND THE LAW* 89-95 (Aspen Systems 1977) [hereinafter cited as *PSROs AND THE LAW*].

111. *Association of Am. Physicians & Surgeons v. Weinberger*, 395 F. Supp. at 138, 140.

112. *Id.* at 132, 133, 136-37, 140, 141.

113. *Id.* at 139. The notion of a property right in one's profession, although suggested in the United States Supreme Court's opinion in *Doe v. Bolton*, 410 U.S. 179 (1973), and in *Roe v. Wade*, 410 U.S. 113 (1973), has been severely restricted, if not eliminated, by subsequent decisions. See *Bishop v. Wood*, 426 U.S. 341 (1976); *Board of Regents v. Roth*, 408 U.S. 564 (1972).

114. See *supra* notes 51-56 and accompanying text. The utilization review regulations remained in force following enactment of the PSRO law. A state could satisfy its peer review requirement, in the absence of PSROs or PROs, through this mechanism.

115. See *PSROs AND THE LAW*, *supra* note 110, at 95-98. The *AMA* initially sought a preliminary injunction to bar enforcement of the new Utilization Review program regulations. These regulations mandated admission screening of *all* Medicare and Medicaid patients instead of focusing on specific admissions, such as admissions for costly procedures thought to be of marginal benefit to patients. See *supra* notes 12-13 and accompanying text.

116. *American Medical Ass'n v. Weinberger*, 395 F. Supp. 515, 523 (N.D. Ill. 1975). The *AMA* had argued in federal district court that the disputed regulations abridged a Medicare or Medicaid beneficiary's first and ninth amendment rights to treatment in addition to the

nary injunction based on the possibility of irreparable harm to the health of the affected patients, which barred enforcement of the UR regulations pending conclusion of a full trial on the merits.¹¹⁷ The Court of Appeals for the Seventh Circuit affirmed the order.¹¹⁸

The *AAPS* and *AMA* cases reflected the continuing problems that the PSRO program faced in obtaining physician support. While both cases suggest that the PSRO program provisions would survive judicial review,¹¹⁹ the *AMA* case did reveal judicial concern about HEW's choice of review methods. Physician groups have resorted to litigation in other instances to limit HEW's discretionary use of its peer review authority.¹²⁰

After seven years of conflict, the administrative and judicial problems with PSROs finally drew the attention of Congress. Con-

beneficiary's fifth amendment right to the protection of life, liberty and property. *Id.* at 517. The *AMA* distinguished between preadmission certification, which it argued was repugnant to all three amendments because of overbreadth and lack of relationship to the Utilization Review law, and concurrent and retrospective review. The latter review mechanisms, according to the *AMA*, infringed on both the physician's and the patient's first amendment rights to freedom of communication in the treatment process. *PSROs AND THE LAW*, *supra* note 110, at 96. Blum suggests that there may be grounds for subsequent challenges to the constitutionality of preadmission certification where less drastic methods of peer review are available, such as concurrent or retrospective review. Preadmission certification can interfere with a patient's ability to obtain the type of medical treatment sought at a convenient time and place. If a delay turned out to be life-threatening or even if the treatment proved to be "medically necessary," then the patient and the physician could argue that the review procedure was overbroad. If a court found that the government had less invasive and less costly review methods at its disposal, then the burden of persuasion would shift to the government to show that the less invasive procedures had failed in the past and would be unlikely to promote cost control and quality assurance in the future. *Id.* at 106-07.

117. *American Medical Ass'n v. Weinberger*, 395 F. Supp. at 525. The full trial never took place, as HEW withdrew the disputed regulations shortly thereafter. *PSROs AND THE LAW*, *supra* note 110, at 98.

118. *American Medical Ass'n v. Weinberger*, 522 F.2d 921, 927 (7th Cir. 1975).

119. Although the *AMA* did prevail at the preliminary injunction stage, both the district court and the Seventh Circuit expressed skepticism that the *AMA* would prevail at a full trial on the merits. *Id.*

120. *See, e.g., Yaretsky v. Blum*, No. 76 Civ. 3360 (S.D.N.Y. June 10, 1980) (available Oct. 10, 1984, on LEXIS, Genfed library, Newer file). *Yaretsky* was another example of how physicians and providers used the courts to limit the PSRO program's discretionary authority. In *Yaretsky*, the district court declared that the New York State Medicaid program was required to incorporate a court order establishing procedures for nursing home level-of-care determinations into their peer review agreements with the local PSROs. The state's restrictive policies regarding nursing home utilization had been at issue in a previous suit by plaintiffs against the Medicaid program. The PSROs in *Yaretsky* unsuccessfully argued that their subsequent memoranda of understanding with the Medicaid program were unaffected by the prior order. The court held that the prior order did not bind the PSROs; instead, the judgment prohibited the Medicaid agency from entering into any memoranda of understanding that did not include the court-ordered review procedures.

gress was concerned, however, primarily with the cost effectiveness of PSROs. A Congressional Budget Office (CBO) study of HEW's 1978 PSRO data found that PSRO program costs more than doubled reported savings.¹²¹ The CBO report led to congressional committee hearings¹²² and to a Reagan administration proposal to gradually phase out PSRO and UR requirements altogether.¹²³

The PSRO program probably survived the initial congressional oversight only because Congress determined that it either had to improve or replace the program. Whenever the CBO advanced its cost concerns regarding the PSRO program before Congress, program proponents usually argued that elimination of the PSRO program would increase, not decrease, federal Medicare and Medicaid outlays.¹²⁴ The conflicting views of PSRO effectiveness and the re-

121. *PSRO Program: Hearing Before the Subcomm. on Health of the House Comm. on Ways and Means*, 96th Cong., 2d Sess. 2 (1980) [hereinafter referred to as *PSRO Effectiveness Hearing*]. Representative Philip Crane stated that, "A May 1980 CBO report reveals that, according to 1978 data, for every dollar spent on PSRO review of Medicare patients only \$.40 in resources were recouped. . . . We owe our constituents the duty of . . . seriously questioning the value of continuing this \$193 million program automatically year after year." *Id.*

122. *See Proposed Phaseout of PSRO's and Utilization Review Requirements: Hearing Before the Subcomm. on Health of the Senate Comm. on Finance*, 97th Cong., 1st Sess. 37, 39-40 (1981) (statement of P. Ginsburg, Chief, Income Security and Health Unit, CBO) [hereinafter referred to as *PSRO Phaseout*]; *see also PSRO Effectiveness Hearing*, *supra* note 121, at 2.

123. *See PSRO Phaseout*, *supra* note 122, at 10-16 (testimony by Dr. Carolyn Davis, Administrator, Health Care Financing Administration).

124. *See id.* at 48-50 (statement of Helen Smits, M.D., Research Associate, the Urban Institute); *id.* at 50-54 (statement of Jay Constantine, former Chief, Health Staff, Senate Finance Committee). Dr. Smits argued that the PSROs could play a critical role in the implementation of DRGs nationwide and should be preserved for that purpose. *Id.* at 49. Constantine, who worked with Senator Bennett in designing the PSRO legislation, identified seven separate cost control problems with the program that were beyond the immediate control of individual PSROs. Some of these problems included the overabundance of hospital beds, the lack of long-term institutional and home care services to meet the needs of patients who were inappropriately hospitalized, and the paucity of reliable studies on the cost-effectiveness of PSROs. Constantine also argued that the CBO's cost-shifting thesis on PSROs was analytically improper because the CBO does not consider any additional indirect costs to taxpayers from government action when analyzing other federal programs. Constantine concluded his remarks by highlighting the continuing viability of the program's purpose:

The expenditure of some \$80 billion in taxpayer dollars for Medicare and Medicaid continues to require accountable trusteeship and prudent payment of those funds for the care of the poor and the elderly.

Reasonable controls—such as professional review—are integral to fulfilling those responsibilities. A poor PSRO should be promptly replaced—but you should not, because of individual poor performance, condemn the group or the concept.

It seems to me that given our experience thus far, the question for the broad-brush, penny-wise and pound-foolish critics of professional review is to answer: What have

sults from private review initiatives¹²⁵ eventually led Congress to develop a plan for phasing out PSROs and replacing them with a new peer review model.¹²⁶

III. THE UTILIZATION AND QUALITY CONTROL PEER REVIEW ORGANIZATION (PRO) PROGRAM

A. Program Development and Legislative History

Congress enacted the PRO program as an accompanying subtitle to the Medicare prospective payment amendments.¹²⁷ The new program reflected congressional dissatisfaction with the effective-

you got that's better, believable and workable?

Id. at 52-54.

125. During the 1970's, RAND received HEW approval to organize a statewide health insurance experiment in New Mexico that included a private, voluntary peer review program for Medicaid services. See R. BROOK, K. WILLIAMS & J. ROLPH, *CONTROLLING THE USE AND COST OF MEDICAL CARE: THE NEW MEXICO EXPERIMENTAL MEDICAL CARE REVIEW ORGANIZATION—A FOUR-YEAR CASE STUDY* (1980). The RAND project ("EMCRO") was a voluntary peer review effort that relied heavily on the cooperation and assistance of local physicians, the Medicare intermediary, and the state Medicaid program. Although the project only reviewed claims for services billed to Medicaid, the EMCRO's review authority was more comprehensive than a PSRO's. The EMCRO reviewed Medicaid beneficiary utilization in the hospital, nursing home, and ambulatory settings. *Id.* at 69.

Although the RAND demonstration project encouraged voluntary physician participation, the project was conspicuously ineffective in controlling Medicaid program costs. The study's findings showed that, with the exception of injections, the use of services per Medicaid-eligible recipient per month in all age categories increased over time and the per capita medical expenditures for the study group rose faster than the national average for analogous services. There was no perceptible change in hospital utilization over time despite the program's emphasis on use of ambulatory services. *Id.* at 70.

These results can be explained by arguing that the Medicaid-eligible population in the survey was substantially underserved prior to 1971. However, the authors of the study contend that the results show that peer review, by itself, cannot meaningfully reduce medical care expenditures. *Id.* at 73. Other commentators argued that PSROs could not be held accountable for the continuing escalation in federal health care expenditures because there was no direct relationship between hospital utilization and hospital reimbursement under Medicare or Medicaid during the 1970's. See W.K. KELLOGG FOUNDATION, *PRIVATE INITIATIVE IN PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS (PSRO): FINAL REPORT* vi (1978).

126. See The Peer Review Improvement Act of 1982, PUB. L. NO. 97-248, tit. I, § 143, 96 Stat. 392 (1982) (codified as amended at 42 U.S.C. §§ 1320c to 1320c-12 (1982 & Supp. I 1983)). Congress also addressed Medicare utilization and program costs in creating the Medicare prospective payment system for hospitals. See The Social Security Amendments of 1983, PUB. L. NO. 98-21, 97 Stat. 65 (1983) (to be codified as amended in scattered sections of 42 U.S.C.). The per-case payment for Medicare patients reduced congressional reliance on peer review programs to control Medicare costs. See *supra* notes 23-32 and accompanying text.

127. See The Peer Review Improvement Act of 1982, PUB. L. NO. 97-248, tit. I, § 143, 96 Stat. 392 (1982) (codified as amended at 42 U.S.C. §§ 1320c to 1320c-12 (1982 & Supp. I 1983)).

ness of the PSRO program in controlling unnecessary utilization of hospital services.¹²⁸ Congress gave PROs many of the same review functions as PSROs, intending to preserve the beneficial aspects of the PSRO program. Further, Congress wanted individual PSROs that were successful in the area of cost control to apply for PRO designation.¹²⁹

Congress made very few substantive changes in the PSRO Act when it created the PRO program. The PRO statute did eliminate the availability of delegated review, a provision that was widely viewed as a source of inconsistent results in previous peer review programs.¹³⁰ Other provisions of the PRO Act, such as the designation of individual PROs, paralleled the procedures followed under the PSRO program.¹³¹ The areas of particular concern to physicians, providers and patients, namely the PRO review criteria and the PRO appeals and sanctions process, are discussed in sequence in the next section.

128. See S. REP. No. 494, 97th Cong., 2d Sess. 41, reprinted in 1982 U.S. CODE CONG. & AD. NEWS 781, 817 (Senate Finance Comm. report).

129. *Id.* at 817.

130. Historically, the Utilization Review program and the PSRO program had relied heavily upon intra-hospital utilization review committees to perform many of the peer review functions. The delegation of review authority was a convenient way for under-staffed PSROs to carry out their mandate. However, there was an inherent conflict of interest in asking a hospital-based physician's group to determine the medical necessity of a particular hospital patient's care. As Constantine stated, an internal committee's decision that patient care was unnecessary would be "contrary to the economic interests of the hospital and associates on the medical staff. There is an in-house incentive to use the facility's beds and services. The reference points on which such judgments are made are often too narrow and requisite expertise lacking. . . ." *PSRO Phaseout*, *supra* note 122, at 51 (statement by Jay Constantine).

Other persons applauded Congress' decision to eliminate the delegated review loophole in the PSRO law in 42 U.S.C. § 3120c-4(e) (1976). See *PSRO Proposals*, *supra* note 39, at 110 (statement of Willis Goldbeck, Executive Director, Washington Business Group on Health). But see *id.* at 215-16 (statement of the American Hospital Association) ("Utilization review is most effective when incorporated in the education of medical staff. Professionals are more receptive to the findings from quality assurance activities when these activities are performed by the hospital and its medical staff."). The American Hospital Association also indicated that its member hospitals were required to perform utilization review for both ethical reasons and for JCAH accreditation. Therefore, the new rules required the PROs to duplicate the internal activities of hospitals. See *id.* at 213-14.

131. See *supra* notes 61-62 and accompanying text.

B. PRO Act Changes in the Peer Review Process

1. PRO Review of Physician DRG Designations and Patient Admissions

The new prospective payment system under Medicare¹³² eliminates many of the incentives to provide more services to hospital patients, the object of much review activity by PSROs. The DRG admission code payment method provides a fixed fee per admission and thereby automatically limits the amount of compensated care provided for each patient admission.¹³³ However, the Medicare intermediaries that pay hospitals the DRG rates cannot specify the number of times a patient can be admitted, nor do they oversee the DRG designation selected. Adoption of the DRG payment system thereby created a new role for peer review groups.¹³⁴ The PROs now validate the accuracy of diagnoses and review the appropriateness of the admission and the quality of care provided to each patient when a claim for reimbursement is submitted.¹³⁵

The early implementation of the PRO program mirrored the slow development of the PSRO program.¹³⁶ The Health Care Financing Administration (HCFA), the agency responsible for program organization, did not release its request for contract proposals from eligible organizations until February 29, 1984,¹³⁷ and designation of individual PROs did not begin until mid-1984. At that time, HCFA's only guidance to designated PROs in their ne-

132. See *supra* notes 26 & 29 and accompanying text.

133. *Id.*

134. See also *PSRO Phaseout*, *supra* note 122, at 49 (statement of Helen Smits, M.D.) (suggesting the need for peer review as the Medicare system moves from cost-based to per-case reimbursement).

135. See 42 U.S.C. § 1320c-3(a)(1) (1982) (PRO review responsibilities); PRO Review Responsibility Rules, 50 Fed. Reg. 15,312 & 15,330 (1985) (to be codified at 42 C.F.R. 466).

136. The Health Care Financing Administration (HCFA) has moved very slowly in developing regulations to cover PRO admissions review and DRG validation procedures. Although HCFA released final regulations for PRO geographic areas and contractor eligibility on February 27, 1984, see PRO Area Designations and Definitions of Eligible Organizations, 49 Fed. Reg. 7202 (1984), the final rules on PRO review and sanction responsibilities were not released until April 17, 1985. See PRO Review Responsibility Rules, *supra* note 135.

137. The PRO contracts with HCFA were based on successful responses by contract applicants within each PRO geographic area to a HCFA Request for Proposal. See Request for Proposal (RFP) No. HCFA-84-015 for the Utilization and Quality Control Peer Review Org. Health Care Fin. Admin. 62 (Feb. 29, 1984) [hereinafter cited as PRO RFP]. The RFP includes three sections (Articles I—*Scope of Work*, VIII—*Technical Direction*, and IX - *Conditions of Performance*) that require the PRO contractor to conduct its review activities in accordance with PRO program regulations (codified at 42 C.F.R. §§ 462-76) and PSRO and PRO program directives.

gotiations with hospitals consisted of information in the PRO contract and in PSRO and PRO program directives.¹³⁸ Because hospitals were under pressure to enter into Memoranda of Understanding (MOUs) with PROs by November 15, 1984, or risk the loss of Medicare funds,¹³⁹ the administrative delays in designating PROs and issuing final rules for PRO operation contributed to a growing sense of urgency and impending confrontation among hospital groups.¹⁴⁰

The Virginia PRO program's experience is typical of many PROs across the country. HCFA refused to accept the Medical Society of Virginia Review Organization's (MSVRO) first proposal in response to the HCFA Request For Proposal.¹⁴¹ After revising its admissions objectives, MSVRO submitted its proposal and was designated as the statewide PRO on October 3, 1984.¹⁴² The designation date left a mere forty-three days for Virginia hospitals to negotiate MOU agreements with MSVRO or risk the loss of eligibility for Medicare funds.¹⁴³

Following HCFA designation and the development of MOUs,

138. See PRO Program Directive No. 2, Health Care Fin. Admin. (Aug. 3, 1984) [hereinafter cited as PRO Program Directive No. 2]; PSRO Program Transmittal Nos. 107 & 108, Health Care Fin. Admin. (Sept. 1983). HHS Secretary Heckler's failure to submit the substantive content of these rules to notice and comment rulemaking pursuant to the Administrative Procedure Act prompted the American Hospital Association to petition HHS for rulemaking. See American Hospital Association Petition for Rulemaking for Promulgation of Regulations Implementing the Peer Review Improvement Act of 1982 (Oct. 10, 1984). The AHA reportedly has filed suit to force HHS to use notice and comment rulemaking. Interview with John Di Nardi, Assistant Director, MSVRO (Feb. 27, 1985).

139. See The Deficit Reduction Act of 1984, Pub. L. No. 98-369, 98 Stat. 494 (1984). The 1984 Act extended the deadline for PRO-hospital agreements by amending § 1866(a)(1)(F) of the Social Security Act which, pursuant to title IV of the Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 414 (1983), had set a deadline of October 1, 1984, for all MOUs.

140. See *Implementation of PRO's for Medicare: Hearing Before the Subcomm. on Health of the Senate Comm. on Finance*, 98th Cong., 2d Sess. 67 (1984) (statement of Alan Nelson, M.D., AMA); see also *id.* at 116-18 (statement of the AHA); *id.* at 141 (statement of the Federation of American Hospitals).

141. Address by Robert Morton, President, MSVRO, at a Virginia Hospital Association Meeting on Negotiating a Memorandum of Understanding with a Professional Review Organization, in Richmond, Virginia (Oct. 16, 1984) [hereinafter cited as VHA-PRO Conference].

142. *Id.*

143. See *supra* note 139. The MSVRO also had a 30-day deadline for becoming operational following PRO designation by HCFA. See American Hospital Association, Medicare Policy: Peer Review Organizations—Special Briefing Supplement on Negotiating Hospital-PRO Agreements 2 (July 1984) [hereinafter cited as AHA Briefing Supplement]. The end result of these deadlines was a frantic rush to negotiate a uniform MOU between the MSVRO and the VHA.

each PRO began to perform reviews of area hospital services as specified in its PRO contract with HCFA. The MSVRO contract included three "admissions" objectives and five "quality" objectives.¹⁴⁴ These objectives required: (1) preadmission review of procedures that, in the PRO's view, could be performed on an outpatient basis;¹⁴⁵ (2) pre-procedure review of specific DRGs covering elective surgical procedures;¹⁴⁶ (3) retrospective review of every admission by particular hospitals or physicians identified as generating a significant pattern of unnecessary patient admissions;¹⁴⁷ (4) retrospective review of all readmissions; (5) review of medical records for patients given particular drugs to check for toxic reactions; (6) retrospective review of all hospitals whose acute myocardial infarction mortality rates exceed twenty-four percent; (7) development of practice norms for gastrointestinal endoscopic procedures and review of claims submitted by physicians performing these procedures unnecessarily; and (8) reviews of patient

144. See MSVRO Contract, HCFA No. 500-0038, at 18-25 [hereinafter cited as MSVRO Contract].

145. The MSVRO Board of Directors identified 54 procedures, based on Blue Cross and PSRO experience, that are often performed on an inpatient basis. In the Board's opinion, these procedures usually could be performed safely and effectively on an outpatient basis. MSVRO designed the preadmission screening program to weed out those procedures that could be performed in an ambulatory setting. *Id.* at 18.

146. The MSVRO Board reviewed the top 20 surgical procedures for Virginia Medicare patients and found that the incidence of surgery in six DRG groups had increased by 16.5% between 1982 and 1983. The Board decided that the non-emergency cases within these DRGs were appropriate for preadmission certification. *Id.* at 19; see also Lipp, *The Effect of the Prospective Payment System on Hospital QA/UR Systems*, 10 Q. REV. BULL. 283, 287 (1984) (review of surgery and potential for suits by patients); *Medicare Agencies Now Judging Surgery*, Rich. Times Dispatch, Dec. 3, 1984, at 1, col. 4 (report on testimony at a congressional subcommittee hearing regarding preadmission review of surgery).

147. The MSVRO Board has set an overall retrospective review goal of reducing inappropriate or unnecessary admissions and invasive procedures by 85%. The Board also wants to reduce readmissions by 90%. MSVRO plans to perform retrospective review of all admissions by physicians and hospitals which continue to overadmit patients. MSVRO Contract, *supra* note 144, at 20. Each PRO must perform retrospective review of all admissions within each review category, see *infra* note 160 and accompanying text, where a provider's unnecessary admissions per category exceed 2.5% of the provider's Medicare admissions reviewed by the PRO. See Dep't of Health and Human Services, Peer Review Organization Manual, Health Care Fin. Admin., Attachment A-1 (Mar. 1985) [hereinafter cited as PRO Manual]; American Hospital Association, Medicare Policy: Peer Review Organizations—Special Briefing on PRO Implementation and Medical Review Requirements 4 (July 1984) [hereinafter cited as AHA on PROs]. PSROs used to calculate the 2.5% favorable presumption by reference to all Medicare patient admissions, not just those subject to review. PRO use of the new formula will lead to more 100% retrospective reviews and additional adverse determinations. See *Implementation of Peer Review Organization (PRO) Program: Hearing Before the Subcomm. of Health of the Senate Comm. on Finance*, 98th Cong., 2d Sess. 86-87 (statement of Jack W. Owen, AHA) [hereinafter cited as PRO Hearing II].

profiles in cases of avoidable post-operative complications so as to identify quality of care concerns of the physician and hospital.¹⁴⁸

The MSVRO established a preadmission review plan that became effective on December 1, 1984, and includes a toll-free telephone number for physicians seeking admission certification for patient procedures falling under the plan.¹⁴⁹ Non-physician review analysts respond to the calls and determine whether the proposed admission meets the PRO norms and criteria.¹⁵⁰ If the admission falls within the criteria and is therefore medically justifiable, the PRO sends a letter to the Medicare intermediary and the attending physician.¹⁵¹ The letter explains the reasons for admitting the patient and authorizes the Medicare intermediary to pay the physician and the hospital for the admission.¹⁵²

Where a proposed admission does not meet the preadmission criteria, the review analyst will refer the case to a consulting physician for a determination.¹⁵³ After reviewing the certification information and obtaining any clarification from the attending physician,¹⁵⁴ the consulting physician may decide that the admission is not medically justifiable. In such cases, the PRO sends a letter of adverse determination to the physician and the Medicare intermediary.¹⁵⁵ Any subsequent admission for that procedure will not receive Medicare payment.

Each month, MSVRO representatives travel to hospitals across Virginia in order to check the MSVRO's preadmission review records for consistency with the hospital's treatment records.¹⁵⁶

148. See PRO Program Directive No. 2, *supra* note 138, at 4-6 (general PRO objectives followed by MSVRO).

149. See MSVRO Memorandum of Understanding with the Virginia Hospital Association 15 (June 1985) [hereinafter cited as June 1985 MOU]; MSVRO Contract, *supra* note 144, at supp. 2-3 (Plan for Preadmission Review).

150. See MSVRO Contract, *supra* note 144, at supp. 3-3.

151. *Id.* at supp. 3-3 to 3-4.

152. *Id.*

153. *Id.* at supp. 3-3.

154. *Id.* at supp. 3-3 to 3-4.

155. *Id.* at supp. 3-4.

156. *Id.* There are other issues associated with the performance of retrospective reviews that are also controversial. First, there can be no provision in PRO contracts with hospitals for payment of additional compliance costs associated with the intensified review. Although hospital DRG rates include some moneys for peer review functions, the increased copying costs and clerical time required for assisting PROs in performing on-site and off-site reviews far exceed the current peer review allowance. Many hospitals have objected to the additional costs; however, the PROs have no funds in their HCFA contracts to cover these expenses. See PRO Program Directive No. 2, *supra* note 138, at 2; AHA Briefing Supplement,

The MSVRO representative also reviews all treatment records for DRGs requiring preadmission certification to ensure that the hospital's physicians actually called the PRO before admitting the patient. The MSVRO physician consultant reviews any discrepancies between the two records identified by review analysts and may recommend a letter of adverse determination if he finds a discrepancy that cannot be satisfactorily resolved.¹⁵⁷ The MSVRO also has procedures for mandatory meetings with recalcitrant physicians and, in such cases, may perform full concurrent or retrospective reviews of a physician's Medicare patient admissions.¹⁵⁸ The MSVRO also may recommend that the Secretary of HHS impose formal sanctions on physicians that consistently refuse to cooperate.¹⁵⁹

Each month, the MSVRO review analyst also must look at treatment records for many of the hospital's non-preadmission review patients. The HCFA-PRO contracts require each PRO to perform retrospective reviews of the appropriateness of all cardiac pacemaker implantations, all readmissions, all inpatient transfers from one hospital to another, all hospital admissions where the hospital is experiencing unusually large increases in volume, and one out of every twenty admissions not otherwise under review.¹⁶⁰ The review analyst must validate the DRG admission codes for patients subject to preadmission and retrospective reviews and must also check the DRG codes for an additional five percent of the other Medicare patients admitted.¹⁶¹

supra note 143, at 7-8.

A second issue is the confidentiality of patient and physician records. Confidentiality was of particular concern during the PSRO program when a federal district court ruled that a PSRO's confidential, physician-specific data were accessible under the Freedom of Information Act. The D.C. Circuit eventually reversed the lower court by holding that the PSROs do not fit the definition of a federal agency. See *Public Citizen Health Research Group v. Dep't of Health, Educ. & Welfare*, 477 F. Supp. 595 (D.D.C. 1979), *rev'd*, 668 F.2d 537 (D.C. Cir. 1981). The PRO statute follows the D.C. Circuit's opinion and specifically excludes the PROs from FOIA requests. 42 U.S.C. § 1320c-9(a) (1982). However, the same section may allow PRO data to be discoverable in malpractice suits. See *Hastings, supra* note 65, at 295-99; see also 50 Fed. Reg. 15,353-54 (1985) (HCFA comments).

157. See MSVRO Contract, *supra* note 144, at supp. 3-4; see also 50 Fed. Reg. 15,331 & 15,333 (1985) (to be codified at 42 C.F.R. §§ 466.78, .88) (final rules on PRO inspection of hospital records).

158. See MSVRO Contract, *supra* note 144, at 20.

159. See *id.* at supp. 3-4; see also 50 Fed. Reg. 15,333 (1985) (to be codified at 42 C.F.R. § 466.90) (final rule regarding lack of provider cooperation).

160. See AHA on PROs, *supra* note 147, at 3-4.

161. See PRO Program Directive No. 2, *supra* note 138, at 4. During the DRG validation process, the PRO review analyst compares the diagnostic and procedures coding on the patient's bill with the diagnoses and procedures recorded in the patient's treatment record.

Finally, the MSVRO review analyst must examine hospital claims to DRG outlier cases¹⁶² to see if the patient days or services beyond those authorized under the DRG admission code are medically appropriate.¹⁶³ In the case of cost outliers, a hospital is normally entitled to additional Medicare funds if it is able to prove that it incurred extraordinarily high costs in treating a particular patient.¹⁶⁴ Outlier reviews include a procedure for notifying the hospital and the Medicare intermediary of any necessary adjustment in DRG coding.¹⁶⁵

The PRO or its non-provider subcontractor then must perform its own analyses of these various admissions criteria. MSVRO outlined its responsibility to perform admission criteria analyses on Medicare patients in its initial MOU with Virginia hospitals.¹⁶⁶ A MOU also may give a PRO access to non-Medicare patient records so that PROs may contract to perform reviews for other organizations, including Medicaid.¹⁶⁷ The PRO staff must perform all of

The PRO review analyst also determines if the DRG coding is in fact supported by the patient's medical record data and if the physician has attested to its accuracy. *See* 50 Fed. Reg. 15,330-31 (1985) (to be codified at 42 C.F.R. § 466.70).

The physician attestation requirements have been particularly controversial. The PRO Manual requires attending physicians to sign a certification statement contained in each Medicare patient's medical record attesting to the accuracy of primary and secondary diagnoses and major procedures performed. The admitting hospital also must have on file a signed acknowledgement by the physician that he has received the following notice:

Notice to Physicians: Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

PRO Manual, *supra* note 147, at 40.

These attestation requirements have created administrative problems for hospitals and have led to inadvertent denials. The MSVRO, responding to VHA concerns, has allowed hospitals a reasonable opportunity to supply missing attestations prior to notifying the intermediary of an adverse determination. *See* June 1985 MOU, *supra* note 149, at 15.

162. *See supra* note 31 (definition of "day" and "cost" outliers).

163. *See* PRO Manual, *supra* note 147, at 31-37.

164. *See* PRO Program Directive No. 2, *supra* note 138, at 5. A hospital also may be entitled to receive additional funds for day outliers if a patient requires a level of medical care for a period of time exceeding the outlier threshold for a particular diagnosis. *Id.*

165. *Id.*

166. *See* MSVRO Memorandum of Understanding with the Virginia Hospital Association 6-8 (Nov. 1, 1984). This MOU has been superseded by a more detailed description of PRO review responsibilities. *See* June 1985 MOU, *supra* note 149.

167. *See* PRO Program Directive No. 2, *supra* note 138, at 7. As of February, 1985, 14 organizations had contracts or were negotiating contracts with the MSVRO to perform peer review on non-Medicare patients. The VHA has sent guidelines to all Virginia hospitals to assist them in the negotiation of private review MOUs. *See* Memorandum to VHA Institu-

the review functions except for quality of care reviews.¹⁶⁸ A PRO may subcontract for quality of care reviews with hospital utilization review committees if HCFA approves the delegation proposals.¹⁶⁹

2. The PRO Appeals Procedure

The PRO statute and regulations provide general guidelines for denial of payment and for sanctions procedures. The review procedures discussed above require PROs to make adverse determinations where a Medicare beneficiary receives medical care services that do not satisfy the statutory tests of medical necessity, quality, and appropriateness of care.¹⁷⁰ The PRO must deny payment in such cases to both physicians and hospitals unless the waiver of liability provisions¹⁷¹ or other allowances apply.¹⁷² The PRO must also give the physician and the hospital an opportunity to discuss a proposed adverse determination and the patient's condition with the PRO before the PRO can make the initial denial.¹⁷³ Normally, the PRO must make adverse decisions within thirty days of the

tional Members on VHA Guidance on Private Review (Feb. 15, 1985).

168. PRO Program Directive No. 2, *supra* note 138, at 8.

169. *Id.*

170. See 42 U.S.C. §§ 1320c-3(a)(1) to -3(a)(2) (1982). One PRO reported that it has denied payment in seven percent of the cases it has reviewed to date. See *PRO Hearing II*, *supra* note 147, at 79 (statement of Harry Weeks, M.D., Medical Director, West Virginia Medical Institute). By contrast, Virginia has the fifth lowest payment denial rate in the country. Interview with Katherine Webb, Vice President of the Virginia Hospital Association (Dec. 4, 1985).

171. See AHA on PROs, *supra* note 147, at 6 (availability of a "favorable presumption" regarding payment for unnecessary admissions or procedures, unless the hospital or physician knew or should have known that the admission or procedure was unnecessary); see also *supra* notes 83 & 147 and accompanying text.

In certain instances, the PRO presumes that actions by the physician or provider are deliberate efforts to circumvent the DRG payment system, and the waiver of liability provisions are inapplicable. If a physician or provider inappropriately discharges a patient and shortly thereafter readmits the same patient, the PRO must deny payment for the second admission. Similarly, the PRO must deny payment where a patient is transferred from a level of care covered by the Medicare prospective payment system (PPS) to a PPS-exempt level of care (such as acute psychiatric care). See PRO Manual Transmittal No. 5, Health Care Fin. Admin., §§ 3010, 3015 (Aug. 1985), reprinted in *MEDICARE & MEDICAID GUIDE* (CCH) 34,840 (1984).

As a method of reducing Medicare costs and unnecessary medical care, Congress has created several peer review systems to review physician and hospital treatment practices.

172. See, e.g., 42 U.S.C. § 1320c-3(a)(2) (1982) (includes payment for two days of inpatient care beyond the DRG rate; allows patients and physicians to arrange for post-discharge care in limited circumstances).

173. *Id.* § 1320c-3(a)(3).

date that the hospital files the claim. However, HCFA can approve subsequent denials in special cases.¹⁷⁴

Any physician, hospital, or beneficiary who is dissatisfied with an adverse determination may request reconsideration of the initial decision within sixty days of receipt of the written denial notice.¹⁷⁵ A dissatisfied party also may obtain a speedy review of a preadmission review denial if it files a request for reconsideration within three working days of a beneficiary's receipt of the PRO's denial notice.¹⁷⁶ The beneficiary may obtain pertinent portions of his or her medical record during the reconsideration process, and any party may submit additional information for consideration by the reviewer.¹⁷⁷ Late filing of a request for reconsideration or a hearing is allowed if good cause is shown.¹⁷⁸

The final regulations require the PRO to use a different consulting physician for the initial denial and the reconsideration review. This goes beyond the language of both the statute and the proposed rule which recommended only that, "to the extent practicable," the reconsideration *should* be performed by a different physician.¹⁷⁹ This adds an element of impartiality to the review process. The reviewer must send a written notice to the parties that explains the basis and rationale for the reconsideration decision and which should also contain information on the Medicare payment consequences of the reconsideration and the beneficiary's appeal rights.¹⁸⁰ The reconsidered determination is final and binding on all parties unless appealed or reopened,¹⁸¹ and the PRO must maintain the reconsideration record for at least four years or until all appeal rights have been exhausted.¹⁸²

174. See 50 Fed. Reg. 15,334 (1985) (to be codified at 42 C.F.R. § 466.96) (final rule on review period for denials includes provisions for reopening determinations for up to four years in case of new evidence or reviewer/clerical errors; also provides for the reopening of fraudulent determinations at any time).

175. See *id.* at 15,372 (to be codified at 42 C.F.R. § 473.20).

176. See *id.* at 15,372-73. The PRO must conduct preadmission review reconsiderations within three working days if received within the three-day period; otherwise a PRO may reconsider cases within 30 days. See *id.* at 15,373 (to be codified at 42 C.F.R. § 473.32).

177. See *id.* (to be codified at 42 C.F.R. § 473.28).

178. See *id.* at 15,372 (to be codified at 42 C.F.R. § 473.20).

179. See *id.* at 15,373 (to be codified at 42 C.F.R. § 473.28). The MSVRO also agreed to use different physician consultants for initial reviews and reconsiderations. See June 1985 MOU, *supra* note 149, at 28.

180. See 50 Fed. Reg. 15,373 (1985) (to be codified at 42 C.F.R. § 473.34).

181. See *id.* at 15,374 (to be codified at 42 C.F.R. § 473.38).

182. See *id.* at 15,373-74 (to be codified at 42 C.F.R. § 473.36).

A physician or hospital may appeal a waiver of liability determination,¹⁸³ but only the beneficiary may assert his or her right to appeal an adverse determination following reconsideration. However, the PRO's determination following reconsideration is final for all reimbursement claims of less than two hundred dollars.¹⁸⁴ Where the amount in controversy¹⁸⁵ equals or exceeds two hundred dollars, a Medicare beneficiary may seek review of the adverse determination by an administrative law judge.¹⁸⁶ A subsequent administrative appeal to the Appeals Council is also possible.¹⁸⁷ The Appeals Council's decision on all claims for less than two thousand dollars is final. If the amount in controversy equals or exceeds two thousand dollars, a beneficiary then may seek judicial review of the final administrative decision.¹⁸⁸

The PRO's denial of Medicare payment for a physician or a hospital in individual cases can lead to future penalties. Possible penalties range from a shifting of the burden of proof in waiver of liability determinations¹⁸⁹ to formal sanctions against the provider,¹⁹⁰ which may include monetary penalties and temporary exclusion from the Medicare program.¹⁹¹

The PRO sanctions process differs significantly from the PSRO process in that a PRO is now *required* to initiate sanction proceedings if a physician or provider exhibits a pattern of unnecessary utilization in a substantial number of cases.¹⁹² The PRO regulations do require that the physician or provider receive notice prior to an initial sanction determination¹⁹³ and provide for an opportunity to take voluntary corrective action.¹⁹⁴ However, where a violation is found to be "gross and flagrant," the PRO must bypass the

183. See *id.* at 15,372 (to be codified at 42 C.F.R. § 473.14(c)).

184. See *id.* at 15,374 (to be codified at 42 C.F.R. § 473.40).

185. See *id.* (to be codified at 42 C.F.R. § 473.44).

186. See *id.* (to be codified at 42 C.F.R. § 473.40).

187. See 42 U.S.C. § 1320c-4 (1982).

188. *Id.*

189. See AHA on PROs, *supra* note 147, at 6.

190. See 42 U.S.C. § 1320c-5(b)(1) (1982).

191. *Id.*

192. *Id.* The final PRO rules defined the term "substantial violation in a substantial number of cases" as "a pattern of care [which] has been provided 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." See 50 Fed. Reg. 15,344 (1985) (to be codified at 42 C.F.R. § 474.0(b)); PRO Manual Transmittal No. 6, Health Care Fin. Admin., § 6010A (Oct. 1985) [hereinafter cited as PRO Transmittal No. 6].

193. See PRO Transmittal No. 6, *supra* note 192, § 6015A.

194. *Id.* § 6015 B. Such corrective action must be taken in accordance with a written plan.

initial notice and opportunity for corrective action and make an immediate, initial sanction determination.¹⁹⁵ In either case, if the physician or provider does not satisfactorily respond within thirty calendar days of the initial determination, the PRO must notify the Office of the Inspector General (OIG) of HHS to initiate formal sanctions.¹⁹⁶

The physician or provider has thirty days to submit any additional, specific information to OIG regarding the sanction recommendation.¹⁹⁷ The OIG review is limited to determining whether: (1) a violation occurred; (2) a physician or provider has demonstrated an unwillingness or inability to substantially comply with a peer review obligation; and (3) the PRO has followed proper procedures.¹⁹⁸ The OIG assumes that if the PRO has followed the above procedures, the review has been reasonably performed,¹⁹⁹ and there is no subsequent inquiry into any underlying factors prompting the sanction recommendation.

The critical difference between the PSRO and PRO procedures is that, in the case of program exclusions, the PRO recommendation will take effect automatically if the OIG fails to act within 120 days.²⁰⁰ Monetary penalties still require OIG review and approval of the PRO recommendation.²⁰¹ As with the PSRO program, the affected party can obtain further administrative or federal district court review of final sanctions.²⁰²

195. See *id.* § 6020A; see also 42 U.S.C. § 1320c-5(b)(1)(1983). The PRO rules define the term "gross and flagrant violation" as "a violation of an obligation [which] has occurred in one or more instances [and] which presents an imminent danger to the health, safety or well-being of a Medicare beneficiary." 50 Fed. Reg. 15,344 (1985) (to be codified at 42 C.F.R. § 474.0(b)); see also PRO Transmittal No. 6, *supra* note 192, § 6010A.

A panel at a recent HCFA conference on the PRO program decided that one occurrence of a particular PRO violation might constitute "a gross and flagrant" violation if sufficiently extreme. In most cases, however, at least three violations would be necessary before formal action is taken. See Sax, *Peer Review Organizations May Increase Inspector General's Sanction Activity*, 8 HEALTH L. VIGIL 15, 16 (1985).

196. See 50 Fed. Reg. 15,345 (1985) (to be codified at 42 C.F.R. § 474.36); PRO Transmittal No. 6, *supra* note 192, §§ 6015C, 6020A.

197. See PRO Transmittal No. 6, *supra* note 192, §§ 6015E, 6020C, 6030.

198. See *id.* § 6035B.

199. See 50 Fed. Reg. 15,339 (1985) (commenting on the scope of OIG review of PRO evidentiary findings).

200. See *id.* at 15,346 (to be codified at 42 C.F.R. § 474.42).

201. *Id.*

202. See 42 U.S.C. § 1320c-5(b)(4) (1982); see also notes 93-94 and accompanying text (PSRO sanction appeal provisions).

C. *Potential Problems with the PRO Program*

1. Use of Review Criteria

As with the PSRO program, the PRO's use of general review criteria in its medical necessity and level of care determinations can lead to arbitrary results in individual cases. The PROs still use PSRO norms and criteria to establish unnecessary admission targets.²⁰³ However, under Medicare prospective payment, PROs no longer use diagnosis-specific norms and criteria to establish reasonable costs for patient stays and ancillary procedures.²⁰⁴ The PRO program must, nonetheless, develop and rely upon specific criteria for preadmission certifications and DRG outlier reviews.

The preadmission review criteria merit particular scrutiny in light of *American Medical Association v. Weinberger*.²⁰⁵ If the certification process places patients in jeopardy of receiving inadequate care, then the regulation may violate a patient's constitutional right to treatment²⁰⁶ or the physician's statutory right of noninterference with the practice of medicine.²⁰⁷ However, the likelihood of patient harm from preadmission screening of a limited number of elective procedures is considerably less than the threat posed by the concurrent review of all admissions, the subject of controversy in the *AMA* case.

The use of arbitrary, uncirculated review criteria by non-physicians to deny admissions or outlier payments might also pose significant health risks to Medicare patients. However, the MSVRO, like most PROs, has agreed to provide its review criteria for preadmission screening to hospitals and physicians on a timely basis.²⁰⁸ Making the criteria accessible and ensuring the active participation of the consulting physician in any denial decision should eliminate most physician and provider concerns about the PRO's use of norms and criteria, as long as any changes in review criteria are made available prior to their use in review decisions.²⁰⁹ How-

203. Cf. 50 Fed. Reg. 15,334-35 (1985) (to be codified at 42 C.F.R. § 466.100) (final rule on use of norms and criteria).

204. See *supra* notes 23-32 and accompanying text.

205. 395 F. Supp. 515 (N.D. Ill.), *aff'd*, 522 F.2d 921 (7th Cir. 1975); see *supra* notes 114-20 and accompanying text.

206. See *supra* notes 110, 116 and accompanying text.

207. See 42 U.S.C. § 1395a (1982).

208. See June 1985 MOU, *supra* note 149, at 10.

209. See Memorandum to VHA Institutional Members on PRO Review Activities—Problems and Solutions 3 (June 28, 1985) (reporting MSVRO agreement to inform

ever, PRO reviewer bias or lack of expertise in a particular medical discipline could still be a basis for legal challenges to the denial of admission or payment in individual cases.²¹⁰

2. The Appeals and Sanctions Process

The new payment denial and sanctions process provides PROs with considerably more power with which to deal with recalcitrant providers than was available to PSROs. As one HCFA official stated, "Adverse determinations will become more commonplace."²¹¹ One may anticipate an additional number of sanctions proceedings, too, as physicians and providers intentionally try to obtain longer hospital stays through improper DRG coding or additional admissions.²¹² Unfortunately, the same trap may apply to the inadvertent physician or provider, who may not understand how a couple of coding errors or patient readmissions could lead to sanction proceedings.

The PROs can exercise a considerable amount of discretion in their physician and provider sanction reviews.²¹³ Although final sanctions are subject to appeal, there is no meaningful appeal from adverse determinations which preceded and were incorporated into the sanctions process. The PRO's discretion in recommending sanctions will create conflicts between PROs, physicians, and providers over patient treatment unless the parties involved adhere to

hospitals prior to use of new criteria).

210. See 50 Fed. Reg. 15,334-35 (1985) (to be codified at 42 C.F.R. §§ 466.96, .98, .102); see also Sax, *supra* note 195, at 17 (discussing need to raise procedural objections at the earliest opportunity).

211. Interview with Bill Davis, Assistant to the Regional Administrator, HCFA (Oct. 16, 1984).

212. Under the Medicare prospective payment system, the amount of payment is directly related to the DRG code selected for each patient admission. Physicians and providers have undoubtedly realized that it is in their best interests to select those DRG categories that enhance their Medicare payments and to emphasize the relevant aspects of each admission supportive of their DRG selection. See *supra* notes 134-35 and accompanying text. In order to guard against such potential abuses, HCFA requires PROs to validate DRG selections and to treat some patient readmissions and transfers as deliberate attempts to circumvent the prospective payment system. See *supra* note 171. However, these safeguards are not foolproof and can lead to sanction proceedings in cases of inadvertent errors or good faith efforts to comply with the law.

213. For example, one PRO may decide that a failure to adequately document in the medical record the reasons for admitting a patient is a "substantial violation" while another PRO, or the same PRO under similar circumstances, may determine it to be a "gross and flagrant violation." See PRO Transmittal No. 6, *supra* note 192, at 12-9 to 12-15, 12-19 to 12-22.

standard treatment and recordkeeping practices.

Further, there are no statutes or regulations which define the terms "substantial number of cases" or "gross and flagrant violations."²¹⁴ Left undefined, these terms can become a problem for the well-intentioned provider during a sanction proceeding where two adverse determinations could be substantial and many problem types could be classified as gross and flagrant. The existence of PRO bias and prejudice toward a particular provider could also go unnoticed during a sanctions process. These conflicts arise from the PRO's discretionary authority in the peer review process and will be the likely subjects of congressional hearings and litigation in the near future.

IV. CONCLUSION

Congress created the Medicare peer review systems as a means of controlling Medicare program costs while maintaining the quality of patient care. While the method of peer review under Medicare has changed considerably since Congress enacted the Utilization Review program in 1965, the individual treatment practices of physicians have remained the major focus of the current PRO program. Physicians retain substantial control over the choice of treatment; however, the new Medicare review entities have greater discretion in denying payment for a beneficiary's care and in penalizing physicians and hospitals for inappropriate care.

The PRO has become an important mechanism for controlling costs under the new prospective payment system, if only because the DRG rates alter hospital payment incentives. Now that most hospitals receive a flat rate for each type of patient admission, hospitals are pressuring physicians to discharge patients earlier and to order fewer ancillary services. Prospective payment thus controls the unit cost of a patient day in the hospital. Unless a hospital has claims for outlier payments, a PRO does not have to approve additional patient days or services. The PRO can now focus its review activities on admission control and quality maintenance. As a consequence, the PRO reviews may spot more instances of inappropriate or unnecessary care, leading to more denials of payment and provider sanctions than under its predecessor programs.

214. See Sax, *supra* note 195, at 15. The MSVRO does establish a standard of at least three adverse determinations before sanction procedures are initiated in several instances. See MSVRO Contract, *supra* note 144, at 21-22, 24 & *supp.* 3-5.

The PRO program marks the federal government's latest incursion into the health care system. PRO review groups are now making many of the same decisions on patient admissions that the attending physician made a few years ago. Furthermore, Congress gave PROs greater power to deny payment for patient treatment and impose sanctions on physicians and hospitals that consistently overtreat Medicare patients. The government's role in the health care marketplace under prospective payment and the PRO Act has shifted from that of a partner to a controlling interest. Physician and provider groups should continue to insist upon greater legislative or administrative confinement of the PRO's discretion wherever possible²¹⁵ so as to prevent the abuse of review mechanisms and sanctions during PRO reviews.

ADDENDUM

As of April 1986, many physicians and providers have realized that PROs are taking their Medicare peer review activities seriously. The Health Care Financing Administration (HCFA) has put pressure on individual PROs to exercise their payment denial and sanction authority by carefully timed news releases on quality of care issues. Stories depicting widespread physician incompetence have appeared in local newspapers.¹ HCFA statistical inquiries have also uncovered higher than projected mortality rates in certain hospitals.² These and other stories related to the PRO program have clearly put physicians and providers on the defensive.

In addition to addressing quality of care concerns, HCFA's peer review offensive has directly affected physician and provider payments. As of March 24, 1986, physicians and providers can no longer rely on a "favorable presumption" to guarantee payment in

215. See *Medicare Agencies Now Judging Surgery*, Rich. Times Dispatch, Dec. 3, 1984, at 1, col. 4 ("If it turns out that [the PROs] are going to become the primary rationers of medical care, then I think you will see a lot of concern that will become very aggressive."—Statement by AMA official).

1. See, e.g., *Efforts to Discipline Doctors Increasing*, Richmond Times-Dispatch, Jan. 20, 1986, at A-1, col. 5; *Disciplinary System Is Criticized*, *id.*, Feb. 4, 1986, at A-1, col. 3.

2. See Sharon McIlrath, *HCFA Data Release Gets Mixed Reactions*, Am. Med. News, Mar. 28, 1986, at 1, col. 2 (describing HCFA's study of nearly 11 million Medicare patient records showing abnormal mortality and discharge rates at 2,300 U.S. hospitals and public reaction to same); *States Sent Data To Check On Hospitals*, Richmond Times-Dispatch, Mar. 3, 1986, at A-1, col. 6 (discussing initial release of HCFA data to PROs prior to HCFA decision to disseminate information generally in response to Freedom of Information Act requests).

situations where the provider has a small number of payment denial errors.³ This rule change requires that PROs review each instance of Medicare payment for noncovered services.⁴ In support of the new role, HCFA relied on a 1983 General Accounting Office recommendation⁵ and its own program experience.⁶ Accordingly, HCFA decided that general waivers of liability were no longer necessary.

PRO reviews of current medical practices clearly serve both Medicare cost control and quality of care functions. However, following a pattern reminiscent of the PSRO program's implementation,⁷ the federal government has emphasized the PRO program's quality of care role. The Office of the Inspector General (OIG) now claims, in its own unpublished report of trends in the medical profession, that "20,000 to 45,000 of the nation's 400,000 doctors are likely candidates for some sort of [peer review] discipline."⁸ These statistics are based upon general population prevalence rates of alcoholism, drug abuse, mental illness, criminality, and associated problems and are not physician-specific.⁹ OIG's involvement in the study is certainly more significant than the results, given OIG's role in reviewing PRO proposed sanctions.

The first group of PRO-HCFA contracts are currently under review. HCFA has sent notices to seven of the first fifteen organizations up for renewal stating that their contracts will not be renewed automatically.¹⁰ In anticipation of HCFA pressure during

3. See 51 Fed. Reg. 6222 (1986) (to be codified at 42 C.F.R. §§ 405.332 -.336) (noting that over 80% of all providers had qualified for a favorable presumption); see also *supra* notes 83, 147 & 171 and accompanying text.

4. See 51 Fed. Reg. 6225, 6226 (1986) (HCFA justification).

5. See *id.* at 6224 (discussing GAO's view that provider participation in Medicare over several years educates providers about covered services and that tighter limitation of liability rules would save Medicare program funds).

6. *Id.*

7. See *supra* notes 100-02 and accompanying text.

8. See *Disciplinary System Is Criticized*, Richmond Times-Dispatch, Feb. 4, 1986, at 1, col. 3.

9. *Id.* Although the prevalence of these problems among physicians may not differ from the general population, the OIG's study is seriously flawed by drawing conclusions about physicians from non-physician-specific data.

10. See *7 PROs Get Non-Renewal Notices*, Am. Med. News, Apr. 4, 1986, at 1, col (noting that the seven organizations will still have an opportunity to bid for the contracts). In its non-renewal decisions, HCFA relied on PRO failure to meet contract objectives and, in some cases, PRO failure to impose a sufficient number of payment denials and sanctions against physicians and providers. *Id.* at 69. Some PRO officials accused HCFA of showing little flexibility in interpreting contract goals and overemphasizing numbers of payment denials and sanctions. *Id.* at 69-70.

contract renewals, PROs around the country have initiated disciplinary proceedings against over 950 physicians and 180 hospitals.¹¹ Although OIG has sanctioned only one physician as of March 1986,¹² PROs are apparently recommending additional sanction cases to OIG for review as the PRO-HCFA contract renewal deadlines draw nearer. The procedures followed in these PRO sanction reviews have raised significant due process questions, highlighting the problems inherent in unbridled PRO discretion.¹³ Based on the author's personal observation, judicial challenges to PRO sanction procedures cannot be far off.

11. *See Efforts To Discipline Doctors Increasing*, Richmond Times-Dispatch, Jan. 20, 1986, at A-1, col. 5. In spite of the increased sanction activity, an OIG report found "serious deficiencies" in PRO reviews of Medicare cases dating from October, 1983 (over nine months before the first PRO-HCFA contracts began) to May, 1985 (the first full month after final sanction rules were released). The OIG report found that 74 out of 4,724 cases flagged by PROs as suspicious discharges were "so outrageous" that they would justify HHS disciplinary action. However, PROs referred none of the 74 cases to OIG for action. The Inspector General questioned the lack of followup and stated that the PROs "should ask the physician why he discharged this person, and question the decision. If they're not satisfied with the answer, or if they see that it's part of a pattern of activity knock that sucker out of the program right off the bat." *Medicare: Controls Assailed*, Richmond Times-Dispatch, Jan. 27, 1986, at A-1, col. 2.

12. *See Physicians Fin. News*, Mar. 30, 1986, at 1, col. 4 (reporting that OIG had nine other cases awaiting sanction approval). Interestingly enough, during its 10 year history, the PSRO program produced 70 sanctions against physicians and hospitals. *See Efforts To Discipline Doctors Increasing*, Richmond Times-Dispatch, Jan. 20, 1986, at A-1, col. 5.

13. The author currently has a case pending before OIG for review. The Medical Society of Virginia Review Organization (MSVRO) gave the physician little opportunity to respond to MSVRO allegations of gross and flagrant conduct. The MSVRO Quality Assurance Committee held one meeting on the case, at which it cross-examined the physician without allowing participation by counsel, even in an advisory role. The MSVRO then produced a "record" of the meeting containing excerpts, taken out of context, from the taped discussion. Counsel was not allowed to review or respond to this record until after the MSVRO Board of Directors ratified its committee's sanction recommendation and sent the record to OIG. The MSVRO then refused to release the committee meeting tape until after the physician's 30-day period for sending any rebuttal to OIG had expired.

Although OIG has a statutory duty to review the merits of the sanction recommendation and the procedures followed, the Inspector General's statements about PRO sanction inactivity raise questions about OIG impartiality in reviewing such cases. *See supra* addendum note 11. The result could be that the merits of sanctioning the physician for his treatment of one Medicare patient and the questionable procedures followed in reaching this result will remain unexamined prior to OIG action (or inaction) within the 120-day sanction review period.