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Administrative Law Issues Involving the Medicare Utilization and Quality Control Peer Review Organization (PRO) Program: Analysis and Recommendations

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I. INTRODUCTION

The Medicare Utilization and Quality Control Peer Review Organization (PRO) program is an administrative law curiosity. The PRO program is the federal government's primary tool for assuring that services provided to Medicare beneficiaries are medically necessary, are of a quality that meets professionally recognized standards of health care, and are provided in an appropriate setting.¹ It both protects the health and safety of Medicare beneficiaries and controls the cost of the Medicare program.

The power of PROs over Medicare providers, practitioners, and beneficiaries is sweeping. If a PRO determines that medical services do not meet utilization or quality standards, it may retrospectively deny Medicare payment for those services.² A PRO may also deny payment prospectively for some prescribed procedures, effectively blocking a beneficiary from receiving those services unless the beneficiary can independently afford them.³ It may also recommend to the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) that a provider or practitioner⁴ be fined or excluded from receiving payment under the Medicare program. As a practical matter, exclusion from Medicare may make it impossible for a physician to practice; thus the PRO's power over physicians is nearly as great as that of state licensure boards.

More striking than the scope of the PRO's authority is the fact that in many instances PRO decisions are either not reviewable or are reviewable only after they have been implemented. A hospital or physician, for example, cannot in most cases obtain independent review of the decision of a PRO to deny payment for a claim from either an Administrative Law Judge (ALJ) or a court—the PRO's decision is final.⁵ PRO-initiated sanctions and penalties assessed against providers and practitioners are usually not reviewable until months after they have been implemented.⁶

From an administrative law perspective, however, the most striking feature of PROs is that, despite their substantial, often unreviewable power, they are private entities that provide services for the federal government on a contractual basis.⁷ The

1. Social Security Act, 42 U.S.C. § 1320c-3(a)(1) (1982 & Supp. IV 1986).

2. *Id.* § 1320c-3(a)(2).

3. HEALTH CARE FIN. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., THIRD SCOPE OF WORK § X, at 26 (1987) [hereinafter THIRD SCOPE OF WORK]. The *Third Scope of Work* is the request for proposals governing PRO contracts during the current contract cycle; for further explanation, see *infra* text following note 56.

4. Under the Medicare law, a provider is an institutional health care entity, such as a hospital or nursing home, 42 U.S.C. § 1395x(u). A practitioner is a physician or other individual who provides health care.

5. See *infra* text accompanying notes 423-27.

6. 42 U.S.C. § 1320c-5(b)(2) (1982); 42 C.F.R. §§ 1004.100(b), .130(a)(3) (1987). A recent draft report of the HHS OIG notes that on average it takes 15 months from the date of a PRO recommendation to the OIG to completion of the appeal. OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVS., THE UTILIZATION AND QUALITY CONTROL PEER REVIEW ORGANIZATION (PRO) PROGRAM: SANCTION ACTIVITIES (draft) 16 (Mar. 1988) [hereinafter OIG SANCTION REPORT]. There is, however, a special exception for certain rural practitioners, who may receive a pre-exclusion ALJ hearing. 42 U.S.C. § 1320c-5(b)(5) (1982).

7. 42 U.S.C. §§ 1320c-1 to -2(b) (1982 & Supp. IV 1986).

private nature of PROs is intentional and based on the philosophy of medical peer review. From the beginning, PROs (like the Professional Standards Review Organizations before them) were established so that private doctors participating in the Medicare program could have their work reviewed by other private doctors, with a minimum of interference from the federal government. The quasi-private nature of PROs is also reflected in the scope of their activities. Though many PROs were formed explicitly to perform Medicare review, they are not limited to this function; indeed federal law encourages them also to perform review for private and other public entities.⁸ A recent study found that, in fact, 73% of PROs conduct review for business entities and 68% for state Medicaid programs.⁹ Several spent less than 50% of their time on Medicare-related activities.

As private entities, PROs are not generally subject to the statutes governing federal administrative law. The court in *Public Citizen Health Research Group v. HHS*¹⁰ concluded that Professional Standards Review Organizations (PSROs), the predecessors of PROs, were private independent contractors and not federal agencies for purposes of the Freedom of Information Act (FOIA). A more recent case held that PROs are not federal agencies for purposes of the attorneys fees provisions of the Equal Access to Justice Act.¹¹ Presumably PROs are also not federal agencies for purposes of the Administrative Procedure Act (APA).¹²

This is not to say that PROs are unfettered by administrative law. The federal PRO statute, regulations, and *Manual* specify procedures to be followed by the PROs for rulemaking, adjudication, and data disclosure. Indeed, as the importance of the PRO program has grown, these requirements have tended to proliferate, providing increasingly more protection for those affected by the PROs, but also leaving the law affecting PROs in an increasingly confused state. Moreover, in carrying out their federal review activities, PROs are, as will be discussed below, federal actors subject to the due process requirements of the Constitution.¹³ There is, therefore, a substantial body of statutory, regulatory, and constitutional law that dictates how the PROs should conduct themselves in relating to the beneficiaries, providers, and practitioners they regulate.

8. *Id.* § 1320c-3(a)(11) (1982). See Hastings, *Legal Issues Raised by Private Review Activities of Medical Peer-Review Organizations*, 8 J. HEALTH POL. POL'Y & L. 293 (1983) (an excellent article considering the PRO private review side, which is not considered in this Article).

9. OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVS., *THE UTILIZATION AND QUALITY CONTROL PEER REVIEW ORGANIZATION (PRO) PROGRAM: AN EXPLORATION OF PROGRAM EFFECTIVENESS* (draft) 3 (June 1988) [hereinafter *OIG EFFECTIVENESS REPORT*].

10. 668 F.2d 537 (1981). This holding is reaffirmed by the more recently adopted PRO statute, which explicitly states that PROs are not federal agencies under the FOIA. 42 U.S.C. § 1320c-9(a) (1982).

11. *Oster v. Bowen*, 682 F. Supp. 853, 856-57 (E.D. Va. 1988); 28 U.S.C. § 2412(b) (1982 & Supp. IV 1986).

12. 5 U.S.C. §§ 551-559 (1982); *but see* J. BLUM, P. GERTMAN & J. RABINOW, *PSROs AND THE LAW* 119-29 (1977) (arguing that PSROs should be considered federal agencies under the APA and FOIA).

13. *See infra* notes 98-99, 259-70. The question of whether PROs are federal actors has not come up in cases to date. Most decided cases have challenged sanctions imposed by the OIG, which clearly is part of the federal government. In these cases, the question of the constitutionality of PRO procedures arises only derivatively, as part of the process of generating sanctions ultimately imposed by the OIG. In one case, however, *Kuown v. Southeast Mo. PSRO*, 811 F.2d 401 (8th Cir. 1987), *cert. denied*, 108 S. Ct. 1994 (1988), the court decided that PSROs were federal actors absolutely immune from civil rights claims under the Constitution and thus held implicitly that they were in fact subject to the Constitution, as the question of immunity would not arise were they not.

This Article examines both what the law with respect to PROs is and what the law should be. Part II provides a general description of the PRO program. Parts III through X consider the following eight areas in which administration of the PRO program affects beneficiaries, providers, and practitioners: the adoption by HHS of rules, policies, contracts, and instructions that govern the PROs; the formulation and dissemination of criteria, norms, and standards by the PROs; the PRO process for sanctioning providers and practitioners who provide care that is unnecessary or of substandard quality; denial of payment for substandard care; the investigation by the PROs of beneficiary complaints regarding practitioners and providers; the PRO process for reviewing proposed hospital discharges of beneficiaries; the processes through which PROs deny payment for improper utilization of medical care and reconsider those denials; and the considerations governing PRO data dissemination and confidentiality. As to each of these subjects, this Article examines the current state of the law and practice and relevant policy considerations and recommends improvements in current procedures.

This Article draws on a variety of information sources. It is based in part on a review of the relevant statute, regulations, manual instructions, and scopes of work governing the PRO program and the rapidly growing body of court cases and ALJ opinions considering PRO issues. It also draws on dozens of articles from the medical and legal literature; testimony to congressional committees; position statements of affected groups; and reports from the General Accounting Office, HHS OIG, and other evaluators of the PRO program. Finally, it draws on interviews with nearly eighty informants, including seventeen representatives of national, state, and local beneficiary organizations; eleven representatives of provider groups; twelve attorneys who represent providers; twenty-three PRO representatives; and fourteen representatives of the federal government. These included in-depth interviews with representatives from twelve PROs (in most instances executive directors) reviewing the current procedures of those PROs in each of the areas under consideration.¹⁴ Finally, this Article considers comments received on an earlier draft from interested persons and organizations.

II. THE PRO PROGRAM

The initial Medicare law adopted in 1965 gave little attention to regulating the medical necessity, appropriateness, and quality of services provided Medicare beneficiaries. It required only hospital-based utilization review committees to assure appropriate utilization of services,¹⁵ state licensure to assure that physicians were minimally qualified,¹⁶ and accreditation by the Joint Commission on Accreditation of Hospitals to guarantee the quality of hospitals.¹⁷ By the early 1970s, however, it was

14. The PRO representatives interviewed were from the states of New Jersey, Pennsylvania, Virginia, Florida, Illinois, Texas, North Dakota, Iowa, California, Washington, Minnesota, and Michigan. The Iowa PRO also has the contract for Nebraska and the Washington PRO for Idaho and Alaska, so these programs were also discussed.

15. Social Security Amendments of 1965, Pub. L. No. 89-97, § 1861(k), 79 Stat. 285, 318-19 (1966).

16. *Id.* § 1861(r), 79 Stat. 285, 321.

17. *Id.* § 1865, 79 Stat. 285, 326-27.

becoming apparent that further controls were needed to limit excessive utilization of Medicare services.¹⁸ Out of this concern grew the PSRO program, which used regional nonprofit physicians groups to review independently the use of medical services by beneficiaries of federal medical assistance programs, including Medicare.¹⁹ Though the primary emphasis of PSROs was on utilization review, they also conducted Medical Care Evaluation Studies (later Quality Review Studies) aimed at improving the quality of medical care. PSROs never succeeded in meeting the expectations of their supporters or overcoming the criticisms of their increasingly vocal detractors. In 1982 the Tax Equity and Fiscal Responsibility Act (TEFRA) abolished the PSRO program and created in its stead the PRO program.²⁰

The PRO program was intended to be a leaner and more effective program than its predecessor. The 195 PSRO regions were trimmed to 54 statewide areas. The old system of grant-funding was replaced by biennial (now triennial) contracts, to be awarded by competitive bidding. Ineffective PROs were to be terminated. PROs could no longer delegate utilization review functions to hospitals, as had the PSROs. Though PROs were initially to be physician-sponsored organizations (as were the old PSROs), the statute allows HHS to turn to other organizations, including insurance companies or Medicare fiscal intermediaries, for PRO services if initial physician-sponsored contractors prove ineffective. Unlike PSROs, PROs could be for-profit entities. Finally, the PROs were given enhanced sanction and payment denial authority to enforce their power.²¹

In the year following the creation of the PRO program (before it was in fact implemented), Congress adopted a prospective payment system (PPS) for Medicare based on diagnosis-related groups (DRGs).²² This system ended the prior cost-related reimbursement system, under which Medicare had reimbursed hospitals the costs they incurred in caring for Medicare patients, and substituted for it a program that paid hospitals primarily on a lump sum per hospitalization basis.

This change solved one problem addressed by the PROs, but created others. The old system had rewarded hospitals for keeping patients in the hospital as long as possible (which increased their costs and thus their reimbursement); thus a major focus of PSRO utilization review had been controlling the length of inpatient hospital stays. Because the new DRG system creates incentives for hospitals to minimize their costs by discharging patients as soon as possible, the problem of excessive length-of-stay has been solved. This problem has been replaced, however, by other serious problems: the DRG system creates incentives for hospitals to discharge patients prematurely, to underserve them while in the hospital, and to try to game the

18. See SENATE COMM. ON FIN., S. REP. NO. 1230, 92d Cong., 2d Sess. 254-69 (1972); SENATE COMM. ON FIN., MEDICARE & MEDICAID, PROBLEMS, ISSUES AND ALTERNATIVES, 91st Cong., 2d Sess. 105-09 (Feb. 9, 1970).

19. Social Security Amendments of 1972, Pub. L. No. 92-603, § 249F, 86 Stat. 1329, 1429-45 (1972).

20. Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 143, 96 Stat. 324, 382 (1982).

21. See CISLOWSKI, CONGRESSIONAL RESEARCH SERVICE REPORT FOR CONGRESS, THE PEER REVIEW ORGANIZATION PROGRAM 4-5 (1987); LOHR, PEER REVIEW ORGANIZATIONS: QUALITY ASSURANCE IN MEDICARE (The Rand Paper Series) 7, 14-15 (1985); Mellette, *The Changing Focus of Peer Review Under Medicare*, 20 U. RICH. L. REV. 315 (1986) (describing the changes from the PSRO to PRO program).

22. Social Security Amendments of 1983, Pub. L. No. 98-21, Title VI, 97 Stat. 65, 149-72 (1983).

system, either by transferring patients between hospitals or units within hospitals or by assigning improper DRGs. These practices can potentially lead to lower quality care for patients; therefore, every major budget reconciliation act since 1983 has included provisions redirecting the mission of PROs to address the potential quality and access problems created by the DRG reimbursement system.

There are currently forty-four PROs serving the fifty-four PRO areas.²³ Sixty-eight percent were formerly PSROs.²⁴ Eighty-four percent are "physician-sponsored"—that is, they are either composed of at least 20% of the physicians practicing in the review area or of 10% of the physicians in the area and are otherwise representative of the state physician community.²⁵ The remaining PROs are "physician access" organizations, usually insurance companies, having a sufficient number of physicians available to carry on review functions.²⁶ HHS is supposed to give preference in contracting to "physician-sponsored organizations," if any are available.²⁷ PROs must include on their boards at least one consumer representative.²⁸ The PROs vary significantly in size, the largest having hundreds of employees and budgets of millions of dollars. The proposed budget for the PRO program for fiscal year 1989 is \$257.4 million, an increase of 50% over fiscal year 1988.

PROs are delegated review responsibility under contracts with HHS. Until this year, these contracts were bid on a two-year cycle, but now they last for three years.²⁹ HHS may terminate a PRO that has substantially failed to carry out its contract.³⁰ HHS monitors PRO performance primarily through three methods: (1) periodic data reporting from the PROs, (2) the PRO Monitoring Protocol and Tracking System (PROMPTS-2) regional office review system, and (3) the SuperPRO, an independent contractor, which verifies PRO reviews.³¹ The PRO program is supervised by the Health Standards and Quality Bureau (HSQB) of the Health Care Financing Administration (HCFA) of HHS.

The primary tasks of the PROs are to process data concerning health care services provided to Medicare beneficiaries³² and to intervene when these data indicate that services have been provided unnecessarily, inappropriately, or with inadequate quality. Because hospitals consume over two-thirds of Medicare expenditures, PROs have focused their review traditionally on care provided to beneficiaries by doctors in hospitals. Recently many of the PROs have begun to review care provided by health

23. OIG EFFECTIVENESS REPORT, *supra* note 9, at 3.

24. *Id.*

25. *Id.*; 42 C.F.R. § 462.102 (1987).

26. 42 C.F.R. § 462.103 (1987).

27. 42 U.S.C. § 1320c-2(b)(1) (1982).

28. *Id.* § 1320c-1(3) (Supp. IV 1986).

29. *Id.* § 1320c-2(c)(3) (1982).

30. *Id.* § 1320c-2(c)(6). Such a termination is not subject to judicial review. *In re Pa. Peer Review Org.*, 50 Bankr. 640 (1985); 42 U.S.C. § 1320c-2(f) (1982).

31. OIG EFFECTIVENESS REPORT, *supra* note 9, at 12-18; GAO, MEDICARE: IMPROVING QUALITY OF CARE ASSESSMENT AND ASSURANCE 53-58 (May 1988).

32. PROs also review Medicaid cases for states that contract for such assistance, 42 U.S.C. § 1320c-7, and review for private payers, *id.* § 1320c-3(a)(11).

maintenance organizations and competitive medical plans (HMOs/CMPs) with Medicare risk-sharing contracts.³³ The Omnibus Budget Reconciliation Act of 1986³⁴ (OBRA '86) also requires PROs to stretch their review capacity to cover services provided in other settings, including post-acute care provided by skilled nursing facilities and home health agencies; ambulatory and hospital outpatient care; and beginning in 1989 care provided by physicians in their offices.³⁵ Most PROs, however, still focus the vast majority of their resources on review of care provided in hospitals, the primary concern of this Article.

The principal source of data for PRO review is the hospital record. PROs regularly receive from fiscal intermediaries (the insurance companies and other entities that handle Medicare reimbursement to providers) data on bills paid for services rendered to Medicare beneficiaries. The PRO selects a sample of these cases for review and requests medical records on these cases from the hospitals, which are reviewed at the hospital or at the PRO office.³⁶ The sampling criteria that PROs use for selecting cases for review, and the focus of their review in examining the records, have varied over the three contract cycles during which PROs have been in operation. During each contract cycle, the screening criteria and focus of PRO activity have been established by a scope of work.³⁷

The sampling criteria mandated by the *Third Scope of Work*, currently being implemented, require a PRO to review, for each PPS hospital (hospitals reimbursed under the DRG prospective payment system) under its jurisdiction, a 3% random sample of all discharges; 50% of cases involving transfers from one PPS hospital to another; 10% of transfers to a psychiatric bed in a PPS hospital (and 100% of certain problem transfers to psychiatric beds); 25% of transfers from a PPS hospital bed to a nursing home bed in the same hospital; 25% of cases in which a patient discharged from a PPS hospital is readmitted within thirty-one days; 20% of cases in the 25% discharge and readmission sample just mentioned, in which the patient received care from a nursing home, home health agency, or hospital outpatient area during the period intervening between hospitalizations; 25%, 50%, or 100% of cases coded with certain problem DRGs; 25% of day and cost outliers (cases in which hospitals received extra payment beyond the DRG reimbursement because the case required an extraordinarily long or expensive hospital stay); all cases with targeted principal diagnoses, such as obesity or pacemaker fitting or adjustment; all cases in which a hospital has requested that a case be adjusted from a lower to a higher DRG; all cases in which a hospital has determined that an admission was not covered but the patient required Medicare-covered care at some time during the stay; and all cases referred

33. See Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, § 9405, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 83, 201 [hereinafter COBRA '85], as amended by Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9353(a), 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 1874, 2044 [hereinafter OBRA '86].

34. OBRA '86, Pub. L. No. 99-509, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 1874.

35. *Id.* § 9353(a), (f), 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 1874, 2046, 2052.

36. A recent study found that 61% of PROs usually perform review on-site at the hospital; 20% always perform it on-site. OIG EFFECTIVENESS REPORT, *supra* note 9, at 3.

37. For a further description of a scope of work, see *infra* text following note 56.

to the PRO by the fiscal intermediary or by HCFA.³⁸ PROs are also required to review a random sample of 15% of discharges from non-PPS units of PPS hospitals (for example, rehabilitation units) and from non-PPS-reimbursed hospitals and a 5% random sample of cases from ambulatory surgical centers.³⁹ When reviews indicate that a hospital is committing errors in more than 5% of its cases (or six cases if this amount is greater), the PRO is to intensify review to 50% or 100%, depending upon the problem, of the hospital's Medicare cases.⁴⁰

To this point, all the reviews listed are retrospective. The PROs must also perform preadmission or preprocedure review of ten specific procedures and the use of assistants for cataract surgery.⁴¹ Finally, a separate HMO/CMP *Scope of Work* provides a sampling procedure for identifying HMO/CMP cases to be reviewed. The intensity of sampling of HMO/CMP cases is related to the confidence that the PRO has in the HMO/CMP's own internal quality control capacity. In total, sample cases under the second contract cycle totaled about 26% of all Medicare hospital admissions.⁴²

Once medical records fitting these sample criteria are identified and copied, they are reviewed by professional reviewers (usually nurses), who apply criteria screens to identify utilization or quality problems. This review must be completed within sixty days from the date of receipt of the list of cases from the fiscal intermediary.⁴³ Each inpatient hospital discharge is to be reviewed for quality using HCFA's generic quality screens, for necessity and appropriateness using PRO discharge and admission criteria screens, and for DRG validation.⁴⁴ Care provided outside of the hospital setting is reviewed only for quality and not for utilization problems.

Once a PRO identifies a problem through this review of medical records, the case is routed to a physician reviewer. If the physician confirms the problem, the case can go in one of two directions. First, if a quality problem is identified, the case is routed to the PRO quality assurance system, which can interpose various interventions (including sanctions ultimately) to correct the problem.⁴⁵ If, on the other hand, the problem is identified as a utilization problem, the case is considered for a payment denial.⁴⁶ PROs also continually assemble profile data in an effort to identify aberrant providers and physicians. Profiles are kept on patients, physicians, hospitals, DRGs, diagnoses, and procedures to monitor PRO impact and identify problems for further study.⁴⁷

PROs have a number of other functions unrelated to their data gathering and analysis functions. They are responsible for reviewing cases when hospitals inform

38. THIRD SCOPE OF WORK, *supra* note 3, § VI, at 16-22.

39. *Id.* §§ VII-VIII, at 22-23.

40. *Id.* § IX, at 24-26.

41. *Id.* § X, at 26-27.

42. HCFA *Official Outlines PRO Program Objectives*, HOSPITALS, Aug. 5, 1987, at 122.

43. THIRD SCOPE OF WORK, *supra* note 3, § III(B), at 2-3.

44. These screens, and problems associated with them, are described further in Part IV of this Article.

45. The PRO quality assurance/sanction process is described in Part V of this Article.

46. Payment denials and reconsiderations are considered in Part IX below.

47. THIRD SCOPE OF WORK, *supra* note 3, § XV, at 29-32.

patients that their care is not, or is no longer, covered by Medicare.⁴⁸ PROs are also responsible for monitoring to assure that hospitals provide beneficiaries with a statement of their rights to PRO discharge review at the time of admission.⁴⁹ They are required to investigate complaints by Medicare beneficiaries about the quality of Medicare-covered services received from Medicare-certified hospitals, nursing homes, home health agencies, or ambulatory surgical centers.⁵⁰ Finally, PROs are responsible for educating beneficiaries and providers as to their existence and functions.⁵¹

III. PUBLICATION OF PRO PROGRAM POLICIES AND PROCEDURES

One major administrative law issue that has arisen under the PRO program concerns the extent to which directives and guidelines governing the program must be promulgated as rules under the APA. At the time the program was initiated in 1982, some regulations survived from the PSRO program that preceded it. Additional regulations have been promulgated that address issues such as PRO eligibility, area designations, imposition of sanctions, confidentiality and disclosure, reconsiderations and appeals, and review activities.⁵²

These regulations, however, represent only a small portion of the instructions HHS has issued to govern the PRO program. First, HHS has issued a *PRO Manual*, supplemented periodically by manual transmittals and interim manual instructions. Chapters in the *Manual* address such issues as PRO review procedures; PRO denials, reconsiderations, and appeals; waiver of liability determinations; sanctions; data and reports; and PRO administration. Some portions of the *Manual* track closely the statute and regulations.⁵³ Even these sections, however, cover details not addressed by the regulations.⁵⁴ Other parts of the *Manual* cover issues not addressed by the

48. 42 U.S.C. § 1320c-3(e) (Supp. IV 1986). This procedure is discussed at Part VIII below.

49. THIRD SCOPE OF WORK, *supra* note 3, § XVI, at 33-34.

50. 42 U.S.C. § 1320c-3(a)(14) (Supp. IV 1986); THIRD SCOPE OF WORK, *supra* note 3, § XVII(A), at 36-38.

51. 42 U.S.C. § 1320c-3(a)(4)(B) (Supp. IV 1986); THIRD SCOPE OF WORK, *supra* note 3, § XVI(C), at 34-35. For further background on the PRO program, refer to CISLOWSKI, *supra* note 21; LOHR, *supra* note 21; Mellette, *supra* note 21.

52. The initial set of regulations was promulgated at 401 Fed. Reg. 7,201 (Feb. 27, 1984) and 50 Fed. Reg. 15,311 (Apr. 17, 1985) and codified at 42 C.F.R. pts. 400, 405, 420, 422, 431, 433, 456, 460, 462, 466, 473, 474, 476, and 489 (1987). On September 30, 1986, rules governing imposition of sanctions were redesignated to 42 C.F.R. pt. 1004 (1987). On October 7, 1987, HHS published rules governing PRO HMO/CMP review. 52 Fed. Reg. 37,545 (Oct. 7, 1987). These rules were published as final without a notice of proposed rulemaking (NPRM) under the APA good-cause exception to effectuate in a "timely manner" provisions of OBRA '86, adopted in October of 1986, which were to be in effect by April of 1987. 52 Fed. Reg. 37,456 (Oct. 7, 1987). Corrections to this notice were published in December of 1987, 52 Fed. Reg. 47,003 (Dec. 11, 1987). Finally, on March 16, 1988, HHS proposed further regulations to implement provisions of COBRA '85, Pub. L. No. 99-272, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 83, and OBRA '86, Pub. L. No. 99-509, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 1874, and to make technical changes necessitated by experience with the PRO program. 53 Fed. Reg. 8,654 (Mar. 16, 1988). Additional provisions requiring PRO review of proposed changes in DRG assignments were also published at 52 Fed. Reg. 33,033, 33,059-60 (Sept. 1, 1987).

53. See, e.g., U.S. DEP'T OF HEALTH & HUMAN SERVS., PEER REVIEW ORGANIZATION MANUAL §§ 4080-4086, Reconsiderations and Appeals (1988) [hereinafter PRO MANUAL].

54. 53 Fed. Reg. 8,666 (Mar. 16, 1988). For example, PRO Manual § 4084 requires that a reconsideration reviewer be a physician who practices in a similar setting to that of the physician being reviewed whenever possible and that the physician be board-certified or board-eligible in the specialty of the reviewed physician. 42 C.F.R. § 473.28

regulations but clearly internal to the PROs, such as the data and reporting requirements appearing in detail in *Manual* Chapter 8. Finally, some *Manual* provisions that have effects external to the PROs differ materially from the PRO regulations.⁵⁵ PRO activities are also affected by provisions in other HCFA manuals, such as the *Medicare Hospital Manual*.⁵⁶

The other central documents governing the PRO program are the PRO scopes of work and PRO contracts. HHS has recently issued the *Third Scope of Work* for the third contract cycle, and last year it issued a separate *Scope of Work* for review of HMOs and CMPs. HHS is currently entering into contracts reflecting the *Third Scope of Work*. The *Scope of Work* specifies in great detail PRO review responsibilities and data requirements and incorporates by reference the PRO statute, regulations, and *PRO Manual*. PRO contracts specify in even greater detail the review responsibilities and specific objectives of individual PROs. Finally, PROs are also governed by a variety of less formal instructions, such as regional medical review letters.

The practice of relying on manual transmittals, program instructions, and contracts in lieu of regulations promulgated through notice and comment rulemaking is not unique to the PRO program. Throughout its administration of the Medicare and Medicaid programs, HHS has often used such materials in preference to rules adopted through the APA notice and comment process.⁵⁷ It is not difficult to understand HHS's preference for issuing instructions informally. Public notice and comment rulemaking has always been burdensome. The requirements of 5 U.S.C. section 553 that the public be given an opportunity to comment on proposed rules, that the agency consider the comments, and that publication of final rules precede their effective date by at least thirty days necessarily slow down the process of implementing policy. Recent restrictions on notice and comment rulemaking, including Executive Orders No. 12,291 and No. 12,498, requiring Office of Management and Budget (OMB) review of some rules, and 5 U.S.C. section 603, requiring regulatory flexibility analyses, have made APA rulemaking increasingly burdensome and time-consuming.⁵⁸ It can easily take a year or more to promulgate a rule under these procedures.⁵⁹ Regulations implementing sections 9401 and 9403 of COBRA '85⁶⁰ have been under consideration for over two years and have only very recently been published as a notice of

currently only requires that the reconsideration physician be a specialist in the type of services under review, though proposed rule 473.28 (proposed on March 16, 1988) is identical to the *PRO Manual* provision.

55. *PRO Manual* § 6025, for example, implements the 1987 HCFA/AMA/AARP compromise on sanction procedures, discussed in Part V below and provides procedural protections to providers and practitioners beyond those specified in 42 C.F.R. pt. 1004.

56. See HEALTH CARE FIN. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., MEDICARE HOSP. MANUAL § 312 (July 1988) (dealing with notices to beneficiaries of PRO review of care) [hereinafter MEDICARE HOSP. MANUAL].

57. See *St. Mary's Hosp. of Troy v. Blue Cross Blue Shield*, 788 F.2d 888 (2d Cir. 1986); *Cubanski v. Heckler*, 781 F.2d 1421 (9th Cir. 1986); *Powderly v. Schweiker*, 704 F.2d 1092 (9th Cir. 1983); *Rio Hondo Memorial Hosp. v. United States*, 689 F.2d 1025 (Ct. Cl. 1982); *Samuels v. Heckler*, 668 F. Supp. 656, 664 (W.D. Tenn. 1986); *New York State Dep't of Social Serv. v. Bowen*, 648 F. Supp. 850 (D.D.C. 1986); *Bond Hosp. Inc. v. Heckler*, 587 F. Supp. 1268, 1272 (D.D.C. 1984), *aff'd*, 762 F.2d 137 (D.C. Cir. 1985); Kinney, *The Medicare Appeals System for Coverage and Payment Disputes: Achieving Fairness in a Time of Constraint*, 1 ADMIN. L.J. 54 (1987).

58. Although Exec. Order No. 12,291, 46 Fed. Reg. 13,193, only requires OMB review of "major rules," in fact OMB reviews all rules proposed by HCFA.

59. DeMuth & Ginsberg, *White House Review of Agency Rulemaking*, 99 HARV. L. REV. 1075, 1159 (1986).

60. COBRA '85, Pub. L. No. 99-272, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 83, 196-200.

proposed rulemaking (NPRM).⁶¹ Given the rapid changes in the Medicare and Medicaid programs generally and in the PRO program in particular, it is not surprising that HHS has sought means other than notice and comment rulemaking for program management.

While HHS's eschewal of notice and comment rulemaking may be understandable, it is not necessarily right. There are sound policy reasons grounding the APA's requirement of notice and comment rulemaking. First, it "reintroduces public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies."⁶² It also assures a prepublication dialogue, which permits persons affected by a rule to educate the agency as to their concerns. This in turn allows the agency to achieve a more rational regulatory scheme or a more intelligible explanation of the scheme it originally proposed.⁶³ It forces the agency to think carefully about its policies, so as to justify them before a skeptical public.⁶⁴ It "assures that the agency will have before it the facts and information relevant to a particular administrative problem, as well as suggestions for alternative solutions."⁶⁵ Finally, public participation in rulemaking contributes to public acceptance of the legitimacy of the regulatory result.⁶⁶ The Administrative Conference of the United States (ACUS) has consistently urged HHS to provide greater opportunity for public comment on its policies for making coverage and payment determinations.⁶⁷

More specifically, the attempts of HHS to govern the PRO program without using the APA rulemaking process have subjected the PROs to a continual and confusing stream of instructions, which have severely hampered their ability to carry out their mandate.⁶⁸ They have also angered the providers and practitioners governed by the program.

In October 1984 an association of those providers, the American Hospital Association (AHA), filed a petition with HHS for rulemaking,⁶⁹ which requested HHS to promulgate comprehensive regulations for the PRO program. When HHS failed to do so, the AHA brought suit claiming that HHS had violated the APA. The District Court for the District of Columbia held that HHS had indeed violated the APA by promulgating the PRO *Scope of Work*, contracts, and several manual transmittals without notice and comment rulemaking.⁷⁰ HHS appealed this determination to the

61. Medicare and Medicaid Programs; Denial of Payment for Substandard Quality Care and Review of Beneficiary Complaints, 54 Fed. Reg. 1956 (1989) (to be codified at various parts of 42 C.F.R.) (proposed Jan. 18, 1989) (proposed rule) [hereinafter PROPOSED SUBSTANDARD CARE REGULATIONS]. See also *infra* Part VI.

62. *Batterton v. Marshall*, 648 F.2d 694, 703 (D.C. Cir. 1980); see also *National Ass'n of Home Health Agencies v. Schweiker*, 690 F.2d 932, 949 (D.C. Cir. 1982), cert. denied, 459 U.S. 1205 (1983).

63. *American Bus Ass'n v. United States*, 627 F.2d 525, 533 (D.C. Cir. 1980).

64. *New Jersey v. Department of Health & Human Servs.*, 670 F.2d 1262 (3rd Cir. 1981).

65. *Guardian Fed. Sav. & Loan v. Federal Sav. & Loan Ins. Corp.*, 589 F.2d 658, 662 (D.C. Cir. 1978).

66. *Chamber of Commerce of the United States v. OSHA*, 636 F.2d 464 (D.C. Cir. 1980).

67. 1 C.F.R. §§ 305.86-5, .87-8 (1987).

68. *Baldwin & Fackelmann, Blizzard of Paperwork, New Rules are Burying PROs and Hospitals*, MOD. HEALTHCARE, Jan. 3, 1986, at 46, 47-48.

69. See 5 U.S.C. § 553(e) (1982).

70. *American Hosp. Ass'n v. Bowen*, 640 F. Supp. 453 (D.D.C. 1986). The court also held two manual transmittals to be valid interpretive rules, not subject to notice and comment rulemaking. This holding was not appealed.

District of Columbia Circuit Court of Appeals, which reversed the district court.⁷¹ The appellate court's majority opinion, written by Judge Wald, found the contract, *Scope of Work*, and manual transmittals to have been covered by exceptions to the APA. Judge Mikva dissented in part, arguing that the challenged contract objectives should have been promulgated through APA rulemaking procedures.⁷² Ultimately, Congress seems to have had the last word, as provisions of the Omnibus Budget Reconciliation Act of 1987 (OBRA '87)⁷³ call for publication of PRO contract provisions, though not necessarily using APA procedures. Before turning to this legislation, the rulemaking requirements of the APA in general, and the interpretation of them in *American Hospital Association v. Bowen* in particular, will be considered in greater detail.

The notice and comment and publication requirements of 5 U.S.C. section 553 are subject to a number of exceptions, several of which arguably apply to the PRO program. Most obviously, section 553 does not apply to "a matter relating to . . . public property, loans, grants, benefits or contracts."⁷⁴ As PROs assist in running a benefit program (Medicare) under contract with HHS, instructions governing the administration of the PRO program would seem to fall within this exception. This exception has been widely criticized as an atavistic survival of simpler days when government benefit programs were uncommon rather than pervasive and when the law still drew a clear line between rights and privileges.⁷⁵ The Secretary of HHS has yielded to these criticisms and voluntarily waived the protection of this exception.⁷⁶ HHS is legally bound by this waiver.⁷⁷

In its brief in *American Hospital*, HHS argued that, even though it has generally waived the APA contract exception, the PRO statute expressly exempts PRO contracts from any APA constraints.⁷⁸ 42 U.S.C. section 1320c-2(e) provides that the Secretary's authority in making PRO contracts is not to be trammelled by "any provision of law relating to the making, performance, amendment, or modification of contracts of the United States."⁷⁹ This provision was adopted by Congress to promote flexibility and avoid restriction of "innovation in new approaches to review."⁸⁰ The D.C. Circuit, however, rejected this argument, noting that the provision exempted PRO contracting from "the vast corpus of law establishing rules regarding the procurement of contracts from the government"⁸¹ and not from the

71. *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037 (D.C. Cir. 1987).

72. *Id.* at 1058-62 (Mikva, J., dissenting).

73. Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, 1987 U.S. CODE CONG. & ADMIN. NEWS (101 Stat.) 1330 [hereinafter OBRA '87].

74. 5 U.S.C. § 553 (1982).

75. See Bonfield, *Public Participation in Federal Rulemaking Relating to Public Property, Loans, Grants, Benefits, or Contracts*, 118 U. PA. L. REV. 540 (1970); 1 C.F.R. § 305.69-8 (1987).

76. 36 Fed. Reg. 2,532 (Feb. 5, 1971).

77. *Herron v. Heckler*, 576 F. Supp. 218, 229 (N.D. Calif. 1983).

78. Brief for Appellant at 35-39, *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037 (D.C. Cir. 1987) (No. 86-5579).

79. 42 U.S.C. § 1320c-2(e) (1982).

80. S. REP. NO. 494, 97th Cong., 2d Sess. 41, 43, reprinted in 1982 U.S. CODE CONG. & ADMIN. NEWS 817-19.

81. *American Hosp.*, 834 F.2d at 1054.

APA. The court noted that nothing in the provision's legislative history indicated that Congress intended to retract HHS's own waiver of the APA contract exemption.⁸²

Because HHS was precluded by its waiver from relying on the grants, benefits, and contracts exception in *American Hospital*, it instead relied primarily on exceptions found in 5 U.S.C. section 553(b)(3)(A) for "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice."⁸³ The law governing these exceptions to the APA is terribly obscure, described by various cases as "tenuous," "blurred," "baffling," and "enshrouded in considerable smog."⁸⁴

In the district court, HHS argued unsuccessfully that the manual instructions were interpretive rules. Interpretive rules are provisions that "merely clarify or explain existing law or regulations."⁸⁵ They track and fine-tune statutory or regulatory requirements or remind regulated individuals or entities of existing duties,⁸⁶ elucidating what an administrative officer thinks a statute or rule means.⁸⁷ They have no independent force of law.⁸⁸

Some provisions of the *PRO Manual*, scopes of work, and contracts merely restate and clarify statutory obligations. Examples include provisions dealing with data confidentiality or disclosure. But most provisions of the *PRO Manual* and contracts address issues not directly covered by statutes and regulations, such as review sampling and data reporting requirements, and thus cannot properly be classified as interpretive rules. The district court in *American Hospital* so held,⁸⁹ and the court of appeals affirmed.⁹⁰

The court of appeals, however, relied on other exceptions found in 5 U.S.C. section 553 to uphold the *PRO Manual* instructions, contract, and *Scope of Work*. First, it held that several manual instructions focusing PRO review on particular objectives were validly exempt from notice and comment rulemaking because they were procedural rules, exempt under 5 U.S.C. section 553(b)(A).⁹¹ The procedural rule exception exists to allow agencies flexibility in arranging their internal operations—"it covers agency actions that do not themselves alter the rights or interests of parties, although it may alter the manner in which parties present themselves or their viewpoints to the agency."⁹² As procedural rules do not directly

82. *Id.*

83. 5 U.S.C. § 553(b)(3)(A) (1982).

84. *See, e.g.,* Community Nutrition Inst. v. Young, 818 F.2d 943, 946 (D.C. Cir. 1987) (and cases cited therein).

85. Alcaraz v. Block, 746 F.2d 593, 613 (9th Cir. 1984) (quoting Powderly v. Schweiker, 704 F.2d 1092, 1098 (9th Cir. 1983)).

86. Cabais v. Egger, 690 F.2d 234, 238 (D.C. Cir. 1982). *See* Assimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 DUKE L.J. 381, 393-97.

87. American Postal Workers Union v. United States Postal Serv., 707 F.2d 548 (D.C. Cir. 1983), *cert. denied*, 465 U.S. 1100 (1984); *In Home Health Care v. Bowen*, 639 F. Supp. 1124 (D.D.C. 1986).

88. Herron v. Heckler, 576 F. Supp. 218, 231 (N.D. Cal. 1983).

89. American Hosp. Ass'n v. Bowen, 640 F. Supp. 453, 462-63 (D.D.C. 1986).

90. American Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1050 (D.C. Cir. 1987).

91. *Id.* at 1049-51.

92. *Batterton v. Marshall*, 648 F.2d 694, 707 (D.C. Cir. 1980) (footnote omitted); *see also* Neighborhood TV Co. v. FCC, 742 F.2d 629 (D.C. Cir. 1984); Mayton, *A Concept of a Rule and the "Substantial Impact" Test in Rulemaking*, 33 EMORY L.J. 889, 900 (1984).

govern public conduct, it is argued, their formation does not require the public participation mandated by the APA.⁹³ In *American Hospital*, Judge Wald articulated the key test for identifying a procedural rule as “whether the agency action also encodes a substantive value judgment or puts a stamp of approval or disapproval on a given type of behavior.”⁹⁴ A rule governing procedure that does not enforce such a substantive value judgment is exempt from APA rulemaking requirements, regardless of its actual impact on the rights of those affected by agency action. This interpretation expands the procedural rule exemption and is at variance with earlier authorities, which placed emphasis on whether the rule in fact had a substantial impact on substantive rights.⁹⁵

Applying this definition of procedural rule, Judge Wald upheld as exempt from APA rulemaking requirements manual provisions establishing sampling procedures for targeting PRO review. This holding is consistent with other cases holding that strategies for enforcement or timing of review are procedural in nature.⁹⁶ It is, however, based on two questionable premises.

First, Judge Wald’s opinion is clearly based on the proposition that PROs are, in effect, agents or extensions of HHS. If the PROs are in reality a part of HHS, the disputed manual transmittals establishing procedures to be used by the PROs in effect dictate the internal procedures of a federal agency.⁹⁷ Following this line of reasoning, Judge Wald posited that any impact of the challenged HHS directives on PROs was not relevant to the question of whether such directives had a sufficiently substantial effect to render them substantive rather than procedural rules.

PROs are, of course, federal entities for some purposes.⁹⁸ But they are also independent, private corporations, contracting to provide a service to the government.⁹⁹ If PROs are part of the federal government solely because they provide a service under contract, so are Medicare carriers and intermediaries and, for that matter, hospitals and physicians who provide services as agents of the government to the ultimate beneficiaries of the Medicare program. In fact, when HHS has engaged in notice and comment rulemaking, it has considered the impact of its rules on PROs as if they were “small entities” under the Regulatory Flexibility Act, thus recognizing their independent existence.¹⁰⁰

It could be argued, of course, that the federal government should be able to deal with its contractors without being bothered by notice and comment rulemaking, and

93. *United States Dep’t of Labor v. Kast Metals Co.*, 744 F.2d 1145 (5th Cir. 1984).

94. *American Hosp.*, 834 F.2d at 1047.

95. *See, e.g., Pickus v. United States Bd. of Parole*, 507 F.2d 1107, 1112–13 (D.C. Cir. 1974).

96. *See International Union, UAW v. Brock*, 783 F.2d 237, 251 n.18 (D.C. Cir. 1986); *Kast Metals*, 744 F.2d at 1145; *Neighborhood TV*, 742 F.2d at 629; *Donovan v. Wollaston Alloys Inc.*, 695 F.2d 1, 9 (1st Cir. 1983); *Davis Walker Corp. v. Blumenthal*, 460 F. Supp. 283 (D.D.C. 1978).

97. *American Hosp.*, 834 F.2d at 1048–49.

98. *See Kwoun v. Southeast Mo. PSRO*, 811 F.2d 401, 407 (8th Cir. 1987), *cert. denied*, 108 S. Ct. 1994 (1988) (holding PSRO officials to be federal officers for application of immunity doctrine in damage action); *Smith v. North La. Medical Review Ass’n*, 735 F.2d 168, 173 (5th Cir. 1984) (holding PSRO to be federal rather than state entity for application of state action requirement).

99. *See supra* notes 7–9 and accompanying text.

100. *See* 53 Fed. Reg. 8,662 (Mar. 16, 1988).

as noted earlier, the APA explicitly exempts from notice and comment rulemaking matters pertaining to government contracts. Yet, HHS has waived the protection of this exemption generally, and this waiver includes within its scope, presumably, HHS's governance of PROs as well as of hospitals. Turning again to the policies underlying the APA notice and comment requirement, PROs indisputably have an interest in participating in the process used for determining their responsibilities and have valuable information to contribute to that process. Thus, Judge Wald's conclusion that the substantive impact of HHS rules on PROs is irrelevant to a consideration of whether such rules are procedural or not is simplistic and probably wrong. The AHA may not have had standing to challenge the effect of HHS's informal policy on the PROs, but this issue is a real one.

Second, Judge Wald's opinion is also based on the notion that manual transmittals directing enforcement strategy have only a minimal impact on hospitals and other providers. Providers, of course, have no legitimate interest in freedom from effective oversight, but they may well have an interest in avoiding enforcement strategies that create excessive burdens¹⁰¹ or that unfairly single out particular classes of providers.¹⁰² Other courts have noted that enforcement strategies may have substantive effects.¹⁰³

HHS did not take the position that its enforcement strategy was secret; indeed, HHS has described this strategy in the *PRO Manual*. Having chosen to make its enforcement strategy public, HCFA would not have suffered a great additional burden in seeking information from the public as to the wisdom of that strategy.

The court of appeals upheld the validity of the *PRO Scope of Work* and contracts under another exception to section 553, the "general statement of policy" exception. This exception to the APA is probably the most mysterious. Cases attempting to explicate it describe "general statements of policy" as akin to press releases, announcing to the public an agency's intention as to what plans and priorities it will seek to establish in the future.¹⁰⁴ Policy statements do not create binding norms that constrain the agency's discretion.¹⁰⁵ They are tentative and do not foreclose agency alternatives or conclusively affect rights.¹⁰⁶ Some cases exclude from this category statements having a substantial impact on substantive rights,¹⁰⁷ while others reject this distinction.¹⁰⁸ Most cases have considered the binding nature of a pronouncement

101. Cf. *Burlington Memorial Hosp. v. Bowen*, 644 F. Supp. 1020 (W.D. Wis. 1986) (considering HCFA's alleged responsibility to reimburse providers for costs of photocopying necessitated by PRO review).

102. See *infra* text accompanying notes 169-70.

103. *Community Nutrition Inst. v. Young*, 818 F.2d 943 (D.C. Cir. 1986); *Estate of Smith v. Bowen*, 656 F. Supp. 1093 (D. Colo. 1987).

104. *Mada-Luna v. Fitzpatrick*, 813 F.2d 1006, 1013 (9th Cir. 1987); *Pacific Gas & Elec. Co. v. Federal Power Comm'n*, 506 F.2d 33, 38 (D.C. Cir. 1974).

105. *Mada-Luna*, 813 F.2d at 1014.

106. *Batterton v. Marshall*, 648 F.2d 694, 702 (D.C. Cir. 1980).

107. *W.C. v. Bowen*, 807 F.2d 1502 (8th Cir. 1987); *Pickus v. United States Bd. of Parole*, 507 F.2d 1107, 1112 (D.C. Cir. 1974).

108. *Jean v. Nelson*, 711 F.2d 1455 (11th Cir. 1982), *aff'd*, 472 U.S. 846 (1985). See also Note, *An Analysis of the General Statement of Policy Exception to Notice and Comment Procedures*, 73 Geo. L.J. 1007 (1985) (arguing for both a binding norm and substantial effect test).

to be decisive in determining whether it is a "general statement of policy" or not.¹⁰⁹ Policy statements that narrow the field of vision of a decisionmaker, minimizing the influence of some factors and encouraging decisive reliance on other factors that might not have been decisive had rulemaking procedures been followed, must be promulgated as rules.¹¹⁰

Judge Wald's position that PRO scopes of work are general statements of policy is certainly plausible. They are, after all, primarily statements by HHS of what it hopes to achieve through its contracts. The court's holding that PRO contracts are mere general statements of policy, however, is more questionable. In particular, the court's argument that objectives found in the contracts are not binding upon the PROs and thus will have no substantial effect on the PRO application of standards in necessity and quality review seems highly suspect. One of the primary arguments relied on by Congress for replacing the PSRO program with the PRO program was that the PROs would be more effective in controlling utilization and quality precisely because they would be held to their contractual objectives under threat of nonrenewal.¹¹¹ In fact, some PRO contracts were not renewed after the first contract cycle because the PROs failed to meet contract objectives,¹¹² and HCFA's evaluation of PROs for renewal of contracts in the second cycle relies heavily on the PROs' contractually assumed review activities.¹¹³ Indeed, when HHS has engaged in rulemaking, it has acknowledged the significant effects that review of PROs pursuant to their contracts will have on providers, practitioners, and beneficiaries.¹¹⁴ It is disingenuous for HHS to say, therefore, that PRO contracts have no binding effect on the PROs and thus no impact on beneficiaries or providers.

Judge Mikva, in dissent, pointed persuasively to the analogy between the PRO contract objectives and efforts of the Social Security Administration to target its review on ALJs who granted a disproportionate number of disability awards. This effort was held earlier by the Ninth Circuit to be subject to APA rulemaking requirements because it effectively discouraged disability awards.¹¹⁵ Similarly, PRO contract objectives undoubtedly have an impact on PRO payment denials, which in turn affect provider and physician behavior and, ultimately, the services received by Medicare beneficiaries.

All of this is not to say that Judge Wald's opinion reaches the wrong conclusion. If its legal foundations are questionable, its result is certainly politic. In creating the PRO program, Congress intended to establish a system that could respond rapidly, flexibly, and creatively to developments in the delivery of health services. To impose

109. See *Community Nutrition Inst. v. Young*, 818 F.2d 943, 946-48 (D.C. Cir. 1987); *Telecommunications Research & Action Center v. FCC*, 800 F.2d 1181, 1186 (D.C. Cir. 1986); *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533 (D.C. Cir. 1986) (use of permissive or mandatory language may be decisive); *American Bus Ass'n v. United States*, 627 F.2d 525, 529 (D.C. Cir. 1980).

110. *Pickus*, 507 F.2d at 1113.

111. See S. REP. NO. 494, 97th Cong., 2d Sess. 41, reprinted in 1982 U.S. CODE CONG. & ADMIN. NEWS 781, 817; 42 U.S.C. § 1320c-2(c)(7) (1982).

112. *Growing Contract Denials Dispirit the Nation's PROs*, HOSPITALS, May 20, 1986, at 28.

113. OIG EFFECTIVENESS REPORT, *supra* note 9, at 21.

114. 50 Fed. Reg. 15,322-25 (Apr. 17, 1985).

115. *W.C. v. Bowen*, 807 F.2d 1502 (8th Cir. 1987).

on this program the cumbersome requirements of APA notice and comment rulemaking, with its encrustation of OMB oversight, would seriously impede the implementation of this intent, as evidenced by the delay attendant to promulgation of the substandard care denial and second opinion rules mandated by COBRA '85, which have just reached the NPRM stage.¹¹⁶ It would be particularly unfortunate if both the PRO scopes of work and contracts were forced to go through separate, largely redundant rulemaking proceedings that involve four separate Federal Register publications. Nevertheless, as has been pointed out, the *American Hospital* case imposes a very expansive reading on the APA exceptions and gives inadequate scope to the policies supporting notice and comment rulemaking.

As was stated at the outset, Congress has had the last word on this question, at least for now. Several sections of OBRA '87 attend to earlier recommendations of ACUS that HHS take a more public posture in formulating its policies governing the Medicare program.¹¹⁷ Section 4035(b), for example, provides:

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation¹¹⁸

The amended statute further requires the Secretary to permit at least sixty days for public comment on rules so promulgated.¹¹⁹ Under language adopted by OBRA '86, this provision does not apply when statutes require implementation of a rule with a shorter comment period or within a period of less than 150 days or when the APA good cause exception applies.¹²⁰ In effect, these provisions explicitly forbid the Secretary from revoking HHS's waiver of the APA contracts and benefits exception and bind HHS to APA rulemaking when its instructions to the PROs have substantive impact. These provisions do not, however, reverse *American Hospital*, which specifically found that the challenged provisions did not have substantive impacts. Other provisions of OBRA '87, however, do affect the *American Hospital* result.

First, section 4035(c)(1) requires HHS to publish every three months "a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability" that are promulgated to carry out the Medicare program but are not promulgated as rules and have not been published in an earlier list.¹²¹ This provision assures that the public will at least be made aware of HHS instructions affecting the PRO program. More specifically relevant to PROs, section 4091

116. COBRA '85, Pub. L. No. 99-272, §§ 9401, 9403, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 83, 196-200. See *supra* note 61 and *infra* Part VI.

117. See 1 C.F.R. §§ 305.86-6, .87-8 (1987).

118. OBRA '87, Pub. L. No. 100-203, 1987 U.S. CODE CONG. & ADMIN. NEWS (101 Stat.) 1330, 1330-78 (to be codified at 42 U.S.C. § 1395hh(a)(2)).

119. 42 U.S.C. § 1395hh(b)(1) (Supp. IV 1986).

120. *Id.* § 1395hh(b)(2).

121. OBRA '87, Pub. L. No. 100-203, 1987 U.S. CODE CONG. & ADMIN. NEWS (101 Stat.) 1330, 1330-78 (to be codified at 42 U.S.C. § 1395hh(c)(1)).

provides that “[t]he Secretary shall publish in the Federal Register any new policy or procedure adopted by the Secretary that affects substantially the performance of contract obligations under 42 U.S.C. § 1320c-2 [authorizing contracts with PROs] not less than 30 days before the date on which such policy or procedure is to take effect.”¹²² It further requires that “[t]he Secretary shall publish in the Federal Register the general criteria and standards used for evaluating the efficient and effective performance of [PRO] contract obligations . . . and shall provide opportunity for public comment with respect to such criteria and standards.”¹²³

These provisions make considerable progress toward solving the problem addressed by *American Hospital*. First, they support the court’s conclusion that many HHS policies and procedures affecting PROs, and specifically the criteria and standards for evaluating PRO performance, are not subject to the full panoply of procedures that accompany APA rulemaking. The statute does not designate these criteria and standards as “rules” subject to the prepublication requirements of Executive Order No. 12,291 or No. 12,498 or 5 U.S.C. sections 601 through 612. Rather, it simply calls for publication of the criteria and standards in the Federal Register and for an opportunity for comment. This should significantly enhance the ability of HHS to respond flexibly to the complexity and volatility of the issues raised by the PRO program.

Second, these sections nonetheless affirm Congress’ commitment to the principles that undergird notice and comment rulemaking. HHS should interpret these provisions liberally to honor this commitment. In particular, HHS should construe the amendments to require publication for comments of proposed scopes of work. The scope of work is the most basic document used to evaluate contract proposals and is thus ultimately used to judge contract performance. Even though scopes of work are arguably, as the D.C. Circuit held, statements of policy rather than rules, they have a substantial effect on the PRO program and should be promulgated pursuant to notice and comment procedures.

Drafts of proposed scopes of work have in the past apparently been leaked to interested parties before publication. Indeed, a notice of the availability of the *Second Scope of Work* was published in the Federal Register, and HHS received comments on it.¹²⁴ HHS would suffer no significant additional burden in sharing them with the public generally for comments. With the PRO contract cycle expanded to three years, HHS should find that it has ample time to publish proposed scopes of work for comment.

In accordance with the requirements of OBRA ’87, HCFA published a summary of the *Third Scope of Work* as a notice in the Federal Register on September 12, 1988.¹²⁵ This summary was only published, however, after contracts were already being negotiated to implement the *Third Scope of Work*. Moreover, HCFA did not

122. *Id.* at 1330-134 (to be codified at 42 U.S.C. § 1320c-2). This paragraph, like the provisions relating to regulations mentioned above, does not apply when inconsistent with a statutory deadline.

123. *Id.*

124. 50 Fed. Reg. 46,702 (Nov. 12, 1985) (comments due by Nov. 27, 1985).

125. 53 Fed. Reg. 35,234 (Sept. 12, 1988).

solicit comments on it. While publication of the summary is a positive step, HCFA should do more to involve interested parties in the process of devising scopes of work.

Third, these statutes clarify the status of PROs in their relationship to HHS. The statutes reject Judge Wald's position that PROs are mere tools of the federal government, no more entitled to an opportunity to participate in policymaking than a low level government employee. They recognize rather the quasi-independent nature of PROs and their right to notice and an opportunity to comment on the criteria under which their performance will be evaluated and to some notice before changes are made in their contract obligations.¹²⁶

Fourth, these provisions focus on the appropriate level for public participation in policymaking. HHS is required to publish policies and procedures "substantially" affecting performance of contract obligations and "general" criteria and standards. The public should be made aware of and allowed to participate in the formulation of broad policy; the minutiae, however, should be left to HHS. In particular, this language should be understood not to require publication of individual contracts. The intention of Congress in establishing the PRO program, evidenced in 42 U.S.C. section 1320c-2, was to run the program through bid contracts. It is difficult to conceive of how competitively bid contracts can be subjected to notice and comment rulemaking. Moreover, if a scope of work has been run through the notice and comment process, there is little need for individual contracts, which reflect the scope of work, to be run through a similar process. Despite arguments made earlier that the PRO contracts resemble legislative rules, the result arrived at by a combination of the *American Hospital* decision and the OBRA '87 requirements—that the scopes of work be published for notice and comment rulemaking, but contracts need not be—seems the most workable result.

Finally, the provisions requiring notice and comment proceedings are rendered inapplicable when they conflict with statutory deadlines. Thus, they withhold from HHS any excuse for further foot-dragging in complying with statutory mandates.

IV. ISSUES CONCERNING PRO CRITERIA, NORMS, AND STANDARDS

The previous Part considered the rules under which HHS governs the PRO program. Each PRO, however, also has its own "rules," by which it governs the providers, physicians, and beneficiaries under its jurisdiction. Among the most important of these are the criteria, norms, and standards reviewers use to identify utilization or quality problems.

The concepts of criteria and norms have evolved over time. The initial vision of the PSRO program was that PSROs would develop objective norms against which the performance of providers and physicians could be reviewed. To quote from the legislative history:

126. See OIG EFFECTIVENESS REPORT, *supra* note 9, at iii, v (concurring with the need for this change).

The review process would be made more sophisticated through the use of professionally developed regional norms of diagnosis and care as guidelines for review activities, as opposed to the present usage of arbitrarily determined checkpoints. The present review process, without such norms, becomes a long series of episodic case-by-case analyses on a subjective basis which fail to take into account in a systematic fashion the experience gained through past reviews or to sufficiently emphasize general findings about the pattern of care provided.¹²⁷

Such regional norms, under the original PSRO legislation, were to be informed by national norms developed by a National Professional Standards Review Council. The goal was to develop objective standards of care accepted nationally.¹²⁸

Though the dream of objective national standards for evaluating the quality and effectiveness of medical care continues to inspire scholars,¹²⁹ and remains high on the research agenda of HHS,¹³⁰ PROs have reconciled themselves to the real world where such ideal standards do not generally exist.

To function in such a world, PROs use two kinds of norms for evaluating care. First, they use written screening criteria, applied by nonphysician professional record reviewers (usually nurses), to identify potential quality and utilization problems. All PROs must use utilization, quality, and discharge screens.¹³¹ PROs must use HHS generic quality screens for evaluating quality problems.¹³² These screens look for problems such as death during or following surgery, nosocomial infection, trauma suffered in the hospital, or discharge of a patient with an inappropriately elevated temperature, high blood pressure, or depressed pulse.¹³³ PROs are also to apply their own criteria screens to identify premature discharges, unnecessary admissions, inappropriate performance of invasive procedures, and, for PPS hospitals, improper assignment of DRGs.¹³⁴ Most PROs, including all but one of the PROs with which I spoke, use an adapted version of the ISD-A¹³⁵ criteria developed by InterQual for making medical necessity and appropriateness determinations.¹³⁶ This system considers the intensity of services delivered to patients, the severity of the patient's condition, the patient's stability at discharge, and the use of special care units and clinical support services to determine the necessity and appropriateness of care.¹³⁷

127. SENATE COMM. ON FIN., S. REP. NO. 1230, 92d Cong., 2d Sess. 257 (Sept. 26, 1972).

128. See Chenen, *PROs and Poor Quality Medical Care—They Can't Sanction It Until They Define It!*, 2 MED. STAFF COUNS. 25 (Spring 1988).

129. See, e.g., Dubois & Brook, *Assessing Clinical Decision Making: Is the Ideal System Feasible?*, 25 INQUIRY 59 (Spring 1988); Eddy & Billings, *The Quality of Medical Evidence: Implications for Quality of Care*, 7 HEALTH AFF. 19, 29-30 (Spring 1988); Wennberg, *Improving the Medical Decision-Making Process*, 7 HEALTH AFF. 99 (Spring 1988).

130. GAO, *supra* note 31, at 144-56.

131. THIRD SCOPE OF WORK, *supra* note 3, § XIII, at 27-29.

132. *Id.*, Attach. 1.

133. *Id.* (Generic Quality Screens, Hospital Inpatient).

134. *Id.* § IV, at 3-5.

135. Intensity, severity, diagnosis—appropriateness.

136. See AMA, PEER REVIEW ORGANIZATION (PRO EXECUTIVE) SURVEY Table 8 (1987) [hereinafter AMA PRO EXECUTIVE SURVEY]; GAO, *supra* note 31, at 46-51. For an example of PRO screening criteria, see Black, *Impact of PROs on Hospitals and Pharmacy Practice*, 44 AM. J. HOSP. PHARMACY 77, 79 (Jan. 1987).

137. PROSPECTIVE PAYMENT ASSESSMENT COMM'N, A STUDY OF THE PREADMISSION REVIEW PROCESS 1-2 (Dec. 1987).

Second, once problems are identified by nurse reviewers, physician reviewers apply their own judgment, using implicit unarticulated standards, to evaluate the quality or necessity of the care rendered.¹³⁸ It is ultimately on the basis of these judgments that PROs deny payment to or sanction providers. Because of the potential subjectivity of this system, PROs rely heavily on repetitive review to assure accuracy and fairness. An AMA survey, for example, determined that, depending on the PRO, between three and thirty-five physicians will review a case before an initial sanction letter is sent. The mean number of reviewers was ten; the median was seven.¹³⁹ Thus, although PROs do not apply written criteria in making their final decisions, they do seek a consensus medical judgment that transcends the subjective judgment of individual reviewers.

The concepts of criteria, norms, and standards are defined in the PRO statute and regulations. 42 U.S.C. section 1320c-3(a)(6) mandates that PROs:

shall . . . apply professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice within the geographic area served by the organization as principal points of evaluation and review, taking into consideration national norms where appropriate. Such norms with respect to treatment for particular illnesses or health conditions shall include—(i) the types and extent of health care services, which, taking into account differing, but acceptable, modes of treatment and methods of organizing and delivering care, are considered within the range of appropriate diagnosis and treatment of such illness or health condition, consistent with professionally recognized and accepted patterns of care; and (ii) the type of health care facility which is considered, consistent with such standards, to be the type in which health care services which are medically appropriate for such illness or condition can most economically be provided.¹⁴⁰

While the PRO statute speaks only of norms, implicit in it is the distinction made by the current PRO regulations among criteria, norms, and standards. Norms are defined as “numerical or statistical measures of average observed performance in the delivery of health care services.”¹⁴¹ Criteria are “predetermined elements of health care, developed by health professionals relying on professional expertise, prior experience, and the professional literature, with which aspects of quality, medical necessity, and appropriateness of a health care service may be compared.”¹⁴² Standards are defined as “[p]rofessionally developed expressions of the range of acceptable variation from a norm or criterion.”¹⁴³ In short, norms represent the real, criteria the ideal, and standards the acceptable deviations from either the real or the ideal.¹⁴⁴

This neat distinction among norms, standards, and criteria becomes blurred in section 466.100, which delineates the use of norms, criteria, and standards. First,

138. The term “standards” is used in a generic rather than a technical sense, as defined below (*see infra* text accompanying notes 141–44).

139. See AMA PRO EXECUTIVE SURVEY, *supra* note 136, Table 11.

140. 42 U.S.C. § 1320c-3(a)(6) (1982).

141. 42 C.F.R. § 466.1 (1987).

142. *Id.*

143. *Id.*

144. See A. GOSFIELD, PSRO'S: THE LAW AND THE HEALTH CONSUMER 34–35 (1975) (further exploring this distinction).

section 466.100(c) requires PROs to “[e]stablish written criteria based upon typical patterns of practice in the PRO area, or use national criteria where appropriate.”¹⁴⁵ Typical practice patterns, of course, should be reflected in norms, not criteria, given the definitions of the regulations. Section 466.100(a) requires use of “national, or where appropriate, regional norms in conducting review to achieve PRO contract objectives.”¹⁴⁶ Section 466.100(b) requires the use of criteria to review patient care in health facilities to determine the necessity of admission, of continuing stay for day outliers,¹⁴⁷ or of surgical and other invasive diagnostic and therapeutic procedures, and to determine the appropriateness of providing care in particular types of facilities. Finally, section 466.100(d) permits the use of variant criteria and standards to evaluate care in particular locations and facilities if the patterns of practice in them are substantially different from practice in the rest of the PRO area and there is a reasonable basis for the variation.

Amendments to the PRO regulations proposed on March 16, 1988, will modify the rules in three important respects. First, they make it clear that norms are used by nonphysician health care professionals, who screen medical records and refer cases that fail the screens to physicians for a final determination. Second, they specify that criteria are to be used for reviewing for the quality as well as the necessity and appropriateness of norms. Finally, they eliminate the notion of standards (that is, acceptable deviations from norms and criteria), noting that PROs in fact have not adopted standards.¹⁴⁸

Several important issues have arisen concerning the application of PRO norms and criteria. First, a continuing dispute exists as to whether the norms and criteria applied by PROs are sufficiently definite to give adequate notice to those who are sanctioned or denied payment by the PROs. Second, differences of opinion exist as to what extent local or regional practice variations should be accommodated by PRO norms. Third, there is controversy as to what extent PRO utilization norms should accommodate social, as opposed to medical, needs for care. Finally, debate continues as to what processes should be used to assure the participation of relevant parties in the formation of PRO norms and to make final norms available to such parties.

A. *Are PRO Norms and Criteria Sufficiently Definite?*

Administrative law has long struggled with the question of whether standards must be prospectively articulated with precision before they can be enforced. There is much to be said for administrative agencies governing through precise and objective written rules. Objective written standards provide guidance to the regulated agencies in planning conduct and thus assure greater voluntary compliance with

145. 42 C.F.R. § 466.100(c) (1987).

146. It further specifically requires the use of national norms to determine the number of procedures selected for preadmission review, a requirement that would be omitted by the proposed regulations, as it does not reflect current PRO practice. See proposed rule § 466.100, 53 Fed. Reg. 8,660, 8,666 (Mar. 16, 1988).

147. Outliers are patients who require hospitalization for periods of time significantly longer than those contemplated by PPS and for whom hospitals receive extra reimbursement.

148. 53 Fed. Reg. 8,654, 8,660, 8,666 (Mar. 16, 1988).

requirements. They also focus and facilitate judicial and political review and generally cabin administrative discretion.¹⁴⁹ ACUS has long supported prospective articulation of agency policies.¹⁵⁰ Courts have on occasion struck down agency actions wholly unfettered by written standards.¹⁵¹

Formulating precise and objective rules, however, may place inordinate demands on agency resources and may result in rules that are too complicated or that are over- or under-inclusive.¹⁵² The Supreme Court has on several occasions permitted agencies to make policy on a case-by-case basis rather than through prospective rulemaking.¹⁵³ And courts have been notably reluctant to strike down standards propounded by agencies as unconstitutionally vague, at least when neither first amendment rights nor criminal prosecutions were involved.¹⁵⁴ This is particularly true where industry or professional practice assists in understanding an imprecise rule.¹⁵⁵

The federal statute and regulations defining conduct sanctionable under the PRO program are remarkably imprecise. 42 U.S.C. section 1320c-5, for example, provides that practitioners or providers have an obligation to assure that services “(1) will be provided economically and only when, and to the extent, medically necessary; and (2) will be of a quality which meets professionally recognized standards of health care.”¹⁵⁶ Practitioners or providers may be sanctioned if they fail “in a substantial number of cases substantially to comply” or in one or more instances “grossly and flagrantly” violate these obligations.¹⁵⁷ The PRO regulations further define “gross and flagrant violation” to mean “[a] violation of an obligation [that] has occurred in one or more instances which presents an imminent danger to the health, safety or well-being of a Medicare beneficiary or places the beneficiary unnecessarily in high-risk situations.”¹⁵⁸ “Substantial violation in a substantial number of cases” is defined as “a pattern of care [that] 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.”¹⁵⁹ These federal standards are fleshed out through objective screening criteria and subjective reviewer judgments at the PRO level.

149. Diver, *Agency Articulation of Policy*, 1983 ADMIN. CONF. OF THE UNITED STATES 390-91; Berg, *Reexamining Policy Procedures: The Choice Between Rulemaking and Adjudication*, 38 ADMIN. L. REV. 149, 163 (1986).

150. See 1 C.F.R. § 305.71-3 and other ACUS recommendations cited by Diver, *supra* note 149, at 389-90.

151. *Morton v. Ruiz*, 415 U.S. 199 (1974); *D & W Food Center v. Block*, 786 F.2d 751, 757 (6th Cir. 1986); *White v. Roughton*, 530 F.2d 750 (7th Cir. 1976); *Holmes v. New York City Housing Auth.*, 398 F.2d 262 (2d Cir. 1968).

152. Diver, *supra* note 149, at 397-98, 505-06, 508-09.

153. *NLRB v. Bell Aerospace Co.*, 416 U.S. 267 (1974); *NLRB v. Wyman Gordon Co.*, 394 U.S. 759 (1969). See also Scalia, *Back to Basics: Making Law Without Making Rules*, 5 REGULATION 25 (July/Aug. 1981).

154. *United States v. Sun Sport Imports Ltd.*, 725 F.2d 184 (2d Cir. 1984); *Vorbeck v. Schnicker*, 660 F.2d 1260 (8th Cir. 1981), *cert. denied*, 455 U.S. 921 (1982). See *Village of Hoffman Estates v. The Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 498 (1982).

155. *PBR Inc. v. Secretary of Labor*, 643 F.2d 890 (1st Cir. 1981); *Brass Plating Co. v. Town of Windsor*, 639 F. Supp. 873 (D. Conn. 1986).

156. 42 U.S.C. § 1320c-5(a)(1)-(2) (1982). The section further requires that providers and practitioners be able to supply evidence of the necessity and quality of services provided.

157. *Id.* § 1320c-5(b)(1)(A), (B).

158. *Id.*

159. 42 C.F.R. § 1004.1 (1987).

The federal PRO statute and regulations have been upheld repeatedly against vagueness challenges.¹⁶⁰ The Fourth Circuit in *Varandani v. Bowen* noted: "The definition of adequate medical care cannot be boiled down to a precise mathematical formula; it must be grounded in what, from time to time, other health professionals consider to be acceptable standards of health care."¹⁶¹ The First Circuit Court of Appeals in *Doyle v. Bowen* further noted that "[t]o the medical profession, which will administer this [federal] standard, it has a reasonably clear meaning."¹⁶²

Nonetheless, physicians sanctioned under the Medicare program, and many of the provider attorneys with whom I spoke, have complained about the lack of precision in PRO criteria for evaluating the necessity and quality of medical care.¹⁶³ While ALJs hearing PRO sanction cases have not rejected PRO sanctions solely because of the imprecision of PRO standards, they have called for more objective, clear, and appropriate standards.¹⁶⁴ On the other hand, some provider associations that I interviewed expressed continuing concern about reducing the practice of medicine to a "cookbook," which ignores the art necessarily involved in medical practice.¹⁶⁵ Devising a definitive and precise formula for evaluating medical practice may be an impossible dream in any event—a recent article that proposed use of Bayesian analysis for devising criteria maps for analyzing patient diagnosis noted that a complete system would include over ten billion pathways of analysis for common medical problems.¹⁶⁶ Some room must be left for informed judgment.

HHS and the PROs continue to attempt to devise more objective criteria for evaluating the effectiveness and quality of medical care. The generic screening criteria uniformly used by the PROs represent one such attempt. Reviews of these criteria are generally positive.¹⁶⁷ HHS has also proposed that more explicit criteria be developed for particular conditions before the denial of payment for substandard care program, mandated by COBRA '85, is implemented.¹⁶⁸ At the PRO level, the

160. *Doyle v. Bowen*, 848 F.2d 296, 301 (1st Cir. 1988); *Varandani v. Bowen*, 824 F.2d 307, 311–12 (4th Cir. 1987); *Association of Am. Physicians & Surgeons v. Weinberger*, 395 F. Supp. 125, 138 (N.D. Ill. 1975).

161. *Varandani*, 824 F.2d at 312.

162. *Doyle*, 848 F.2d at 301; see also *In re Lifshutz*, No. 000-44-7020, 11–13 (Mar. 25, 1988) (ALJ opinion holding that PROs need not apply written criteria, norms, and standards in sanctioning physician).

163. The interviews conducted by the author were generally carried out under an understanding that the identity of interviewees would be kept confidential, so interviewees are not identified here. For published statements to the same effect, see generally Chenen, *supra* note 128; *Hearings on the Peer Review Organization Program Before the Subcomm. on Health and the Env't of the House Energy & Commerce Comm.*, 100th Cong., 1st Sess. 7–9 (1987) (statement of AHA).

164. *In re Greene*, No. HIX-000-00-0219, 8–20 (Dec. 29, 1987); *In re Apakupakul*, No. HIX-000-34-7009, 32–33 (June 1, 1987) (charges too vague).

165. See *Interpreting PSRO "Norms of Care"—Cookbook Medicine or Textbook Medicine?*, AM. MED. NEWS, May 20, 1974, at 21; *PROs, Medical Societies Must Play a Role*, THE INTERNIST, Apr. 1985, at 9.

166. Dubois & Brook, *supra* note 129, at 63.

167. See OFFICE OF INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVS., THE UTILIZATION AND QUALITY CONTROL PEER REVIEW ORGANIZATION (PRO) PROGRAM, QUALITY REVIEW ACTIVITIES 12 (1988) [hereinafter OIG QUALITY REPORT]; Slide Presentation on Quality Assurance, Ernst & Whinney, Slide K-18 (1987 survey results).

168. HEALTH CARE FIN. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., REGULATIONS ON DENIAL OF PAYMENT FOR SUBSTANDARD QUALITY CARE (draft) A12–13 (Feb. 29, 1988) [hereinafter HCFA REGULATIONS]; PROPOSED SUBSTANDARD CARE REGULATIONS, *supra* note 61, at 1958–59, 1963 (to be codified at 42 C.F.R. pt. 462, § 466.100(c) (establishment of criteria and standards)).

Pennsylvania PRO has been experimenting with computerizing its screening criteria, which presumably would require greater precision.

HHS and the PROs should continue to press forward toward formulating more objective and precise necessity and quality criteria when it is possible to do so with the support of scientific evidence and the consensus of the medical community. Until such criteria become feasible, however, the program will continue to have to live with relatively imprecise criteria that are applied to individual cases through the judgment of physician reviewers.

B. *Local or National Norms*

One of the most politically controversial issues affecting the PROs has been whether norms and criteria used for evaluating medical care should be national in scope or whether local practice variations should be accommodated. From 1985 to 1987, 63% of physicians recommended by PROs for sanctions and 65% of the physicians sanctioned by the OIG were from rural areas, despite the fact that only 11% of physicians in the United States practice in rural areas.¹⁶⁹ While there is no consensus as to why this has been true, it has clearly raised the ire of rural practitioners and their patients, who believe that rural physicians are sanctioned disproportionately because PROs depend on reviewers from urban areas who do not understand the practice of medicine in rural areas.¹⁷⁰

It has long been known that there are substantial variations in medical practice between different communities,¹⁷¹ a fact recognized, at least intuitively, in the old malpractice locality rule. On the other hand, there is a certain plausibility to the argument (which has largely won the day in malpractice litigation) that local standards often reflect poor quality care and that a national standard, adjusted for local variations in access to medical resources, is more appropriate. A broken hip or heart attack in rural Texas is, after all, physiologically identical to one in Boston.¹⁷²

From the beginning, the PRO statute recognized that there may be local or regional variations in acceptable norms of treatment and that the PROs should take these into account. The PRO regulations permit the use of variant norms to accommodate local variations in practice.¹⁷³ PRO Interim Manual Transmittal IM-87-1¹⁷⁴ requires PROs, whenever possible, to use physician reviewers who practice in settings similar to that of the physician under review and specifically to use

169. OIG SANCTION REPORT, *supra* note 6, App. XI, Table D. *See id.* at 20 (speculating as to the reasons for this).

170. *See Hearings on Peer Review Organizations, Health and the Env't Subcomm. of the House Energy and Commerce Comm.*, 100th Cong., 1st Sess. 30 (1987) (statement of Rep. Boulter); Reinhold, *Quality-Care Reviews Hurting Rural Doctors*, N.Y. Times, Mar. 24, 1987, at A1, col. 3.

171. Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, 3 HEALTH AFF. 6 (Summer 1984).

172. *See Hall v. Hilbun*, 466 So. 2d 856 (Miss. 1985); Letter from John C. Rother, for the Am. Ass'n of Retired Persons, to William Roper, Administrator, HCFA, at 5 (May 16, 1988) (commenting on March 16, 1988, proposed PRO regulations) ("AARP firmly believes that the standard of care must not change from location to location, although allowance may be made for resource availability.").

173. 42 C.F.R. § 466.100(d) (1987).

174. PRO MANUAL, *supra* note 53, § 3015 (Apr. 1987).

rural physicians to review the work of rural physicians.¹⁷⁵ At least one court has determined that a physician who argued that a PRO must use rural standards in sanctioning a rural physician raised a sufficiently substantial question to secure a preliminary injunction.¹⁷⁶ This interpretation of the PRO legislation was followed by the ALJ in that case on remand.¹⁷⁷ Finally, OBRA '87 further accommodates local practice variations by requiring PRO consideration of the "special problems associated with delivering care in remote rural areas"¹⁷⁸ and by mandating on-site review of at least 20% of the rural hospitals in a PRO's area.¹⁷⁹

In practice, PROs are increasingly sensitive to the concerns of rural practitioners. None of the PROs I interviewed had special criteria sets for regional areas, but all tried to use rural reviewers for rural providers and physicians. The OIG sanction activity investigation found that 63% of those interviewed believed there was no bias against rural physicians and providers in PRO quality review activities.¹⁸⁰

While substantial political and, perhaps, medical arguments can be made both for and against the use of local or national standards, little can be said about the issue from an administrative law perspective. One point, however, should be made (and here this Article briefly gets ahead of itself). OBRA '87 provides that before HHS can exclude a provider or practitioner located in a rural health manpower shortage area or in a county with a population of less than 70,000 from the Medicare program, the provider or practitioner must be afforded a hearing, at which HHS must prove by a preponderance of the evidence that the provider or practitioner will pose a serious risk to beneficiaries if allowed to continue in the program.¹⁸¹ As of late October 1988 three exclusions appealed under this procedure had been stayed (two by consent of the OIG), and two others remained pending.¹⁸² None of the contested cases has been decided within forty-five days. Thus, prehearing exclusions of rural practitioners from the program have effectively halted.

The appropriate procedure for sanctioning physicians or providers is an important issue and will be discussed below. Whatever procedure is appropriate, however, fundamental constitutional notions of equal protection and administrative law principles of fairness demand that the same procedure be applied both to rural and urban practitioners. There are arguments, of course, for applying more favorable procedures in rural areas: there is the charge of PRO bias against rural practitioners and the concern that beneficiaries in rural areas may have no alternatives if the sole

175. Proposed rule § 466.98 also adopts this policy. 53 Fed. Reg. 8,665 (Mar. 16, 1988). A recent GAO report found that only about half of PRO reviews of cases handled by rural physicians were in fact reviewed by rural practitioners at the initial review stage. GAO, MEDICARE PROS: EXTREME VARIATIONS IN ORGANIZATIONAL STRUCTURE AND ACTIVITIES 21 (1988) [hereinafter GAO MEDICARE PROs].

176. *Greene v. Bowen*, 639 F. Supp. 554 (E.D. Cal. 1986).

177. *In re Greene*, No. HIX-000-00-0219, at 15, 20 (Dec. 29, 1987).

178. OBRA '87, Pub. L. No. 100-203, § 4094(a), 1987 U.S. CODE CONG. & ADMIN. NEWS (101 Stat.) 1330, 1330-136.

179. *Id.* § 4094(b), 1987 U.S. CODE CONG. & ADMIN. NEWS (101 Stat.) 1330, 1330-137.

180. OIG SANCTION REPORT, *supra* note 6, at 19.

181. 42 U.S.C. § 1320c-5(b)(5) (1982).

182. Telephone interview with William Libercci, Office of Inspector General, U.S. Dep't of Health & Human Servs. (Oct. 31, 1988).

provider or practitioner in the area is excluded from the Medicare program. But the charge of bias has been generally rejected, and potential bias problems can be addressed through less drastic means, such as requiring the use of rural physicians to review care delivered in rural areas. The OIG already considers “the availability of alternative sources of services in the community”¹⁸³ in determining whether or not to exclude a provider or practitioner. Neither problem is serious enough to justify supplying rural practitioners and providers with radically different procedural protections than those offered others.¹⁸⁴ Congress, therefore, should repeal this provision.

C. *Consideration of Social Criteria*

One of the major tasks of the PRO program is “appropriateness” review—determining whether care provided on an inpatient basis could have been provided more appropriately through less expensive outpatient treatment.¹⁸⁵ A procedure generally appropriate for outpatient care considering only medical factors may in a particular case be inappropriate because of the social characteristics of the patient or situation. One interviewee, for example, recounted the experience of a patient who traveled from her home in rural North Dakota several hundred miles to Minneapolis to be hospitalized for a medical procedure, only to be told on arrival that she would have to leave the hospital immediately after the procedure was done because the PRO would only permit it to be done on an outpatient basis.¹⁸⁶ Section 4094(a) of OBRA '87 provides that PROs:

shall take into account the special problems associated with delivering care in remote rural areas, the availability of service alternatives to inpatient hospitalization and other appropriate factors (such as the distance from a patient's residence to the site of care, family support, availability of proximate alternative sites of care, and the patient's ability to carry out necessary or prescribed self-care regimens) that could adversely affect the safety or effectiveness of treatment provided on an outpatient basis.¹⁸⁷

While there are substantial arguments for the consideration of social factors in determining the appropriateness of outpatient care (or, for that matter, in determining the appropriateness of hospital discharges), implementation of this provision will

183. 42 C.F.R. § 1004.80(e) (1987).

184. The Hall Amendment's origin in the frustration with and anger toward the Inspector General felt by some physicians is well illustrated by remarks of its drafter, Rep. Hall, responding to the first use of the procedure to stay an exclusion:

This is one of the first judicial victories and should indicate to the inspector general, Richard Kusserow, that he can't sit over there in his ivory castle and make all types of blustery and bragging and misleading speeches; that while he can talk down to men and women who come before him and have heretofore been at his mercy—that there are many Members of Congress who are neither interested in nor impressed by his pomposity.

Even physicians have a right to due process—and in the short 120 days you have left—Mr. Kusserow—I suggest you try to get acquainted with this fact, and never again try to deny any American due process!

134 CONG. REC. E2803-04 (daily ed. Aug. 11, 1988) (extension of remarks by Rep. Hall).

185. 42 U.S.C. § 1320c-3(a)(1)(C) (1982).

186. See also *Hearings on Medicare Peer Review Orgs., Subcomm. on Health and the Env't, House Energy and Commerce Comm.*, 100th Cong., 1st Sess. 12-15 (1987) (statement of Vita Ostrander, AARP) [hereinafter AARP Statement].

187. OBRA '87, Pub. L. No. 100-203, 1987 U.S. CODE CONG. & ADMIN. NEWS (101 Stat.) 1330, 1330-136.

obviously result in more inpatient care and, thus, higher expenditures for the Medicare program. Whether such added expenditures are justified is a policy question, not a question of administrative law. HCFA implementation of this provision, however, does raise an important administrative law issue.

In implementing OBRA '87, HCFA initially took the position that the first comma in the section quoted above should be read as a colon, that is, that the provision only applied to remote rural areas. This is not only contrary to the amendment's clear language, but is also contradicted by the legislative history of the provision, which clearly states that beneficiary location in a remote rural area is only one of the social factors to be taken into account.¹⁸⁸ HHS is apparently reconsidering its position on its interpretation of section 4094(a) and should expeditiously implement it as written.¹⁸⁹

D. *Formulation and Publication of Criteria and Standards*

As has already been briefly noted, the D.C. Circuit held in *Public Citizen Health Research Group v. DHEW* that PSROs were not agencies within the meaning of the FOIA.¹⁹⁰ Because the FOIA adopts the APA definition of "agency," that decision also stands for the proposition that PROs are not agencies under the APA and thus not subject to the rulemaking requirements of 5 U.S.C. section 553. Although the reasoning of the court in *Public Citizen* is somewhat confused (the court held both that the PSRO did not have independent decisionmaking authority and that it was not subject to supervision by HHS),¹⁹¹ its holding seems consistent with congressional intent that PROs are to be independent bodies of practicing physicians and not government agencies.¹⁹² The holding is also consistent with other cases that have considered the status of PSROs and PROs.¹⁹³ PROs are also probably not subject to the Model State APA, which describes an agency as "a board, commission, department, officer, or other administrative unit of this state."¹⁹⁴

Even though PROs are themselves not bound by the rulemaking requirements of the APA, the reasoning behind those requirements¹⁹⁵ argues in favor of PROs seeking participation of affected parties in formulating criteria, standards, and norms and assuring that their criteria, standards, and norms are made available to those affected by them. This is recognized by the documents governing the PRO program. The *Third Scope of Work* requires that:

188. H.R. CONF. REP. TO ACCOMPANY THE OMNIBUS BUDGET RECONCILIATION ACT OF 1987, 100th Cong., 1st Sess. 661, 663.

189. Several beneficiary representatives with whom I spoke also argued for greater consideration of social criteria in determining appropriateness of discharge. This is, however, a policy and not an administrative law issue, and it is thus beyond the scope of this Article.

190. 668 F.2d 537 (D.C. Cir. 1981).

191. *Id.* at 543-44.

192. *See id.* at 542-43.

193. *See Oster v. Bowen*, 682 F. Supp. 853 (E.D. Va. 1988); *Kwoun v. Southeast Mo. PSRO*, 663 F. Supp. 520 (D.C. Mo. 1985); *Taylor v. Flint Osteopathic Hosp.*, 561 F. Supp. 1152 (E.D. Mich. 1983).

194. Model State Admin. Procedure Act § 1-102(1) (1981).

195. *See supra* Part III for discussion.

In the development/refinement of criteria, the PRO shall consult with physicians/practitioners actively engaged in practice in the state. PRO developed criteria are to be submitted to HCFA for review, and sent to the providers and physician organizations (i.e., State medical societies) in the State. In addition, the contractor must furnish the criteria to anyone upon request.¹⁹⁶

The PRO regulations also require that a PRO must disclose “[t]he norms, criteria, and standards it uses for initial screening of cases, and for other review activities.”¹⁹⁷

All of the PROs with which I spoke attempt to involve their state medical community in drafting or modifying their criteria sets. Most PROs seek comments from state medical associations and specialty societies; some circulate drafts to hospital medical staffs or have provider advisory committees. Seventy-three percent of state medical societies reported in an AMA survey that state specialty societies had assisted PROs in developing or modifying criteria, and 39% reported that specialty sections of the state medical society had also provided assistance.¹⁹⁸ The possibility of PROs involving their own state medical community in drafting and reviewing PRO criteria is one of the strongest arguments against the creation of uniform national criteria sets by HCFA.

All of the PROs that I interviewed are also making efforts to publicize their criteria. All send their criteria sets to every hospital in the state. Some have identified PRO liaisons in the hospitals to whom they direct the criteria, others send them to the director of the medical staff, the administrator, or the utilization review/quality assurance supervisor. Most also send them to the state medical society. None sends its criteria to all physicians in the state, though some send out a regular bulletin or newsletter to advise doctors of criteria changes or send specialty criteria to affected specialists. Nevertheless, several state provider representatives with whom I spoke said that providers are not sufficiently educated by the PROs as to PRO criteria.¹⁹⁹ National provider and beneficiary groups have also called for clearer and more public articulation of criteria.²⁰⁰

The task of formulating PRO criteria is ideally suited for a simplified version of negotiated rulemaking.²⁰¹ The parties affected by criteria are relatively few, and their spokespersons are readily identifiable; technical rather than ideological issues are usually (though not always) involved; the adoption of some criteria is usually necessary and inevitable; and opportunities for compromise and consensus are usually

196. THIRD SCOPE OF WORK, *supra* note 3, § XIII, at 27-28.

197. 42 C.F.R. § 476.120(a)(1) (1987). PROs must also make available to the public copies of their contracts (which describe their procedures) and copies of documents describing their administrative procedures. *Id.* § 476.120(a)(2)-(3).

198. AMA PRO EXECUTIVE SURVEY, *supra* note 136, at 2.

199. A recent study by the GAO provides more information on how PROs disseminate their criteria. *See generally* GAO MEDICARE PROs, *supra* note 175.

200. *See Hearings on Medicare PROs Before Subcomm. on Health and the Env't, House Comm. of Energy and Commerce*, 100th Cong., 1st Sess. 7-11 (1987) (statement of AHA); *Information for Consumers About Quality of Medical Care, Subcomm. on Natural Resources, Research, and Env't, House Comm. on Science, Space and Tech.*, 100th Cong., 2nd Sess. 10 (1988) (statement of AARP); AARP Statement, *supra* note 186, at 4.

201. *See* Harter, *Negotiating Regulations: A Cure for Malaise*, 71 GEO. L.J. 1 (1982); Perritt, *Negotiated Rulemaking Before Federal Agencies: Evaluation of Recommendations by the Administrative Conference of the United States*, 74 GEO. L.J. 1625 (1986); 1 C.F.R. §§ 305.82-4, .85-5 (1987).

present.²⁰² Greater involvement of providers and practitioners in the standard-setting process could bring greater understanding of the standards and compliance with them, acceptance of the legitimacy of PRO review, and, most importantly, better standards. Greater involvement of beneficiary organizations would assure that the patient's perspective on care was taken into account, especially when social issues are involved. Dissemination of norms to beneficiaries could also play a valuable educative role.²⁰³ PROs establishing or modifying criteria should, therefore, convene groups of provider and beneficiary organizations and attempt to reach agreement as to appropriate criteria through a negotiating process. Such an approach to criteria setting is in the best tradition of peer review.

Two provisions of OBRA '87 have the potential to make an important contribution to the task of educating the medical community about PRO criteria and norms. Section 4094(c)(1)(B)(i) requires PROs to offer to make available a physician to meet with the medical and administrative staff of each hospital to explain the organization's review of the hospital's services (at individual hospitals or on a regional basis).²⁰⁴ Section 4094(c)(1)(B)(ii) requires PROs to publish at least annually and distribute to practitioners and providers a report describing the types of cases in which the PRO has frequently determined that care has been provided inappropriately, unnecessarily, or not in conformity with professional standards of care.²⁰⁵ These provisions are implemented by the *Third Scope of Work*, which also requires PROs to engage in further efforts at provider education, including making staff available for educational presentations, and publications describing PRO procedures.²⁰⁶ Educational efforts that involve direct discussions with affected providers and practitioners and focus on particular problem areas have great promise for effectively communicating PRO criteria.

V. THE PRO QUALITY ASSURANCE AND SANCTION PROGRAM

A. Introduction

By far the most controversial function of the PRO program has been its sanctioning authority. 42 U.S.C. section 1320-5(a) imposes on practitioners and providers participating in the Medicare program an obligation to assure that services they render are provided economically, are provided only when medically necessary, and are of a quality that meets professional standards of care. It further obligates them to provide evidence to establish that they have met these requirements. It also gives PROs the power and responsibility to sanction providers who fail to fulfill these obligations. If "after reasonable notice and opportunity for discussion" a PRO determines that practitioners or providers have "(A) failed in a substantial number of cases substantially to comply" with these obligations or "(B) grossly and flagrantly

202. See Perritt, *supra* note 201, at 1642-47; 1 C.F.R. § 305.85-5 (1987).

203. See A. GOSFIELD, PSRO'S: THE LAW AND THE HEALTH CONSUMER 32-33 (1975).

204. OBRA '87, Pub. L. No. 100-203, 1987 U.S. CODE CONG. & ADMIN. NEWS (101 Stat.) 1330, 1330-136.

205. *Id.* at 1330-137.

206. THIRD SCOPE OF WORK, *supra* note 3, § XVIII(C), at 40-41.

violated any such obligation in one or more instances," the PRO shall submit a report and sanction recommendation to the HHS OIG.²⁰⁷ If the OIG agrees with the PRO recommendation and determines that the practitioner or provider "has demonstrated an unwillingness or a lack of ability substantially to comply with such obligations," it may exclude the provider or practitioner from "eligibility to provide Medicare services on a reimbursable basis."²⁰⁸ When the provider or practitioner has been sanctioned for providing medically improper or unnecessary care, the OIG may, instead of exclusion, impose a monetary penalty not in excess of the cost of the medically improper or unnecessary services.²⁰⁹ A sanctioned provider or practitioner may obtain a post-exclusion hearing before an ALJ and, ultimately, judicial review. As was discussed earlier, under OBRA '87 rural providers cannot be excluded from the program without a pre-exclusion hearing before an ALJ to determine whether the provider or practitioner poses a serious risk to Medicare beneficiaries.²¹⁰

B. Criticisms of the PRO Sanction Process

The PROs' exercise of their sanctioning authority has made them the target of much criticism. As of December 31, 1987, 38 of the 54 PROs had referred 151 cases to the OIG; the OIG had excluded 60 physicians and 1 facility and assessed a penalty against 24 physicians and 2 facilities.²¹¹ This represents about 19 sanctions per 100,000 physicians serving Medicare beneficiaries. Through September 1987 twenty-three states and the District of Columbia, containing one-fifth of the nation's doctors and Medicare beneficiaries, had not successfully recommended a single sanction.²¹² Though it is impossible, of course, to determine the optimal level of sanctioning, it is difficult to believe that 99.98% of doctors treating Medicare beneficiaries (and 100% in twenty-three states) are doing a satisfactory job, especially given common estimates that incompetency among doctors runs at levels of 5% to 10%.²¹³ Some consumer groups have been sharply critical of the timidity of the PROs in sanctioning doctors,²¹⁴ and the OIG has occasionally joined this criticism.²¹⁵

Attorneys representing providers with whom I spoke, on the other hand, are sharply critical of what they see as oppressive aggressiveness on the part of the

207. 42 U.S.C. § 1320c-5(b) (1982).

208. *Id.* § 1320c-5(b)(1). This provision further states that if HHS fails to take action within 120 days, the practitioner or provider will be excluded until HHS decides otherwise. This clause was put in the statute to address the problem of HHS delay in acting on sanctions recommended by the PSROs. The OIG has consistently taken action on PRO recommendations within 120 days, consigning this provision to desuetude.

209. *Id.* § 1320c-5(b)(3).

210. *Id.* § 1320c-5(b)(5). HHS has implemented these statutory provisions through regulations appearing at 42 C.F.R. pt. 1004 and PRO MANUAL, *supra* note 53, Transmittal No. 15 of May 1987.

211. See OIG SANCTION REPORT, *supra* note 6, at 11.

212. *Subcomm. on Health, Comm. on Ways and Means*, 100th Cong., 1st Sess. 2, 3 (1987) (testimony of Sidney Wolfe, Director Pub. Citizen Health Research Group) [hereinafter Testimony of S. Wolfe].

213. See Derbyshire, *Medical Discipline in Disarray: The Incompetent Physician*, 18 HOSP. PRAC. 30, 31 (Nov. 1983).

214. Testimony of S. Wolfe, *supra* note 212; Kotelchuck, *Watchdog on a Short Chain*, HEALTH/PAC BULL., Spring 1987, at 19, 21.

215. See Webber, *A PRO Report Card*, THE INTERNIST, July 1986, at 7, 9.

PROs.²¹⁶ They properly note the devastating effect that exclusion from the Medicare program has on physicians. While an excluded physician may in theory continue to practice (and even to treat Medicare beneficiaries if he or she is willing to do so without compensation), Medicare nationally pays for 21% of physicians services²¹⁷ and provides a much higher proportion of the income for some specialists. Secondary effects of Medicare exclusion can, moreover, be even more devastating. Attorneys with whom I talked stated that after exclusion their clients ceased to receive referrals from other doctors, were terminated from hospital medical staffs, and were investigated by state licensure agencies. While they waited up to eighteen months for ALJ hearings and judicial review, excluded doctors were forced to maintain the high overhead of their practices and pay high legal fees without income, an ordeal that drove at least one into bankruptcy.

The proceedings that resulted in these consequences were passionately criticized by provider representatives. Though PRO procedures were substantially amended under a May 1987 compromise between the OIG, HCFA, the AMA, and the American Association of Retired Persons (AARP) to assure greater procedural protections for sanctioned providers and practitioners at the PRO level,²¹⁸ provider attorneys still complain of the inability to cross-examine the reviewers (often anonymous) who initiated the proceedings, the informality of the proceedings, and the lack of notice and standards. Their harshest criticism, however, is focused on the perceived bias of PRO sanction proceedings. Physician representatives widely believe that PROs are directly rewarded for sanctioning providers and threatened with contract termination for not doing so, and thus are heavily biased against providers once sanctions are recommended. They also believe that the OIG is prejudiced against providers and does not provide an effective review of PRO recommendations.²¹⁹

The vast majority of those involved in the sanction process, including the PROs and many beneficiary and provider representatives, are somewhere between these poles and most show a marked ambivalence about PRO sanctions. On the one hand, 87% of respondents interviewed in a recent study felt that the PROs' sanction authority strengthened their ability to perform their mission.²²⁰ Without the threat of sanctions, the PROs' educational and corrective efforts would be less likely to get the attention of the medical community. On the other hand, the PROs feel uncomfortable with the hostility the sanction process has generated and are frustrated by the time and resources that go into the sanction process. Two-thirds of PRO CEOs interviewed by the OIG felt that the sanction process continues to be problematic.²²¹ PROs are

216. See also Schorr, *Peer Review: Still Tilting at Windmills*, 27 *PHYS. MGMT.* 124 (Oct. 1987); Remarks by Hanson, *Cal. Med. Ass'n 1987 House of Delegates* (Mar. 10, 1987).

217. Div. of Nat'l Cost Estimates, Office of the Actuary, Health Care Fin. Admin., *National Health Expenditures, 1986-2000*, 8 *HEALTH CARE FIN. REV.*, Summer 1987, at 1, 13.

218. See U.S. Dep't of Health & Human Servs. News Release, *Changes in PRO Sanction Process*, May 13, 1987 (implemented by *Manual Transmittal 15*).

219. See Carlova, *Have Peer Reviewers Put a Price on Your Head?*, *MED. ECON.*, Sept. 5, 1988, at 62.

220. OIG SANCTION REPORT, *supra* note 6, at 12.

221. *Id.* at 15.

particularly frustrated with the inconsistent instructions they get from HCFA and the OIG as to when to sanction, the proportion of PRO sanction recommendations rejected by the OIG (over half in 1987),²²² and their rate of reversal in ALJ proceedings.

One thing is clear: the rate of sanctioning activity has dropped dramatically in the recent past, after climbing steadily since the inception of the PRO program. During 1985 seven cases were recommended to the OIG by the PROs for sanctions and all were accepted. During 1986, the high water year for sanction activity, seventy-seven were recommended, and fifty-five were accepted. During 1987 the level of recommendations dropped slightly to seventy, but the number of OIG acceptances dropped dramatically to twenty-five.²²³ As of July, only ten cases had been referred to the OIG for sanctions in 1988. With individual PROs, the drop-off has been even more dramatic. In the first two years of the program, the California PRO was among the most active in recommending sanctions, but within the last year it has not referred any cases to the OIG for sanctions.

The reasons for this decline in activity are disputed. The most optimistic view is that the initial flurry of sanction activity has cleared up all problems, and further sanctions are not necessary. A more realistic view is that the PROs, having gotten the attention of physicians, can now rely more on less drastic interventions. Additional procedures imposed by the May 1987 compromise may have impeded the sanction activity of some PROs, but many of the PROs had already implemented these protections prior to the compromise. The most likely explanation for the slowdown is that a variety of administrative impediments are discouraging the PROs from sanctioning the physicians. First, the OIG has rejected a large proportion of sanction referrals, which has discouraged PROs from referring cases. Second, PROs have noted the high rate of ALJ reversals of sanction cases and have become reluctant to commit the heavy expenditure of resources necessary to get a case to the ALJ level if reversal seems inevitable.

In order to understand the decline in PRO sanction activity, it is important to consider the reasons why PRO sanction cases are being rejected. Of the fifty-six cases rejected by the OIG in 1987, twenty were rejected because the PRO had failed to establish the inability or unwillingness of the physician or provider to meet statutory obligations.²²⁴ PROs have generally concluded that they will not be able to establish inability or unwillingness without documenting a pattern of violations over a period of time, and they are thus keeping physicians under correction plans for several weeks or months before referring for sanctions. Many PROs have also concluded that the OIG will not accept referrals when only a single instance of gross and flagrant conduct is involved (despite clear statutory language to the contrary) or of cases

^{222.} *Id.* at 17.

^{223.} *Id.*

^{224.} *Id.* at 18.

involving fines.²²⁵ PROs have also experienced difficulty collecting payments from HHS for sanction activities, which are supposed to be separately reimbursed.²²⁶

In sum, despite significant changes in the sanction process over the last two years, the process still seems not to be working very smoothly.

C. *The PRO Quality Assurance and Sanction Process Described*

All PROs, as required by the *Scope of Work* and PRO contracts, have a two-stage process through which cases must go before sanctions are imposed. Sanction cases normally begin in the quality assurance process, which identifies and attempts to correct quality problems.²²⁷ Serious or repeated problems identified through the quality assurance process are sent on to the sanction process. The *Third Scope of Work* establishes broad guidelines for the quality assurance process; the PRO regulations²²⁸ set out more specific guidelines for the sanction process. Both processes vary considerably, however, from PRO to PRO.

In all PROs, the first step down the long road to a PRO sanction is taken (in most instances) when a nurse reviewer kicks out a case for failing one of the generic quality screens or another quality, utilization, or discharge screen.²²⁹ In most PROs, the case is then reviewed by a physician reviewer, who will in all likelihood not belong to the specialty of the doctor under review. If the review is conducted on-site at a hospital, the doctor is even less likely to be specialty-matched.²³⁰

If the initial physician advisor determines that there is a quality problem, one of several things may happen. In four of the twelve PROs I interviewed, the PRO sends a letter to the attending physician or provider and asks for an explanation of the problem. In six of these PROs, the case is referred to one or more specialists matched with the specialty of the physician under question, who further reviews the case. If the specialist agrees that there is a problem, the attending physician or provider is contacted for further information; otherwise the matter is dropped. Finally, in the two other PROs with which I spoke, the case is sent to a medical director or quality review committee simultaneously with or before a request to the attending physician or provider for more information. In several of the PROs, minor problems are noted at this level for future consideration if patterns develop, but they are not immediately acted on.

Once a response is received from the attending physician or provider, the response is reviewed, in most of the PROs, by a matched specialist, usually someone

225. *Id.* at 16. These issues are the subject of a recent GAO investigation. See generally GAO MEDICARE PROs, *supra* note 175.

226. OIG SANCTION REPORT, *supra* note 6, at 16. Payment for sanction activity after an initial sanction letter is sent is supposed to be in addition to the amount included in the PRO contract for quality assurance generally. See 2 Medicare & Medicaid Guide (CCH) ¶ 12,875 (1986).

227. Potential sanction cases can also be identified in the utilization review process, but they seldom are.

228. 42 C.F.R. pt. 1004 (1987).

229. Cases could also be identified by beneficiary complaints or by referrals from fiscal intermediaries, HCFA regional offices, or state medical boards.

230. In the median PRO surveyed by the GAO recently, only 30% of the cases were specialty-matched for the doctor's review. GAO MEDICARE PROs, *supra* note 175, at 21.

other than the initial reviewer. In one-fourth of the PROs I interviewed, however, the record and the physician's or provider's response go directly to a quality assurance committee. In half of the PROs I interviewed, the matched specialist reviewer refers problem cases on to a quality assurance committee, often at a regional level. In two of the remaining PROs, the matched specialist sends out a second letter noting that the problem has not been cleared up and requesting more information. This letter may be sent to hospitals at which the attending physician has staff privileges as well as to the doctor. Again, during this further review, cases may be classified using a grid, with serious cases being pursued aggressively and less serious cases being noted for future profile review.

In three-fourths of the PROs I interviewed, serious or repeated problems eventually end up in a quality assurance committee. In about one-third of the PROs, this committee meets with the physician. These committees vary in size from three to twelve members, often meet at a regional level, and are usually composed of an assortment of specialists. In two of the PROs I interviewed, there are two layers of committee review before a case can be referred for sanctions. The quality assurance committee normally imposes a corrective action plan on the doctor and then monitors compliance over a period of time.²³¹ Some PROs monitor corrective action plans for a set period of time (thirty, sixty, or ninety days). Other PROs (recognizing that a doctor can simply avoid problem cases until a time-limited corrective action plan expires) monitor corrective action plans for a set number of specific kinds of cases.²³²

If a problem persists through all of these layers of review, it enters the sanction process, which is often handled by a different committee. As is clear by now, the number of steps in the review process between the initial identification of a problem and a final decision to pursue sanctions varies considerably from PRO to PRO (though many of the PROs can expedite their normal processes in egregious cases). An AMA study found that the number of physician reviewers who review a case before a sanction letter is sent varied from three to thirty-five, with a mean of ten and a median of seven.²³³ My impression is that the PROs with the most expedited procedures have traditionally been the most active in sanctioning physicians.²³⁴

The *Third Scope of Work* imposes a quality review process that may streamline this process in some PROs and complicate it in others. Under this process, the PRO has sixty days from the date of receipt of fiscal intermediary sampling data to obtain records, run them through criteria screens, and have problems assessed by a physician advisor.²³⁵ Identified problems must then be reviewed within thirty days by a

231. See *OIG SANCTION REPORT*, *supra* note 6, at 8 (describing this process further). The *OIG QUALITY REPORT*, *supra* note 167, at 18, noted that corrective action was relatively uncommon, but my impression in speaking with the PROs was that it was increasingly common. The *AMA PRO EXECUTIVE SURVEY*, *supra* note 136, Table 14, found that the PROs the AMA interviewed had imposed from 0 to 98 corrective action plans, with a mean of 15.6. A recent GAO study includes more information on corrective action plans. See generally *GAO MEDICARE PROS*, *supra* note 175.

232. For example, if a corrective action plan applies for 50 cases, the doctor will be monitored for 50 cases, whether it takes him 1 month or 24 to handle this volume.

233. *AMA PRO EXECUTIVE SURVEY*, *supra* note 136, Table 11.

234. The *OIG SANCTION REPORT*, *supra* note 6, at 14, agrees with this assessment. The *OIG QUALITY REPORT*, *supra* note 167, at 18, notes that, conversely, the PROs with the most complicated procedures sanction the least.

235. *THIRD SCOPE OF WORK*, *supra* note 3, § V(B), at 6.

specialist or quality assurance committee.²³⁶ When problems are not resolved, the provider must be given an opportunity to discuss the case, which consumes another thirty days.²³⁷ Finally, the PRO has 15 additional days to confirm or not confirm the quality problem and to send final notice to the attending physician or provider, for a total of 135 days.²³⁸ Within this 135-day maximum, PROs may adjust the time frame, as long as the attending physician or provider is given 30 days to discuss the problem.²³⁹

The initial reviewer in the *Third Scope of Work* quality assurance process must classify problems into one of three categories depending on the severity of the problem. The most trivial, severity level I, problems are noted but not acted upon unless a pattern emerges.²⁴⁰ Severity level II and III problems are to be profiled on a quarterly basis.²⁴¹ Appropriate interventions are to be pursued by the PRO, depending on the weighted score assigned to confirmed problems.²⁴² These might include notification, education, intensified review, coordination with licensing and accreditation bodies, and, ultimately, sanctions.²⁴³ Though cases appropriate for sanctions will normally be identified through the quality assurance process, the sanction process is independent, and sanctions may be initiated in appropriate cases even though not required by the quality assurance process.²⁴⁴

Once a problem is finally confirmed and a case enters the sanction process, it is governed by 42 C.F.R. part 1004.²⁴⁵ If the case involves a substantial number of substantial violations, the PRO begins by sending a sanction notice to the provider or physician and requesting additional information or a meeting to discuss the problem within twenty days of the receipt of the notice.²⁴⁶ For a gross and flagrant violation, or the case of a substantial number of substantial violations not cleared up through the discussions following this initial notice, a second notice is sent out requesting additional information or an opportunity to meet within thirty days.²⁴⁷ Both notices must clearly explain the problem identified, the obligation violated, the facts relied on, the potential consequences of a sanction, and the importance of the sanction meeting.²⁴⁸ At the thirty-day notice meeting, the physician or provider may have an attorney present who may make opening and closing remarks, ask clarifying questions, and assist in presenting expert witnesses.²⁴⁹ Physicians who are biased

236. *Id.*

237. *Id.*

238. *Id.*

239. *Id.*

240. *Id.* § V(D), at 7.

241. *Id.* § V(F), at 8.

242. *Id.* §§ V(F)-(G), at 8-13.

243. *Id.* § V(G), at 10-12. The most common intervention is a notification letter, used 6 times per 1000 physicians per quarter in 1987-88. PROs consider sanctions to be the most effective intervention for dealing with quality problems. GAO MEDICARE PROs, *supra* note 175, at 25-27.

244. THIRD SCOPE OF WORK, *supra* note 3, § V(G)(4), at 13.

245. A description of this process is included in the OIG SANCTION REPORT, *supra* note 6.

246. 42 C.F.R. § 1004.40 (1987).

247. *Id.*

248. *Id.* §§ 1004.40, .50; U.S. Dep't of Health & Human Servs. News Release, *Changes in PRO Sanction Process*, May 13, 1987.

249. PRO MANUAL, *supra* note 53, § 6025(B).

against or in direct competition with the accused physician or provider, or who were responsible for the findings presented to the sanction committee, may not vote on the sanction recommendation.²⁵⁰

If the PRO decides to recommend that the OIG sanction a physician or provider, it sends its determination to the OIG. The physician or provider may send additional information within thirty days to the OIG.²⁵¹ The PRO report to the OIG must thoroughly explain the basis for the recommended sanction. It must also recommend an appropriate period of exclusion or amount of monetary fine,²⁵² considering the type and severity of the offense involved, the deterrent value of a sanction, the previous record of the sanctioned individual or entity, the availability of alternative services in the community, and other relevant factors.²⁵³ The OIG must then decide, considering these factors, whether or not to impose a sanction and also whether the provider is unwilling or unable substantially to comply with these obligations.²⁵⁴ The sanction is effective fifteen days from the date the physician or provider receives the notice from the OIG.²⁵⁵ The OIG also provides notification of the sanction to the public (through a notice in a local newspaper), state Medicaid fraud control units and state licensing bodies, hospitals and other facilities at which the physician has privileges, medical societies, and medical carriers, intermediaries, and HMOs.²⁵⁶ The sanctioned provider or physician may appeal to an ALJ and ultimately obtain judicial review,²⁵⁷ but this may be done only after the sanction has been implemented.²⁵⁸

D. Major Issues in the PRO Sanction Process

1. Does the Constitution Require a Pre-exclusion Hearing?

To this point, this Article has described the procedures afforded providers and physicians in the sanction process by the PRO statute, regulations, and *PRO Manual*. In a number of cases, sanctioned physicians have argued that these procedures are insufficient to meet the demands of the due process clause of the fifth amendment. In particular, they have argued that the Constitution guarantees them the right to an ALJ hearing before they are terminated from the Medicare program.²⁵⁹

An analysis of the rights that should be afforded physicians and providers must begin with a consideration of whether their participation in the Medicare program is protected by the fifth amendment. As interpreted by the Supreme Court, the fifth and

250. *Id.* § 6025(C)(2).

251. 42 C.F.R. § 1004.60 (1987).

252. *Id.* § 1004.70.

253. *Id.* §§ 1004.70, .80.

254. *Id.* § 1004.90.

255. *Id.* § 1004.100.

256. *Id.*

257. *Id.* § 1004.130.

258. Except for rural physicians; *see supra* text accompanying notes 181–84.

259. *Doyle v. Bowen*, 848 F.2d 296 (1st Cir. 1988); *Cassim v. Bowen*, 824 F.2d 791 (9th Cir. 1987); *Varandani v. Bowen*, 824 F.2d 307 (4th Cir. 1987); *Lavapies v. Bowen*, 687 F. Supp. 1193 (S.D. Ohio 1988); *Ferrer v. Bowen*, No. C86-3523 (N.D. Ohio filed July 6, 1987); *Papendick v. Bowen*, 658 F. Supp. 1425 (W.D. Wis. 1987).

fourteenth amendments do not protect all expectations; they protect only life, liberty, and property interests.²⁶⁰ While it certainly may be argued that a Medicare beneficiary has a property interest in continued receipt of Medicare benefits, it is harder to argue that a provider or physician has a property right in a continued contractual relationship with the government to provide services to Medicare beneficiaries. Some courts have noted, therefore, that providers, who are not the intended beneficiaries of the program, have no rights beyond those provided in their contracts.²⁶¹ Other courts have recognized, on the other hand, the dependence of providers and physicians on Medicare and their expectation that they will not be terminated from Medicare without cause. On this basis, they have found a property right in continued program participation.²⁶² Still other courts have held that the reputational damage and injury to practice caused to a provider terminated from the Medicare program implicates a liberty interest.²⁶³ Most of the cases considering PRO sanctions have been willing to assume the existence of a property or liberty interest and move on to the next question: What process is due?²⁶⁴

The question of whether sanctioned doctors are entitled to a pre-exclusion hearing must be answered under the *Mathews v. Eldridge* calculus by balancing the doctor's interest in greater procedural protection, the government's interest in expedited procedures, and the risk that the lack of a pretermination hearing will produce an erroneous deprivation.²⁶⁵ Applying this calculus, the courts have uniformly rejected physicians' claims for a pre-exclusion hearing.²⁶⁶ First, the courts have tended to minimize the interest of the sanctioned physician, noting that the doctor will continue to be able to serve his non-Medicare patients, that he may even continue to care for Medicare patients without compensation and claim compensation later when vindicated, and that a successful conclusion of a post-termination hearing will restore his reputation.²⁶⁷ Second, they have stressed the compelling importance of expedited

260. *Board of Regents v. Roth*, 408 U.S. 564, 569, 576 (1972).

261. *See Koerpel v. Heckler*, 797 F.2d 858, 863-64 (10th Cir. 1986) (exclusion of doctor from Medicare reimbursement for 10 years); *Geriatrics, Inc. v. Harris*, 640 F.2d 262, 264-65 (10th Cir.), *cert. denied*, 454 U.S. 832 (1981) (termination of Medicaid funding for nursing home); *Green v. Cashman*, 605 F.2d 945 (6th Cir. 1979) (termination of Medicaid payments for nursing home).

262. *See Ritter v. Cohen*, 797 F.2d 119 (3rd Cir. 1986) (termination of physician's participation in Medicaid program); *Hathaway v. Mathews*, 546 F.2d 227, 230 (7th Cir. 1976) (termination of Medicaid payments to nursing home); *Case v. Weinberger*, 523 F.2d 602, 606 (2d Cir. 1975) (removal of Medicare patients from nursing home); *Lavapies*, 687 F. Supp. 1193 (physician sanctioned by PRO); *Papendick*, 658 F. Supp. at 1432 (physician sanctioned by PRO).

263. *Koerpel*, 797 F.2d at 865-66; *Lavapies*, 687 F. Supp. at 1201; *Ferrer v. Bowen*, No. C86-3523, slip op. at 8 (N.D. Ohio filed July 6, 1987). It is ironic that under the reasoning of *Koerpel* a physician or provider terminated for no reason at all would not have a right to due process, since he has no property right in participation in the Medicare program. A physician terminated, however, for gross and flagrant violations of professional standards of care is entitled to full due process protection, because his reputation has been impugned.

264. *Doyle v. Bowen*, 848 F.2d 296, 302 (1st Cir. 1988); *Cassim v. Bowen*, 824 F.2d 791, 796-97 (9th Cir. 1987); *Varandani v. Bowen*, 824 F.2d 307, 310 (4th Cir. 1987).

265. *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).

266. *Thorbus v. Bowen*, 848 F.2d 901 (8th Cir. 1988); *Doyle*, 848 F.2d at 302; *Cassim*, 824 F.2d at 797-98; *Varandani*, 824 F.2d at 310-11; *Koerpel*, 797 F.2d at 868-69; *Ritter*, 797 F.2d at 123-24; *Lavapies*, 687 F. Supp. at 1203; *Papendick*, 658 F. Supp. at 1431; *County of San Diego v. Bowen*, 631 F. Supp. 947, 953 (S.D. Cal. 1986); *Kwoun v. Schweiker*, 528 F. Supp. 1004, 1007 (E.D. Mo. 1981).

267. *Cassim*, 824 F.2d at 797; *Ritter*, 797 F.2d at 123; *Ferrer*, slip op. at 10; *Papendick*, 658 F. Supp. at 1431.

proceedings for protecting Medicare beneficiaries from seriously deficient physicians.²⁶⁸ Finally, the courts have noted that the multiple levels of review afforded physicians before the OIG issues a sanction lower the risk of error to an acceptable level.²⁶⁹ Summing these considerations, the courts have uniformly held that even the procedures provided to physicians before the May 1987 compromise afforded sufficient notice and an opportunity to respond to charges to accord with the requirements of due process.²⁷⁰

One can certainly argue with the weight given to the relevant considerations in these cases. In particular, they tend to trivialize the devastating impact of exclusion on physicians. Nevertheless, the unanimity of their results clearly establishes the constitutionality of exclusions based on PRO recommendations prior to an adversarial hearing before an ALJ. This does not mean, of course, that a pre-exclusion hearing might not make sense. This issue will be considered later. First, however, the procedures that should be followed in the PRO and ALJ process will be further considered.

2. Notice

Though the Constitution does not require a pre-exclusion hearing, it does require that a provider or physician receive notice of the grounds on which the sanction is based.²⁷¹ The PRO regulations and manual set out fairly extensive and specific requirements for notices to be sent to the provider before the thirty-day review in a gross and flagrant case, before the twenty-day and thirty-day reviews in the case of a substantial number of substantial violations, and, finally, before OIG review in both situations.²⁷² The doctor is to be informed of the obligation violated, the basis for the PRO determination, the sanction the PRO will recommend, and the procedural rights the doctor is entitled to in the review process.

Despite these specific requirements, providers have encountered problems with notice in the PRO sanctions process. First, there are difficulties that seem to stem from the unfamiliarity of the doctors running the PROs with legal process. In one PRO sanction decision, for example, the ALJ faulted the PRO for providing the sanctioned doctor only with vague "issues of concern" rather than the clear and specific charges required by the regulations.²⁷³ In other cases, PROs have raised new issues not covered by the original notice at a sanction meeting.²⁷⁴ The May 1987 compromise requires PROs to use model letters that will more clearly give notice to

268. *Doyle*, 848 F.2d at 302; *Cassim*, 824 F.2d at 799; *Papendick*, 658 F. Supp. at 1431-32.

269. *Cassim*, 824 F.2d at 797-98; *Papendick*, 658 F. Supp. at 1431.

270. *Doyle*, 848 F.2d at 302; *Varandani*, 824 F.2d at 313; *Koerpel*, 797 F.2d at 867-68 (citing *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532 (1985)).

271. *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 542 (1985).

272. 42 C.F.R. §§ 1004.40-.70; PRO MANUAL, *supra* note 53, § 6025.

273. *In re Apakupakul*, No. HIX-000-34-7009, at 32-33 (June 1, 1987).

274. Approximately 40% of the sanction recommendations rejected by the OIG in 1987 involved instances of the PROs failing to follow regulatory procedures, including presumably failing to give proper notices. OIG SANCTION REPORT, *supra* note 6, at 18.

providers threatened with sanctions. *Manual Transmittal 15* includes such forms and will, it is hoped, alleviate this notice problem.

The second notice issue is more narrow in focus. As stated earlier, the statute permits a provider or physician to be sanctioned only if it “has demonstrated an unwillingness or a lack of ability substantially to comply” with program obligations.²⁷⁵ The regulations place the obligation to determine this fact on the OIG, after it considers the recommendation of the PRO.²⁷⁶ At no point, however, do the regulations require that the provider or physician be given notice as to the basis for this determination or an opportunity to respond to it. In *Lavapies v. Bowen*,²⁷⁷ the OIG was enjoined from imposing an exclusion until the question of willingness and ability was raised and discussed. If this requirement continues to be part of the law, the regulations should be amended to assure that the PRO gives the provider or practitioner notice of the basis of its unable or unwilling recommendation and an opportunity to respond.

3. Confidentiality and Disclosure Issues

The PRO confidentiality and disclosure statute and regulations have several provisions pertinent to the hearing process. First, 42 U.S.C. section 1320c-9 imposes strict limitations on the disclosure of patient information. These limitations have been relied on to impede the access of expert witnesses called by sanctioned physicians and providers to information necessary for analyzing the patient care at issue in the sanction proceeding. *Manual Transmittal 15*, section 6025(C)(1), clarifies that such information should promptly be made available to expert witnesses and may solve this problem.

A larger issue is raised by 42 C.F.R. section 476.139(a), which prohibits disclosure of PRO deliberations except to the OIG and HCFA. While this regulation, by itself, might seem to leave providers and practitioners in the dark as to why a PRO has sanctioned them, section 476.139(b) requires PROs involved in administrative hearings to give reasons for their decisions, including the detailed facts, findings, and conclusions that support their determinations. These rules are consistent with general administrative law requiring that decisionmakers issue findings of fact and conclusions of law, but prohibiting inquiry into the deliberative process to assure frank and free discussion.²⁷⁸ They should not cause providers undue hardship.

Even more significant to providers or physicians in the PRO sanction proceedings is the question of whether they can discover the identity of the reviewers who initiated or participated in the review process. Section 476.101(b) protects the identity of PRO reviewers as confidential. This provision is supported by the PROs, which believe that their always lean supply of qualified physician reviewers might dry

275. 42 U.S.C. § 1320c-5(b) (1982).

276. 42 C.F.R. §§ 1004.90(d)(7), .70(c)(4) (1987). PRO MANUAL, *supra* note 53, § 6025, states that the physician or provider may address the issue of ability and willingness at the PRO sanction meeting, but does not require the PRO to notify the provider or practitioner of the evidence on which this determination will be made.

277. 687 F. Supp. 1193, 1201-02 (S.D. Ohio 1988).

278. *United States v. Morgan*, 313 U.S. 409, 422 (1941).

up if reviewers became subject to the threat of litigation and to other forms of retaliation that might occur were their identity to become known. These fears are not irrational, as 42 U.S.C. section 1320c-6 only offers physician reviewers qualified legal immunity for their review activities.²⁷⁹ Moreover, specialist reviewers may legitimately fear that they will lose referrals if it becomes known that they are responsible for sanctioning other physicians.

Sanctioned physicians and their representatives, on the other hand, complain that this provision deprives them of the opportunity to confront their accusers, a basic right in Anglo-American jurisprudence. Many of them believe that once a reviewing physician decides that an attending physician's practice has been deficient, subsequent reviewers tend to accept the initial reviewer's analysis uncritically. They are concerned that if the initial reviewer cannot be questioned, it will be difficult to convince the sanction committee that the initial reviewer's reasoning was flawed. Moreover, the regulation conceals from sanctioned physicians not only the initial reviewer's identity, but also his credentials. Denied access to these credentials, providers or physicians cannot determine whether the initial reviewer was competent to review the particular case.

These interests can largely be accommodated. Providers and physicians in the sanction process should be apprised of the identity and credentials of reviewers who present evidence against them before sanction review committees and before ALJs. The identity of the much more numerous physician advisors and specialist reviewers who identify cases involving inappropriate care for referral to the sanction process should not be revealed, however, as long as their opinions are not relied on exclusively by those making the final PRO sanction decision. The credentials of these reviewers—for example, whether or not they are board-certified and in what specialty, the nature of their practice, or how long they have been in practice—should be revealed to the sanctioned physician or provider, if this can be done without revealing the reviewer's identity.

A final disclosure issue involves the method by which beneficiaries are made aware of PRO exclusions. Currently, the OIG is required to publish in a newspaper of general circulation a notice identifying sanctioned providers.²⁸⁰ The May 1987 agreement committed HCFA and the OIG to promulgate a regulation allowing physicians to have the option of notifying their own Medicare patients of their exclusion. This option has not yet been implemented. While allowing physicians to notify their own patients directly may be more protective of their dignity, and may even make it more certain that beneficiaries will be notified of the sanction, it is difficult to understand how this provision will be enforced. The temptation would surely be great for a sanctioned physician to provide his or her patients with something less than the full truth about the exclusion or even not to send the notice

279. They must exercise "due care" to receive immunity (*but see* *Kwoun v. Southeast Mo. PSRO*, 811 F.2d 401 (8th Cir. 1987), *cert. denied*, 108 S. Ct. 1994 (1988) (finding PSRO employees absolutely immune from suit)).

280. 42 C.F.R. § 1004.100(d) (1987).

at all. It is important in implementing this provision for HHS to assure that Medicare beneficiaries do in fact receive a prompt and accurate notice of exclusion.²⁸¹

4. *Burden of Proof and Weight of Evidence Issues*

The PRO statute, regulations, and *Manual* do not clearly identify who bears the burden of proof in establishing the appropriateness of a sanction at the PRO or ALJ level. The APA provides that “[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof.”²⁸² This would seem to put the burden on the PRO or the OIG seeking a sanction to prove up its case before an ALJ. On the other hand, the sanction statute places the obligation on providers and physicians to assure that services provided Medicare beneficiaries are “supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required” by a reviewing PRO.²⁸³ This would seem to support the position of the OIG that the provider or physician when challenged has the burden of establishing that services meet the Act’s requirements.²⁸⁴

Several ALJ opinions have considered the burden of proof issue at the ALJ level. They note that the proceeding is *de novo* and that there is, therefore, no presumption that there has been a violation for which the sanction proposed by the ALJ is appropriate.²⁸⁵ As the OIG initiates the sanction proceedings, these decisions place upon it the burden of offering evidence to establish the statutory requirements for exclusion from the program.²⁸⁶ Once the OIG has presented this evidence, however, the ALJ opinions split. Two ALJ opinions place on the respondent the ultimate burden of proof that the sanction was factually unsupported and legally unjustified.²⁸⁷ A third seems to say that the burden remains on the OIG to prove its case.²⁸⁸ A fourth opines that the burden is “shared.”²⁸⁹

Because physician and provider participation in Medicare has become so widespread and so essential to the practice of medicine, it is appropriate that the proponent of the sanction of exclusion at both the PRO and ALJ level bear the burden of establishing that the exclusion requirements of 42 U.S.C. section 1320c-5 have been met. This is consistent with practice in OIG civil penalty cases²⁹⁰ and with

281. ABA COMMISSION ON LEGAL PROBLEMS FOR THE ELDERLY & THE ADMINISTRATIVE CONFERENCE OF THE UNITED STATES, *MEDICARE PROCEDURES SYMPOSIUM: REPORT AND RECOMMENDATIONS* 30 (1987) [hereinafter ABA/ACUS RECOMMENDATIONS] (suggests individualized mailings as a more effective means of notifying beneficiaries than newspaper notice).

282. 5 U.S.C. § 556(d) (1982).

283. 42 U.S.C. § 1320c-5(a)(3) (1982).

284. See *Fairfax Hosp. Ass'n Inc. v. Califano*, 585 F.2d 602, 611 (4th Cir. 1978) (Medicare provider has burden of establishing validity of disallowed claim in administrative proceedings).

285. *In re Lifshutz*, No. 000-44-7020, at 8-10 (Mar. 25, 1988); *In re Polka*, No. HIP-000-00-0229, at 6 (June 17, 1987).

286. *Lifshutz*, No. 000-44-7020, at 10.

287. *Polka*, No. HIP-000-00-0229, at 6; *In re Apakupakul*, No. HIX-000-34-7009, at 7 (June 1, 1987).

288. *Lifshutz*, No. 000-44-7020, at 10.

289. *In re Santos*, No. 000-54-7029, at 3 (Feb. 25, 1988).

290. See 42 C.F.R. § 1003.114 (1987).

administrative law generally when a party is charged with an illegal or improper act.²⁹¹

The question of the standard of proof is less controversial. Although some provider attorneys have argued that the serious consequences of sanctions call for a clear and convincing evidence standard,²⁹² ALJs have uniformly required only proof by a preponderance of the evidence.²⁹³ This is consistent with the general standard of proof in administrative law²⁹⁴ and is appropriate in these cases, given the balance of weighty considerations favoring both the protection of providers and of beneficiaries.

5. The "Unwilling or Unable" Requirement

As noted earlier, 42 U.S.C. section 1320c-5 prohibits HHS from sanctioning providers or practitioners unless they have "demonstrated an unwillingness or a lack of ability substantially to comply" with program obligations. The failure of the OIG to establish this element to the satisfaction of an ALJ has been the cause of several OIG losses in sanction cases.²⁹⁵ Failure of PROs to establish unwillingness or inability has also been one of the most frequent reasons for rejection of PRO sanction recommendations by the OIG.²⁹⁶ The OIG has noted the confusion involving the determination of unwillingness and inability and has recommended that Congress delete the requirement.²⁹⁷ This would make the PRO legislation consistent with section 1128(b) of the Social Security Act, which allows the OIG to exclude poor quality providers without showing unwillingness or inability.²⁹⁸ It would also restore the law existing under the PSRO program, which permitted proof of the underlying violations of standards to establish unwillingness or inability to comply.²⁹⁹

It is difficult to prove that providers or physicians are unwilling or unable to comply with program obligations. Most doctors faced with sanctions will enthusiastically express their willingness to comply, and many ALJs believe that if a doctor is licensed he should be able to comply. In one case, for example, the ALJ concluded

291. 73A C.J.S. *Public Administrative Law and Procedure* § 128 (1983).

292. See Adams & Krebs-Markrick, *Defending Physicians Before the Peer Review Organization: Practical Strategies and Tactics in Sanction Proceedings*, in NATIONAL HEALTH LAWYERS ASSOCIATION, UTILIZATION, MANAGEMENT, PROS AND QUALITY ASSURANCE: THE LEGAL PITFALLS 21 (1987).

293. *In re Lifshutz*, No. 000-44-7020, at 10 (Mar. 25, 1988); *In re Polka*, No. HIP-000-00-0229, at 6 (June 17, 1987); *In re Apakupakul*, No. HIX-000-34-7009, at 23 (June 1, 1987).

294. See *Steadman v. SEC*, 450 U.S. 91 (1981); *Breeden v. Weinberger*, 493 F.2d 1002, 1005 (4th Cir. 1974); *Whaley v. Gardner*, 374 F.2d 9, 10 (8th Cir. 1967).

295. *Lifshutz*, No. 000-44-7020, at 18-20; *In re Hill*, No. HIX-000-64-7015, at 5-6 (Nov. 16, 1987); *In re Rodabaugh*, No. PS 000-74-7002, at 4-5 (June 9, 1987).

296. OIG SANCTION REPORT, *supra* note 6, at 18.

297. *Id.* at 16, 21.

298. 42 U.S.C.A. § 1320a-7(b)(6)(B) (West 1983 & Supp. 1988). Section 1128 allows the OIG to exclude providers or physicians from Medicare who have been convicted of various crimes, lost their licenses or been excluded from other governmental programs, committed fraud, or refused to cooperate with various program requirements. It also permits exclusion of individuals or entities who provide items or services "substantially in excess of the needs of . . . patients, or of a quality which fails to meet professionally recognized standards." This provision is used relatively infrequently, principally to sanction physicians for errors committed in practice settings not supervised by the PROs, such as in their private offices.

299. Social Security Amendments of 1972, Pub. L. No. 92-603, § 1160(b)(1), 86 Stat. 1548, 1683 (codified at 42 U.S.C. § 1320c-5(b)(1)), amended by Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, 96 Stat. 324, 388.

that in several instances the services provided by the sanctioned doctor had grossly and flagrantly violated professional standards. Noting, however, that the doctor said he was now willing to comply, and seemed to be bright and well-educated, the ALJ threw out the sanction recommendation.³⁰⁰ In another case, the ALJ found that the PRO must attempt a corrective action plan before it can establish unwillingness or inability.³⁰¹ On the other hand, ALJs have excluded doctors when they felt that the doctor lacked a basic understanding of medical symptoms and procedures.³⁰²

At the PRO level, the requirement has generally resulted in PROs imposing lengthy corrective action plans before considering a sanction. Most of the PROs with which I spoke believe that in most cases unwillingness and inability can only be demonstrated by the failure of a corrective action plan. There is much to be said for this approach, as correction through education is the primary focus of the PRO program. It is unfortunate, however, if this approach results in incompetent physicians being kept in practice until they injure a sufficiently large quota of patients.

On balance, the "unwilling or unable" requirement should be repealed. If it is retained, however, HCFA should issue regulations making it clear that unwillingness and inability can be proved by establishing uncooperativeness, lack of basic knowledge or skills, impairment, or extreme incompetence over a period of time in the past, as well as through showing failure to comply with a corrective action plan.

It is especially important that monetary penalties be imposed for deterrence purposes on physicians and providers guilty of gross or repeated violations regardless of their willingness or ability to be good in the future. One plausible interpretation of 42 U.S.C. section 1320c-5 is that the "unwilling or unable" to comply requirement of subsection (b)(1) does not apply to the monetary penalty provision, subsection (b)(3), and one ALJ has read the statute to say this.³⁰³ Under this reading of the Act, further legislation is not necessary to reach this result.

6. Money Penalties

Section 1320c-5(b)(3) allows HHS, in lieu of exclusion, to require a practitioner or provider who has provided improper or unnecessary services to pay a monetary penalty of an amount not in excess of the actual or estimated cost of those services. This provision provides in theory a useful, less drastic, alternative to exclusion. Alternative sanctions to program exclusion that can be applied flexibly to address particular problems have proven very useful in other regulatory schemes, such as nursing home licensure,³⁰⁴ and should be available to the PROs.

300. *In re Hill*, No. HIX-000-64-7015, at 5-6 (Nov. 16, 1987); see also *In re Rodabaugh*, No. PS 000-74-7002, at 4 (June 9, 1987) (willingness of doctor to engage in continuing education and to monitor patients enough to show willingness and ability).

301. *In re Lifshutz*, No. 000-44-7020, at 19 (Mar. 25, 1988).

302. See *In re Betty*, No. HIX-000-64-7003, at 2 (Sept. 30, 1987); *In re Rivero*, No. HIS-000-64-7010, at 24-25 (Sept. 29, 1987).

303. *In re Santos*, No. 000-54-7029, at 22 (Feb. 25, 1988).

304. See INSTITUTE OF MEDICINE, IMPROVING THE QUALITY OF CARE IN NURSING HOMES 162-68 (1986). See also 1 C.F.R. § 305.79-3 (1987) (ACUS recommendations regarding civil penalties).

Unfortunately, the ALJs enforcing the penalty provision have read it very narrowly to limit monetary penalties to the amount of isolated charges strictly applicable to a particular medical procedure determined to be unnecessary or of poor quality.³⁰⁵ The result in one case was a penalty of \$65.44.³⁰⁶ Obviously penalties of this size do not justify the cost of a sanction process, and the OIG has effectively ceased using the monetary penalty authority or accepting PRO recommendations for penalties.³⁰⁷

The PRO legislation ought to be amended to allow the OIG to impose monetary penalties of up to \$10,000.³⁰⁸ This would allow the OIG to impose a sanction that providers and physicians would take seriously but would be short of exclusion from the program. As stated above, this sanction should be for past violations of physician and provider obligations and be aimed at deterring future violations. It should not, therefore, be subject to the “unwilling or unable” to comply requirement.

7. Bias

One of the most fundamental rights afforded by due process to a person subject to an administrative adjudication is the right to a hearing before an impartial tribunal.³⁰⁹ One of the most persistent complaints made against the PROs by physicians and providers is that their hearing procedures are inherently biased against providers and practitioners accused of sanctionable conduct. This charge takes three forms.

First, review by one’s peers can also mean review by one’s competitors. There has been a general concern that reviewers who participate in the quality assurance and sanction process may be competitors of the sanctioned physician, eager to get him or her out of the way to expand their own practice. Conversely, there is the concern that PRO reviewers may be friends and associates of those whose care they review, biased against the public whom they should be protecting. These concerns are addressed to a minimal extent by the PRO regulations, which prohibit persons from reviewing cases if they have participated in treating the beneficiary, are a member of the beneficiary’s family, or have a management or ownership interest in the facility at which services were furnished to the beneficiary.³¹⁰ The *PRO Manual* further requires PROs to assure that members of any hearing panel making a final sanction decision are not affected by personal bias or direct economic competition with the accused provider or practitioner.

In practice, most PROs go beyond these requirements to avoid this sort of bias. All of the PROs with which I spoke refuse to allow physicians to review cases from hospitals or HMOs at which they have staff privileges to guard against both prejudice

305. See *Santos*, No. 000-54-7029, at 19–20; *In re Polka*, No. HIP-000-00-0229, at 20 (June 17, 1987).

306. OIG QUALITY REPORT, *supra* note 167, at 9.

307. See OFFICE OF INSPECTOR GENERAL, PRO TECHNICAL INFORMATION MEMORANDUM No. 2, at 3 (July 24, 1987) (fines only cost effective when an improper pattern of care involving substantial reimbursement is involved).

308. See ABA/ACUS RECOMMENDATIONS, *supra* note 281, at 30; OIG SANCTION REPORT, *supra* note 6, at iii.

309. *Withrow v. Larkin*, 421 U.S. 35, 46 (1975).

310. 42 C.F.R. § 466.98(d) (1987).

and favoritism. One even had a computer system to assure that this would not happen. Several went further, refusing to allow reviewers to review cases from their own community or from communities from which they received referrals. This policy was particularly prevalent in rural areas. Other PROs do not allow doctors on statewide sanction committees to vote on cases from their region and allow the provider or practitioner subject to sanction proceedings to object to committee members who are suspected of bias. These protections seem adequate to the job and have been accepted by the one case that has directly addressed this bias question.³¹¹

A second concern is that the PROs inappropriately combine the prosecutorial and adjudicatory function—that is, reviewers who recommend sanctions are permitted to participate in the decisionmaking process. It is generally inappropriate for an administrative officer to participate in both the prosecution and decision of a case,³¹² though the Supreme Court has rejected calls for strict separation of investigative and adjudicatory functions.³¹³ The one PRO case in which the issue was raised rejected a strict separation requirement.³¹⁴ On the other hand, ALJs have rejected the testimony of PRO experts who participated in a sanction investigation as not credible.³¹⁵

Manual Transmittal 15, growing out of the May 1987 compromise, provides that a physician who “was solely or primarily responsible for making medical judgments and developing the record and initial findings to be used at the discussion shall not vote on the PRO’s final determination about whether or not to recommend a sanction to the OIG.”³¹⁶ This provision does not apply, however, to physicians who summarize the views of others to assemble a record and findings for the sanction meeting. It provides a useful compromise between the need to protect the rights of a physician or provider threatened with a sanction and the need of the sanction committee to have available someone with knowledge of the case. My impression from interviews with the PROs is that this provision has not yet been implemented by all of the PROs. It should be.

Finally, the most serious charge of impropriety against the PROs is that they are inherently biased against providers because renewal of their contracts depends on their meeting a “quota” of sanctioned providers.³¹⁷ The PROs operate pursuant to contracts with HHS, and their multimillion dollar contracts depend on meeting contract objectives. Provider attorneys have frequently claimed that favorable evaluations of the PROs by HHS, and thus renewal of their contracts, depend heavily on the number of sanctions imposed by the PROs. They also claim that OIG officials

311. *Lavapies v. Bowen*, 687 F. Supp. 1193, 1203–04 (S.D. Ohio 1988).

312. *American Cyanamid Co. v. FTC*, 363 F.2d 757 (6th Cir. 1966).

313. *Withrow*, 421 U.S. 35.

314. *Doyle v. Bowen*, 660 F. Supp. 1484, 1488 (D. Me. 1987), *rev'd on other grounds*, 848 F.2d 296, 302 (1st Cir. 1988).

315. *In re Polka*, No. HIP-000-00-0229, at 17 (June 17, 1987); *In re Apakupakul*, No. HIX-000-34-7009, at 32, 35 (June 1, 1987).

316. PRO MANUAL, *supra* note 53, § 6025(C)(5).

317. *See Carlova*, *supra* note 219, at 62.

are rewarded for wringing sanctions out of the PROs.³¹⁸ Thus the PROs and OIG must find victims to sanction, whether or not those victims actually are guilty of sanctionable offenses.³¹⁹

It is, of course, improper for an administrative tribunal to hear a case in which it has a financial interest.³²⁰ Courts that have addressed this allegation, however, have found that the PROs are not improperly biased in this respect. *Doyle v. Bowen*³²¹ noted that although contract renewals depended on meeting contract objectives, including sanctioning substandard care, it had never been suggested that the PROs should sanction physicians who were providing adequate care.³²² Moreover, *Doyle* noted that there was no evidence that individual reviewers in the case were in any way influenced by the PRO's concern about imposing an adequate number of sanctions.³²³ Similarly the court in *Lavapies v. Bowen* rejected the bounty system argument and accepted the testimony of the Ohio PRO's Vice President of Finance that the HHS had never imposed a quota of sanctions.³²⁴

The HHS OIG has shown great interest in PRO sanction activity, which could be interpreted as pressure on the PROs. Some of the PROs have engaged in highly questionable conduct in pursuing PRO sanctions,³²⁵ which might be attributable to overeagerness. Nevertheless, PROs that have issued no sanctions have routinely had their contracts renewed, demonstrating that no absolute quota system is in operation. This is, however, a subject to which the PROs and HHS must be sensitive in the future.

E. Two Alternatives for Improving the PRO Sanction Process

1. Transfer Sanction Authority to the Inspector General and Provide Pretermination Hearings

Many of the problems in the PRO sanction process can ultimately be traced to the difficulty of engrafting enforcement functions onto what is basically a peer monitoring and education program. The tension between enforcement and educative functions in health care regulation has been noted elsewhere.³²⁶ An effective

318. The California Medical Association in *Greene* obtained documents sufficiently supporting these charges to obtain further discovery of federal officials. See *Greene v. Bowen*, No. CIV S-86-0625 LKK (E.D. Cal. 1988) (order of Jan. 22, 1988, at 28); Brief for Plaintiff in Opposition to Federal Defendants' Motion to Dismiss or for Summary Judgment at 7-11, *Greene v. Bowen*, No. S-86-0625-LKK (E.D. Cal. 1988) (filed Sept. 14, 1987); MCGRAW-HILL UTILIZATION REVIEW REPORT 3 (Mar. 24, 1988).

319. One provider attorney with whom I spoke noted that the absence of judicial review for contract denials, 42 U.S.C. § 1320c-2(f), made the PROs even more concerned about HHS pressure to sanction providers.

320. *Marshall v. Jerrico, Inc.*, 446 U.S. 238 (1980); *Ward v. Village of Monroeville*, 409 U.S. 57 (1972); *Tumey v. Ohio*, 273 U.S. 510 (1927).

321. 660 F. Supp. 1484 (D. Me. 1987), *rev'd on other grounds*, 848 F.2d 296 (1st Cir. 1988).

322. *Doyle*, 660 F. Supp. at 1488.

323. *Id.*

324. *Lavapies v. Bowen*, 687 F. Supp. 1193, 1203-04 (S.D. Ohio 1988); see also *Association of Am. Physicians & Surgeons v. Weinberger*, 395 F. Supp. 125, 139-40 (N.D. Ill. 1975) (rejecting the bias charge).

325. See *In re Lifshutz*, No. 000-44-7020, at 23-28 (Mar. 25, 1988); *Doyle*, 660 F. Supp. at 1488-89.

326. See Day & Klein, *The Regulation of Nursing Homes: A Comparative Perspective*, 65 MILBANK MEM. FED. Q.

education program must work with problem physicians in a close consultative relationship based on the assumption that the physician wants to improve his practices if he can be taught how. An effective enforcement program assumes that there are bad as well as good physicians, and it maintains its distance from all as it attempts to effectively ferret out and prosecute the bad ones. In combining these functions, PROs have understandably tended to err on one side or the other. Several PROs have become so focused on correction, and have offered so many layers of review to assure giving problem physicians every opportunity to straighten out, that they have yet to impose a sanction. Other PROs have been overly aggressive. The basic unfamiliarity with legal due process of the physician managers of this latter group of PROs has exacerbated the inquisition-like atmosphere that physicians have experienced before them.

I believe that the public, physicians, and providers would be better protected if the sanction authority were withdrawn from the PROs and given to the OIG. Under this proposal PROs would retain their quality assurance functions. They would continue to monitor medical records and investigate complaints. They would continue to identify quality and utilization problems. When quality problems were identified, they would continue to require corrective action. This could include the interventions suggested by the *Third Scope of Work*: notification, education (including telephone discussions, suggested literature reading, continuing medical education, meetings, and self-education courses), intensified review, and other interventions (including concurrent predischarge review, second opinions or preadmission review, or referral to hospital infection control, tissue, or quality assurance committees).³²⁷ It might also include other interventions used by PROs with which I spoke: requirements of limiting practice, consultation, preceptorships, attendance in a residency program, obtaining board certification, and oversight in surgery. HHS should assist in disseminating information among the PROs as to novel and successful approaches to quality interventions.³²⁸

When a PRO identified a gross and flagrant violation of physician or provider obligations or a failure to cooperate with or satisfactorily complete a correction plan, however, the PRO would refer the case to the OIG. It would not, as now, send a recommended sanction to the OIG, but rather it would refer the case to the OIG for investigation. The OIG would then, using its own medical resources (which it would have to create as its resources are now very limited) or borrowing experts from the PRO, conduct its own investigation and build its own case. Once it decided to proceed against a doctor for exclusion or for a monetary penalty, the provider or physician could appeal directly to an ALJ.

Appeals of exclusions or money penalties should be heard by the ALJs attached to the Departmental Grant Appeals Board. These ALJs deal routinely with sanction

303, 307-11 (1987); Jost, *Enforcement of Quality Nursing Home Care in the Legal System*, 13 LAW, MED. AND HEALTH CARE 160, 162-63 (1985).

327. THIRD SCOPE OF WORK, *supra* note 3, § IV(G)(1).

328. OIG QUALITY REPORT, *supra* note 167, at ii.

appeals³²⁹ and are more experienced in presiding over adversary proceedings than are the Social Security Office of Hearings and Appeals (OHA) judges. Appeals from the decisions of these ALJs would be to the Departmental Grant Appeals Board.³³⁰ The sanction, however, would be effective immediately upon the decision of the ALJ.

This system would solve a multitude of problems. First, the PROs could focus on what they do best—peer review. They could also greatly simplify their current quality review procedures, which in many PROs have become impossibly labyrinthine. The May 1987 compromise has effectively given providers and physicians a full due process hearing before the PRO prior to their being sanctioned. Providers and physicians charged with committing a substantial number of substantial violations are now entitled to two hearings before the PRO. Sanctioned providers and physicians are entitled to a further *de novo* hearing before an ALJ after the sanction is imposed. Under the OBRA '87 amendments, rural practitioners, who have been the subject of two-thirds of PRO sanctions to date, are also entitled to an additional preliminary hearing before an ALJ before their sanctions can go into effect. Many of the PROs interpose additional levels of review, involving up to thirty-five reviewers, before a case even enters the sanction process.³³¹ It is difficult to believe that a system this cumbersome and time-consuming is truly protecting the public when dangerously incompetent doctors are involved.

Because a referral for investigation implicates no property or liberty interest,³³² no PRO hearing would be necessary prior to the initiation of such an investigation. Procedures imposed by the *Third Scope of Work*—an initial review by a physician advisor, a further review by a matched specialist or quality committee before a letter is sent to an attending physician or provider requesting an explanation, and a final review of the response received before a quality problem is confirmed (presumably by a specialist or committee)—would still be appropriate. These procedures assure that the PRO is fairly certain that there is a quality problem before even raising the issue with a physician or provider, and they give the physician or provider a chance to explain before a problem is confirmed. Once a problem is confirmed, however, the PRO should, without further delay or waste of resources, decide to (1) continue to profile the physician or provider, perhaps intensifying review, if the problem were minor; (2) initiate a corrective action plan if the problem were more serious but correctable; or (3) refer the problem to the OIG if it seemed serious.

The OIG, with its law enforcement experience and resources, could investigate all referrals. When the investigation substantiated problems, the OIG would seek exclusion or a fine. The OIG could deputize PRO physicians to serve as experts in investigating and presenting the case, but for this purpose they would serve as OIG, not PRO, experts. As the OIG's experts would be responsible for presenting evidence

329. See 53 Fed. Reg. 25,543 (1988) (assigning ALJs responsibility for hearing civil money penalty and exclusion appeals under most other HHS sanction statutes).

330. See CIVIL MONEY PENALTIES REP., Summer 1988, at 6-7 (describing the Board's ALJs).

331. AMA PRO EXECUTIVE SURVEY, *supra* note 136, Table 11.

332. Cf. *Setliff v. Memorial Hosp. of Sheridan County*, 850 F.2d 1384 (10th Cir. 1988) (hospital investigation of physician does not affect property or liberty interest).

in any hearings and the sanction decision would be solely based on this evidence, there would be no problem with maintaining the confidentiality of PRO reviewers who had earlier identified the problem. If a problem were substantiated by the OIG investigation, the provider or physician would be sent a notice, and a hearing would be scheduled on an expedited basis, perhaps within sixty days. The case would be handled by attorneys from the OIG's office, who could avoid the problems that have occurred when PROs have held hearings without counsel or with less experienced counsel. As the PRO would be merely responsible for referring the case for an investigation, and not for deciding the case, the charges of bias recounted above would no longer be relevant. Hearings would be held at the regional offices to make them accessible to physicians and their attorneys.

From the perspective of providers and physicians, this system should be superior because it would assure a hearing before an impartial ALJ before exclusion. Providers and physicians would no longer have to put up with the quasi-club meeting or the quasi-inquisition atmosphere that has prevailed in some PRO sanction proceedings. They would be dealing with hearing officers experienced in legal process and free from bias. Beneficiaries should welcome the proposal because it would assure that dangerous physicians would be dealt with swiftly and effectively and leave the PROs to focus on education and correction. HHS should welcome this proposal because it would give HHS more direct control over the sanction process. The OIG is already familiar with this kind of process through its experience under its section 1128(b) authority, reaffirmed by the Medicare and Medicaid Patient and Program Protection Act,³³³ and should be comfortable with it. Most of all, the PROs should welcome this proposal because it would free them from their greatest headache. They would still have the ability to threaten a recalcitrant provider with a referral to the OIG, but would themselves be less the brunt of provider and physician hostility and distrust.

It is essential to this proposal that these cases be assigned to ALJs assigned to the Departmental Grant Appeals Board and not to the OHA judges who currently hear sanction cases. The primary reason for this is that OHA ALJs are not used to the expedited time frames necessary if problem providers are to be given pre-exclusion hearings.³³⁴ Further, OHA ALJs are not used to dealing with adversarial proceedings and have approached sanction cases as though they were Social Security cases, in which they are responsible for protecting the claimant as well as for deciding the case. One example of the incorporation of Title II social security disability concepts into sanction proceedings is the *Polka* case, in which the judge gave extra weight to the testimony of the treating physician (as is normally done in disability cases), even though the treating physician was on trial.³³⁵ HHS attempted at one point to develop a trained cadre of judges within the OHA to handle sanction cases, but turnover

333. 42 U.S.C.A. § 1320a-7 (West 1983 & Supp. 1988). See *supra* note 298.

334. As was related earlier, ALJs have not met the 45-day time limit set by HHS for decisions on the pre-exclusion hearings required by the Hall Amendment of OBRA '87. A recent OIG report notes that final decisions in exclusion cases take even longer. It is currently taking about 15 months from the date of a PRO sanction recommendation and 10 months from an OIG sanction recommendation to the conclusion of an ALJ hearing. OIG SANCTION REPORT, *supra* note 6, at 16, 18.

335. *In re Polka*, No. HIP-000-00-0229, at 17 (June 17, 1987).

dispersed the group, which no longer exists. Departmental Grant Appeals Board ALJs have experience in handling sanction cases and should take over these cases as well.

Two final proposals should be considered as ancillary to this larger proposal. First, the OIG should be given summary suspension power for egregious cases, as is possessed by many state medical boards.³³⁶ This would operate much like a temporary restraining order to remove a clearly dangerous doctor from practice for a short period of time (fifteen to thirty days) until an expedited hearing could be held.

Second, if the proposal suggested above were adopted, the OIG would effectively become a national medical board to protect Medicare beneficiaries. It may be advisable for the OIG to have such authority, as there is ample evidence that the medical boards of many states have not been effective in disciplining the profession.³³⁷ When medical boards are effective, however, it might make sense to have a procedure, such as appears in some civil rights and environmental laws, to permit the OIG to certify the state procedures as equivalent in effectiveness to the federal procedures and have the PROs refer cases to the state medical board for investigation rather than to the PRO.

2. Retain Current System, but Streamline and Assure Due Process

While there is much to commend the idea of shifting the sanction authority to the OIG, it is also likely to face opposition. The PROs may worry that they will lose their most important lever for securing cooperation from recalcitrant providers and physicians. Providers and physicians may be concerned with the fairness of the proposed process, given their suspicions regarding the current Inspector General. Beneficiaries may be anxious about the added delay that the proposal could add to the process, which already takes too long. The OIG can be expected to object that unless substantial additional resources were offered to it, it could not adequately handle the additional responsibility. While these objections are not insurmountable, they do counsel consideration of a more cautious approach.

Such an approach should be adequate to address, on the one hand, the concern of providers and physicians that the current system does not guarantee them access to an undisputably impartial presanction decisionmaker and is excessively uneven in its results and, on the other hand, the concern of beneficiaries that the current process has been too much consumed with bureaucratic delay.

First, the twenty-day notice and opportunity to submit additional information or discuss the problem with the PRO, provided by 42 C.F.R. section 1004.40 for cases involving a substantial number of substantial violations, should be abolished. It no

336. See OHIO REV. CODE ANN. § 4731.22(D) (Anderson 1987); FEDERATION OF STATE MEDICAL BOARDS, A GUIDE TO THE ESSENTIALS OF A MODERN MEDICAL PRACTICE ACT 18 (1977), reprinted in H.R. 5110, 99th Cong., 2d Sess. 409 (1986).

337. See OFFICE OF THE INSPECTOR GENERAL, U.S. DEP'T OF HEALTH & HUMAN SERVS., MEDICAL LICENSURE AND DISCIPLINE: AN OVERVIEW 12-15 (1986), reprinted in H.R. 5110, 99th Cong., 2d Sess. 256-59 (1986) [hereinafter OIG LICENSURE & DISCIPLINE REPORT]; Rayack, *Medical Licensure: Social Costs and Social Benefits*, 7 LAW & HUM. BEHAV. 147, 154-57 (1983).

doubt made sense at one time, when many PROs still had abbreviated procedures and the thirty-day notice meeting provided by section 1004.50 was quite perfunctory, to give physicians and providers with a pattern of problems an early opportunity to explain or correct their behavior. The current *Scope of Work* provides thirty days notice and an opportunity to discuss problems as part of the presanction quality assurance process.³³⁸ It also focuses PROs on corrective interventions rather than sanctions for remediable problems.³³⁹ The May 7, 1987, compromise procedures substantially enhance the protections available to providers and physicians in the thirty-day notice hearing. Under these circumstances, the additional twenty-day opportunity for discussion under section 1004.40 seems redundant and an unnecessary cause of delay.

Second, the *Third Scope of Work* should be clarified to assure that the sanction process is initiated immediately upon the confirmation of a quality problem, if it is a problem for which a sanction is the appropriate intervention. Section V(B) of the *Third Scope of Work* requires PROs to issue a final notification to an attending physician or provider within a maximum of seventy-five days of the identification of a problem by a physician advisor.³⁴⁰ During this period the problem must be reviewed by the initial physician advisor and a separate specialist or quality committee, and the physician or provider must be notified of the problem and given an opportunity to discuss it. The confirmed problem will usually not be sufficiently serious to warrant a sanction, in which case some other intervention, such as education or intensification, will be appropriate.³⁴¹ If the problem is sufficiently severe to warrant a sanction, however, the PRO should move immediately into the section 1004.50 process, with the thirty-day notice serving to begin the process. Further delays for further committee reviews or discussions cannot be justified.

Third, the OIG and HCFA could do more to assure greater reliability and uniformity in the sanction process. Training sessions should be offered, for example, by the OIG to lawyers representing PROs to make certain that they understand the procedures the PROs must follow in the sanction process and to educate them as to errors that commonly result in OIG rejection or ALJ reversal. Model forms could be developed by HCFA to help assure that the PROs address the factors enumerated in sections 1004.80 and 1004.90, which must be considered by the PRO and by the OIG in imposing sanctions.

Under this alternative proposal, once the PRO initiated a Medicare exclusion and the OIG confirmed it and gave notice to the physician or provider, an exclusion would go into effect within fifteen days, as provided under the current regulations.³⁴² The physician or provider could, however, within ten days request a stay of the exclusion, as is currently possible for rural physicians and providers under the Hall

338. THIRD SCOPE OF WORK, *supra* note 3, § V(B), at 6.

339. *See generally id.* § V, at 5-15.

340. *Id.* § V(B), at 6.

341. *Id.* §§ V(G)(3)-(4), at 12-13 (which gives guidance to PROs as to the circumstances in which a sanction is appropriate).

342. 42 C.F.R. § 1004.100(b) (1987).

Amendment,³⁴³ if the stay would pose no serious threat to the patients of the physician or provider. The proposal would, however, establish uniform procedures for all, recognizing that there is no defensible reason for distinguishing between rural and urban physicians or providers. It would place the burden of proof on physicians or providers to show that their continued participation in the Medicare program would not pose a serious risk to their patients. By the time the sanction proceeding reaches this point, the physician or provider has already had at least three opportunities to explain the problem on which the sanction is based—once in the quality assurance process, again at the formal meeting with the PRO (to which lawyers and witnesses can be brought), and again when the case is referred to the OIG. Both the PRO and OIG, considering all of the information presented by the physician or provider through this process, have concurred that exclusion is appropriate because either a gross and flagrant violation or a substantial number of substantial violations has been confirmed. At this point it is proper that the provider or physician establish why, in spite of this, the exclusion should be stayed. If the provider or physician asks for such a stay, the effective date of the exclusion should be delayed for thirty days, during which the ALJ should consider the record and any additional information supplied by the physician, provider, OIG, or PRO. The ALJ should render its decision on the stay within thirty days. Regardless of the decision reached by the ALJ on the stay issue, the ALJ should reach a final decision on the merits within one year to assure that, on the one hand, the stay does not continue indefinitely or, on the other hand, that the exclusion is not stayed for an excessive period of time.

VI. DENIALS OF PAYMENT FOR SUBSTANDARD CARE

COBRA '85 amended the PRO legislation to require that PROs deny payment for services provided Medicare beneficiaries when the quality of those services does not meet professionally recognized standards of health care.³⁴⁴ The amendment further required that such denials should be made only “on the basis of criteria which are consistent with guidelines established by the Secretary.”³⁴⁵ This provision has proved intensely controversial, and two-and-one-half years after its enactment it has still not been implemented by HHS, although proposed regulations have been published very recently.³⁴⁶

The judgment of Congress that the Medicare program ought not to pay for poor quality care provided to Medicare beneficiaries makes a great deal of sense. It also

343. 42 U.S.C.A. § 1320c-5(b)(5) (West 1983 & Supp. 1988).

344. COBRA '85, Pub. L. No. 99-272, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 83, 200 (to be codified at 42 U.S.C. § 1320c-3(a)(2)).

345. OBRA '87 further provides that the PRO shall not disapprove payment until 20 days after the PRO has notified the affected provider or practitioner and afforded an opportunity for discussion and review, Pub. L. No. 100-203, 1987 U.S. CODE CONG. & ADMIN. NEWS (101 Stat.) 1330, 1330-135 to -136 (to be codified at 42 U.S.C. § 1320c-3(a)(3)), and prohibits physicians from charging beneficiaries for services for which payment is denied because of substandard quality, *id.* at 1330-139 (to be codified at 42 U.S.C. § 1395u).

346. See PROPOSED SUBSTANDARD CARE REGULATIONS, *supra* note 61. For discussions of the reasons for the long-delayed issuance of the proposed regulations, see *Hospitals Anxious Over Payment Denials*, HOSPITALS, June 20, 1987, at 48, 53; *Payment Denials Spark Questions*, HOSPITALS, June 20, 1987, at 32; *Payment will be Denied for Substandard Care*, MEDICAL WORLD NEWS, Jan. 12, 1987, at 25, 26.

makes sense to notify beneficiaries if the PRO peer review process concludes that the beneficiary has been provided substandard care. Hospitals and doctors fear that the PRO notification of substandard care denials may lead to increased malpractice litigation. But if a patient has been injured by poor quality medical care, he or she has a legal right to sue for redress for the injury. It is difficult to understand why the PRO should assist in covering up the fact that such a patient has received substandard care.

It is, of course, important for the PRO to be very sure that care provided a beneficiary was in fact substandard before the beneficiary is notified of this fact. The statute, however, assures physicians and providers that the PRO can only deny payment pursuant to articulated quality criteria and after notice and an opportunity for discussion.³⁴⁷ Proposed regulations further protect providers by only allowing payment denials when substandard quality care has resulted in “[a]n actual, significant, adverse effect” or “[a]n imminent danger to the health, safety, and well-being of the beneficiary, or places the beneficiary unnecessarily in a high-risk situation”³⁴⁸ and, in most cases, after the case has been reviewed by a specialist in the area of care at issue.³⁴⁹ The proposed regulations would define “actual, significant, adverse effects” restrictively to include patient management that results in “(i) [u]nnecessarily prolonged treatment; (ii) [m]edical complications; (iii) [r]e-admission; (iv) [p]hysiological or anatomical impairment; (v) [d]isability; or (vi) [d]eath.”³⁵⁰

The delay of HHS in implementing the substandard care provision reached the level of unconscionability and, perhaps, illegality. In other contexts, excessive administrative delay has been challenged by the courts.³⁵¹ If the proposal made earlier in this Article to transfer sanction authority to the OIG were adopted, it would become even more important that PROs have the power to deny payment for substandard care in order to assure them some ability to respond directly to poor quality providers and practitioners. HHS’s proposed regulations, therefore, should be implemented expeditiously.

Though the problems addressed by the NPRM as to how to evaluate the quality of medical care are largely beyond the scope of this Article, one comment will be made here. HHS should reconsider its proposal to notify beneficiaries only that payment is being denied because care was substandard and not to reveal the specific reason for the decision.³⁵² The draft rule of HHS mandates that payment only be denied when care is significantly deficient and results in actual significant adverse effects or an imminent threat to the patient. In these circumstances, the beneficiary deserves to be told the nature of the substandard care, both to allow the beneficiary

347. 42 U.S.C. § 1320c-3(a)(2)-(3) (1982 & Supp. IV 1986).

348. PROPOSED SUBSTANDARD CARE REGULATIONS, *supra* note 61, at 1963 (to be codified at 42 C.F.R. pt. 462, § 466.100(b)(4)(i), (ii)).

349. *Id.* (to be codified at 42 C.F.R. pt. 462, § 466.98(a)(4)).

350. *Id.* (to be codified at 42 C.F.R. pt. 462, § 466.100(b)(4)(i)).

351. See *Nader v. FCC*, 520 F.2d 182, 206 (D.C. Cir. 1975); *Environmental Defense Fund, Inc. v. Hardin*, 428 F.2d 1093, 1099 (D.D.C. 1970) (holding that agency inaction over a prolonged period of time can warrant judicial intervention).

352. PROPOSED SUBSTANDARD CARE REGULATIONS, *supra* note 61, at 1960.

to take necessary remedial action to deal with the threatened or actual adverse effects and to relieve, or at least to focus, anxiety that the beneficiary may suffer from receiving a general notice that he or she has received dangerously deficient care. A more specific notice may result in marginally more negligence litigation, but after all, the PRO program exists to protect the beneficiary, not the physician.

VII. PRO INVESTIGATIONS OF BENEFICIARY COMPLAINTS

From the beginning, PROs have based their quality review activities primarily on the hospital records they assemble through the sampling protocols described in Part II.³⁵³ OBRA '86 required PROs to consider a new source of data for identifying health care quality problems: beneficiary complaints.

Section 9353(c) of OBRA '86 requires that PROs:

Conduct an appropriate review of all written complaints about the quality of services (for which payment may otherwise be made under title XVIII) not meeting professionally recognized standards of health care, if the complaint is filed with the organization by an individual entitled to benefits for such services under such title (or a person acting on the individual's behalf). The organization shall inform the individual (or representative) of the organization's final disposition of the complaint. Before the organization concludes that the quality of services does not meet professionally recognized standards of health care, the organization must provide the practitioner or person concerned with reasonable notice and opportunity for discussion.³⁵⁴

HHS has implemented this provision through a modification in the contract and the *Third Scope of Work* and only very recently has proposed an implementing regulation. Under the *Third Scope of Work*, PROs are to investigate complaints about hospital inpatient or outpatient care, skilled nursing services, home health agencies, and ambulatory surgical centers.³⁵⁵ PROs may only investigate written complaints. Once a complaint is received, the PRO must determine whether the complainant is a beneficiary or beneficiary representative, whether the services were provided in a Medicare-certified facility or part of a facility, and whether the services complained of are covered by Medicare (whether or not they were covered for this particular beneficiary).³⁵⁶

Once the PRO determines it has jurisdiction over the complaint, it initially assesses the complaint to determine if investigation is warranted. If the PRO determines that the complaint has merit, it must request the beneficiary's medical records within fifteen calendar days.³⁵⁷ The facility has thirty calendar days to provide the record.³⁵⁸ The PRO review must be completed within fifteen calendar days thereafter if no quality problem is identified.³⁵⁹ If a quality problem is found,

353. See *supra* text accompanying notes 38-40.

354. OBRA '86, Pub. L. No. 99-509, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 1874, 2047 (to be codified at 42 U.S.C. § 1320c-3(a)).

355. THIRD SCOPE OF WORK, *supra* note 3, § XVII(A), at 36-38.

356. *Id.* § XVII(A)(1), at 36.

357. *Id.* § XVII(A)(4)(a), at 37.

358. *Id.* § XVII(A)(4)(b), at 37.

359. *Id.* § XVII(A)(4)(c), at 37.

however, the PRO must contact the physician or provider and afford another thirty days for discussion.³⁶⁰ Within five days after the review is completed, the PRO must respond to the beneficiary. Finally, if the PRO identifies a quality problem, it may initiate sanctions or otherwise proceed through its quality assurance process, and it must notify the regional office.³⁶¹

The *Third Scope of Work* places two restrictions on the PRO's duty to respond to the complaining beneficiary. First, it requires that under certain circumstances the response should be to someone other than the beneficiary. The *Third Scope of Work* provides that within the review time frames set out above the PRO must contact the attending physician of the patient whose care is the subject of the complaint fifteen days before disclosing information to the patient, as provided by 42 C.F.R. section 476.132. Section 476.132 addresses disclosure to patients of information concerning themselves. It requires the PRO to seek the advice of attending practitioners regarding the appropriateness of releasing information to a patient. More particularly, it requires that, when an attending physician believes that disclosure may harm the patient, the PRO must disclose the information to the patient's designated representative rather than to the patient or, when the patient is mentally, physically, or legally unable to designate a representative, to a person the PRO determines to be "responsible for the patient."³⁶²

Second, the *Third Scope of Work* differentiates between physicians and providers as to the appropriate PRO response to a beneficiary complaint. If the complaint involves a facility, the PRO must inform the beneficiary as to quality deficiencies it has discovered and corrective action it requires.³⁶³ It must include within this notice any comments the facility made during the thirty-day discussion period. If the quality problem involves a physician, however, the PRO may only provide "[a] general response that assures the beneficiary that a thorough investigation of his/her complaint is being conducted and that corrective action will be taken when a problem is found."³⁶⁴

The PROs have received few complaints through this process. How few is not known, as HCFA does not collect data on complaints. Thirty-eight PROs that responded to a survey conducted by PRONET, an organization of PRO beneficiary representatives, reported receiving a total of 651 quality complaints between October 1, 1987, and the fall of 1988, with a range of 0 to 97 complaints and an average of 18 complaints.³⁶⁵ Knowledgeable persons with whom I spoke, moreover, confirmed

360. *Id.* § XVII(A)(5), at 37.

361. *Id.* § XVII(A)(7), at 38.

362. 42 C.F.R. § 476.132(c) (1987). The incorporation of 42 C.F.R. § 476.132(c) is maintained by the proposed regulations. See PROPOSED SUBSTANDARD CARE REGULATIONS, *supra* note 61, at 1964 (to be codified at 42 C.F.R. pt. 462, § 466.106(b)).

363. THIRD SCOPE OF WORK, *supra* note 3, § XVII(A)(6)(a), at 37.

364. *Id.* § XVII(A)(6)(b), at 38. This will apparently be changed if the proposed regulations for review of beneficiary complaints are implemented, as they permit disclosure of physician-specific information to beneficiaries. See PROPOSED SUBSTANDARD CARE REGULATIONS, *supra* note 61, at 1960, 1964 (to be codified at 42 C.F.R. pt. 476, subpt. B, § 476.133(b)(4)).

365. PRONET, BENEFICIARY WRITTEN QUALITY COMPLAINT SURVEY 2-3 (1988).

the results of my own less formal survey: most PROs receive from five to forty complaints a month.

The paucity of complaints is not surprising. First, few beneficiaries are aware that the PROs are available to receive complaints. Community outreach is a growing emphasis of the PROs. Under the *Third Scope of Work*, PROs must submit a detailed community outreach plan, which includes such components as a toll-free number (which several of the PROs already have), educational programs and seminars, and publication of informational materials.³⁶⁶ The PROs, however, still have far to go. Several representatives of beneficiary groups complained to me of the difficulties consumers have encountered in locating anyone at their PRO who is willing or able to take a complaint. One said that if a person from their organization calls a PRO to make a complaint, the PRO does not know what they are talking about.

Second, the statutory requirement that the complaint be in writing undoubtedly deters many complaints. PROs responding to the PRONET survey reported receiving 3036 total complaints by telephone, but only 944 in writing.³⁶⁷ Medicare beneficiaries with current or recent experiences of unsatisfactory medical care are often feeble and debilitated. Making a phone call to a PRO to present a coherent complaint requires a major effort. If the PRO tells the caller that the complaint can only be investigated if it is received in writing, the complainant must make a substantial additional effort, which probably will not be forthcoming. Many beneficiaries also interpret such a response to mean that the PRO is an uncaring bureaucracy, which is not interested in the complaint and will not take it seriously.

One PRO with which I spoke attempts to deal with this problem by assisting the complainant in drafting the complaint while on the phone. HCFA or the PROs could also develop a form that could be immediately sent to complainants to fill out, with a stamped return envelope, or that could be completed by the PRO with information gained from the phone call.³⁶⁸ Only two PROs reported to PRONET that they assisted complainants by filling out a complaint form based on the verbal complaint and sending it to the complainant for verification and signature.³⁶⁹ A more sensible move would be to remove the requirement of a writing altogether. It serves no obvious function other than perhaps to deter some frivolous complaints. Though screening is undoubtedly necessary to eliminate vague or unsubstantiated complaints, PROs should be willing to investigate specific oral complaints.³⁷⁰

Third, HCFA should amend its instructions to the PROs to assure protection of the confidentiality of complainants.³⁷¹ Under complaint investigation procedures

366. *THIRD SCOPE OF WORK*, *supra* note 3, § XVI(C), at 34.

367. PRONET, *supra* note 365, at A1. This total includes both the quality-related and nonquality-related complaints.

368. See Letter, *supra* note 172, at 2-3. One HCFA representative with whom I spoke affirmed this idea but suggested the PROs do it as they, unlike HCFA, are not subject to the Paperwork Reduction Act and thus can develop new forms more quickly.

369. PRONET, *supra* note 365, at A1.

370. Cf. CAL. HEALTH & SAFETY CODE § 1419 (West 1979 & Supp. 1988) (complaints involving nursing homes may be submitted in writing, by telephone, or by personal visit; oral complaints shall be reduced to writing by the Department of Health); ILL. ANN. STAT. ch. 111 1/2, ¶ 4153-702(a) (Smith-Hurd Supp. 1988).

371. The Senate version of the complaint investigation provision included a requirement for protecting the

required by the *Third Scope of Work*, a provider or practitioner being investigated will be able to discover immediately the identity of the complainant because the PRO will request specifically the record of the complainant and a response to the complaint. But the PRO is required even to go beyond this and to request specifically the attending physician's opinion as to whether the complainant is sufficiently stable to receive information resulting from the complaint investigation.

The exposure of the complainant's identity throughout the process not only serves to discourage complaints, but it may also actually put some complainants at risk for their health and safety. Two representatives of beneficiaries with whom I spoke noted that the PRO's practice of informing skilled nursing facilities (SNFs) of the identity of residents who had complained about conditions in the SNF could be dangerous to the complainant. The vulnerability of nursing home residents to physical and mental abuse is widely acknowledged³⁷² and has been recognized in state nursing home laws protecting the confidentiality of complainants.³⁷³ Yet even when care in the hospital is involved, and abusive retaliation is less likely, the elderly, debilitated patient or her family may fear that care will suffer further if the provider or physician becomes aware that the patient has complained to the PRO. One interviewee noted the tenuous nature of contemporary physician/patient relationships and expressed the opinion that few beneficiaries would "risk this relationship to complain of problems without strict protection of confidentiality.

Given the broad powers the PROs have to monitor care in institutions under their jurisdiction, they could easily investigate complaints while protecting the identity of complainants. A PRO, for example, could request a facility that was the subject of a complaint to provide the records of ten patients, including the complainant and nine others chosen at random. Indeed, a PRO could intensify review of a particular provider or physician, reviewing all cases or all cases in a particular area. If a problem were identified, the PRO could then approach the provider with a pattern of cases, no one of which would be identifiably linked to a complainant. If it became absolutely necessary at some point in a proceeding to identify a complainant, the complainant could be offered the opportunity (afforded by a number of state nursing home laws) to withdraw the complaint rather than be put at risk.³⁷⁴

The *Third Scope of Work* provision that allows a physician target of a complaint to decide whether a complainant is capable of receiving information about the

confidentiality of the complainant. This requirement was deleted without comment by the Conference Committee. See CONF. REP. 1012, 99th Cong., 2d Sess. 360-61. This does not necessarily preclude HCFA from establishing confidentiality requirements, as they have elsewhere in the PRO program, see 42 C.F.R. § 473, but may argue in favor of the need for a statutory, and not just a regulatory, change.

372. See Stannard, *Old Folks and Dirty Work: The Social Conditions for Patient Abuse in a Nursing Home*, 20 SOC. PROBS. 329 (1973).

373. CAL. HEALTH & SAFETY CODE § 1419 (West 1979 & Supp. 1988); ILL. ANN. STAT. ch. 111 1/2, ¶ 4153-702(c) (Smith-Hurd 1988); IOWA CODE ANN. § 135C.37 (West Supp. 1988); MICH. COMP. LAWS ANN. § 333.21799a(3) (West 1980); A.B.A. MODEL RECOMMENDATIONS: INTERMEDIATE SANCTIONS FOR ENFORCEMENT OF QUALITY OF CARE IN NURSING HOMES 33, 37, 40 (1981).

374. See ILL. ANN. STAT. ch. 111 1/2, ¶ 4153-702 (Smith-Hurd 1988); MICH. COMP. LAWS ANN. § 333.21799a(3) (West 1980).

investigation is particularly offensive, indeed bizarre, and it should be deleted as soon as possible.

It is ironic that although the PRO *Third Scope of Work* offers no protection for the confidentiality of complainants, it goes so far in protecting the privacy of problem physicians that it actually violates the statute. This is a fourth problem with implementation of the beneficiary complaint investigation requirement. OBRA '86 requires that the PRO "shall inform the individual (or representative) of the organization's final disposition of the complaint."³⁷⁵ The *Third Scope of Work*, however, ever solicitous to protect the reputation of physicians, only allows the PRO to give the beneficiary an evasive report that an investigation is being conducted and corrective action, if necessary, will be taken. This response is contrary to the requirements of the statute that the PRO explain its "final disposition."³⁷⁶ Moreover, it is likely to discourage complainants, who may be reluctant to pursue a complaint without any possibility of discovering its disposition. It is hoped that this problem will be cleared up by the proposed regulations, which seem to permit disclosure of physician-specific information.³⁷⁷

Fifth, representatives of beneficiary organizations with whom I spoke also believe that beneficiaries are discouraged from complaining by the cumbersomeness of the process. For example, most PROs define "quality" issues quite narrowly and refuse a significant proportion of complaints lodged with them as inappropriate.³⁷⁸ By contrast, two of the PROs with which I spoke pursued nearly all complaints lodged with them and were quite successful, for example, in straightening out billing and coverage disputes for their beneficiaries. This should be the norm, not the exception.

Next is the problem of delay. Under the process outlined above, it can take the PRO nearly three months to investigate a complaint. Contrast this with state nursing home complaint investigation statutes requiring investigation of abuse and neglect complaints to be completed within seven days, or within twenty-four hours if a resident's life or safety is imminently threatened, and all other investigations within thirty days.³⁷⁹ While the statute requires that practitioners and providers must be given "reasonable notice and opportunity for discussion" before the PRO concludes that their services were of poor quality, the length of time that is reasonable in any particular case should be determined considering the seriousness of the complaint.³⁸⁰

375. OBRA '86, Pub. L. No. 99-509, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 1874, 2047 (to be codified at 42 U.S.C. § 1320c-3(a)).

376. 42 U.S.C. § 1320c-3(a)(9) requires confidentiality of PRO data generally and permits disclosure to the extent necessary "to carry out the purposes of this part." Here disclosure is clearly necessary.

377. See *supra* note 364. Again, it is instructive to consider nursing home statutes that not only require the investigative agency to give the complainant a full accounting of its investigation, but also allow the complainant an opportunity to appeal if dissatisfied with the result. See ILL. ANN. STAT. ch. 111 1/2, ¶ 4153-702(g) (Smith-Hurd 1988); A.B.A. MODEL RECOMMENDATIONS, *supra* note 373, at 37.

378. The PRONET survey discovered that some PROs consider nearly all complaints to be quality complaints, others only a very small percentage. Two PROs classified only 3% of the complaints they received as quality complaints. PRONET, *supra* note 365, at 3.

379. ILL. ANN. STAT. ch. 111 1/2, ¶ 4153-702 (Smith-Hurd 1988).

380. HCFA's recent proposed regulations require PROs to allow practitioners or institutions 30 days to respond to complaints prior to notification to beneficiaries, further slowing the process. See PROPOSED SUBSTANDARD CARE REGULATIONS, *supra* note 61, at 1964 (to be codified at 42 C.F.R. pt. 462, § 466.106(a)). That PROs are capable of greatly

Several beneficiary representatives complained more generally that the PROs will not communicate with complainants once the complaint is lodged and that they tend to dismiss complainants and complaints too readily. One stated that an individual beneficiary would seldom be able to pursue a complaint to a successful conclusion without strong support from a determined family or beneficiary organization. Others complained of the limited scope of PRO complaint investigations—they are generally restricted to the facility record and ignore care received in doctors' offices or following hospitalization. Finally, once PROs identify problems, there is often little they can do to solve them. With nursing homes or home health agencies, for example, the PRO may well end up referring a confirmed problem to the state licensing and certification agency, which could have handled the initial complaint more rapidly and with less danger to the complainant if the complaint had simply been forwarded to it in the first place.

This final observation highlights a basic problem with the PRO complaint investigation procedure: recent federal and state consumer protection initiatives are building a reticulate, and sometimes redundant, system for beneficiary protection. OBRA '87, for example, requires investigation of complaints involving nursing homes and home health agencies at the state level.³⁸¹ All states have physician licensure agencies, most license hospitals, all license nursing homes, all have nursing home ombudsmen programs. Until recently, the PRO role in this network of survey and enforcement agencies has been to monitor hospital data on an ongoing basis and to study and correct problems identified through that monitoring process. The complaint investigation requirements of OBRA '86 require PROs to take on an additional new identity, much more closely akin to traditional law enforcement. This may be appropriate in some settings, such as hospitals, in which PROs have extensive experience and in which there are few alternatives to which the beneficiaries can turn. It is less appropriate in the nursing home setting, in which other modes of state and federal regulation are more established and PROs have little experience.³⁸² PROs will not easily become comfortable in this new role, and if they are to take it on effectively, HCFA will have to give more leadership than it is currently offering.³⁸³

VIII. HOSPITAL NOTICES OF NONCOVERAGE

With the DRG PPS Medicare reimbursement system came a fear that the new system would create incentives for hospitals to discharge patients "sicker and quicker."³⁸⁴ Because hospitals are paid on a per admission basis, it was thought they

expedited review is demonstrated by the notice of noncoverage procedures, discussed in Part VIII below, under which decisions are rendered in three days or less.

381. OBRA '87, Pub. L. No. 100-203, §§ 4025, 4202(a)(2), 1987 U.S. CODE CONG. & ADMIN. NEWS (101 Stat.) 1330, 1330-74, 1330-174 to -179 (to be codified at 42 U.S.C. § 1395x(v)(1)(L), 1395aa(d)).

382. See INSTITUTE OF MEDICINE, *supra* note 304, at 146-70.

383. A draft manual transmittal addressing the PRO complaint investigation authority attempts to describe the kinds of problems PROs should address and those they should refer to others to investigate. This is a step in the right direction. In fact, only 59 of the 517 classified quality complaints received by the PROs identified in the PRONET survey pertain to nursing homes. PRONET, *supra* note 365, at A1.

384. See *Examination of Quality of Care Under Medicare's Prospective Payment System: Hearings Before the*

would attempt to discharge patients as quickly as feasible to reduce their costs and increase their profits. The PROs, as Medicare's primary bulwark against erosion of the quality of medical care, were quickly brought in to assist in assuring that Medicare beneficiaries were not discharged until discharge was medically appropriate. Resulting legislation, regulations, and manual provisions have created a terribly complex process that has left beneficiaries confused and their representatives frustrated.

OBRA '86 created the basic framework under which PROs review hospital notices of noncoverage. If a hospital determines that a Medicare beneficiary no longer needs inpatient care, and the patient's attending physician agrees, the hospital may give the patient a notice of this determination.³⁸⁵ This notice is called a notice of noncoverage, because it is effectively a notice that hospitalization is no longer necessary and, therefore, no longer covered by Medicare.³⁸⁶ If a hospital gives this notice, and the patient refuses to leave, the hospital may begin charging the patient directly for his or her care after the second day following the date of the notice (after two "grace days").³⁸⁷

The patient may, however, request the PRO to review the hospital's determination. If the patient requests the review no later than noon of the first working day after the date he or she receives the hospital notice, the hospital must provide the PRO with the patient's records by the close of that day.³⁸⁸ The PRO must then review these records and discuss the discharge with the patient and the patient's attending physician.³⁸⁹ The PRO must complete its review by the close of the next full working day after it has received the records³⁹⁰ and then send a notice to the patient and hospital of the results of its review. If the patient makes a timely request for review, the hospital may not charge the patient for inpatient hospital services received prior to noon of the day after the patient receives notice of the PRO decision.³⁹¹ Of course, if the PRO decides that discharge is medically inappropriate, the hospital cannot charge the patient until discharge is appropriate.³⁹²

If the hospital determines that inpatient care is no longer needed, but the attending physician disagrees, the hospital may ask the PRO to review its determination.³⁹³ The hospital may not charge the patient until the PRO rules in its favor. If the PRO rules in favor of the hospital, and against the attending physician, the hospital may issue a notice of noncoverage. The patient may then request the PRO to reconsider its earlier decision. The PRO must complete this reconsideration within

Senate Comm. on Fin., 99th Cong., 2d Sess. 114, 142, 276, 290 (1986); *Quality of Care Under Medicare's Prospective Payment System: Hearings Before the Senate Special Comm. on Aging*, 99th Cong., 1st Sess. 363-65 (1986) (Vol. I).

385. 42 U.S.C. § 1320c-3(e)(1) (1982 & Supp. IV 1986).

386. *Id.*

387. 42 C.F.R. § 412.42(c)(3)(ii) (1987).

388. 42 U.S.C. § 1320c-3(e)(3)(B) (1982 & Supp. IV 1986).

389. *Id.* § 1320c-3(e)(5); PRO MANUAL, *supra* note 53, §§ IM4120, IM4130.

390. 42 U.S.C. § 1320c-3(e)(3)(B) (1982 & Supp. IV 1986).

391. *Id.* § 1320c-3(e)(4).

392. 42 C.F.R. § 412.42(c)(4) (1987).

393. 42 U.S.C. § 1320c-3(e)(2) (1982 & Supp. IV 1986). Under a provision of OBRA '87, it must notify the patient that it has done so.

three days.³⁹⁴ As the hospital may begin charging the patient after the two grace days elapse, however, the patient may have to pay for the final day of the reconsideration.

The Medicare statute also requires that hospitals give beneficiaries a description of these appeal rights at the time they are admitted.³⁹⁵ The *Medicare Hospital Manual* requires that this statement be a copy of a document entitled "An Important Message from Medicare." The PROs are to monitor hospitals to be sure that they, in fact, give beneficiaries this notice.³⁹⁶ Under a rule proposed in June 1988, the hospital would have to "obtain a separate signed acknowledgement from the beneficiary attesting to the receipt of the statement, and maintain a copy of the acknowledgement."³⁹⁷ Finally, the PRO is responsible for reviewing all cases in which the hospital charges a patient for care after a notice of noncoverage is sent.³⁹⁸ If the PRO determines that the notice of noncoverage was inappropriate, the hospital must refund inappropriately collected charges.³⁹⁹ The PRO regulations and *Medicare Hospital Manual* also provide for an expedited three-day appeal process when a hospital or PRO denies a patient admission to a hospital on the grounds that the admission is not covered by Medicare because it is not for necessary care.⁴⁰⁰

If the procedures described in the preceding paragraphs seem confusing to the reader, imagine how they must seem to an elderly Medicare beneficiary who has just been admitted to a hospital or is just about to be prematurely discharged. Beneficiary representatives with whom I spoke uniformly complained that HCFA's "An Important Message from Medicare" was unintelligible to many beneficiaries and, until recently, in error. Moreover, most beneficiaries are unaware of the "Important Message," which is generally handed to them with a sheaf of other admission papers at a time when they are obviously distracted by other concerns. One recent survey revealed that 82% of beneficiaries claimed that they had not received the notice at admission.⁴⁰¹ An AARP study of persons over sixty-five who had been hospitalized in 1987 found that more than half of the respondents (56%) either believed that they had not received the notice or did not know whether they had received it or not.⁴⁰² Several beneficiary representatives with whom I spoke claimed that hospitals seldom give patients notice of noncoverage, preferring to work with the doctor to convince the patient to leave without threatening to make the beneficiary pay for the care.⁴⁰³

394. 42 C.F.R. § 473.32(a)(1) (1987).

395. 42 U.S.C. § 1395cc(a)(1)(M) (1982 & Supp. IV 1986). These provisions are implemented by 42 C.F.R. § 466.78(b)(3).

396. MEDICARE HOSP. MANUAL, *supra* note 56, § 312.1; PRO MANUAL, *supra* note 53, § 2005.

397. 53 Fed. Reg. 22,523 (1988) (to be codified at 42 C.F.R. § 498.27) (proposed June 16, 1988).

398. PRO MANUAL, *supra* note 53, § IM2080.

399. 42 C.F.R. § 412.42(c)(3)(v) (1987).

400. *See id.* § 473.32(a)(1); Wilson, *How to Appeal Medicare Hospital Coverage Denials Under the DRG System*, 20 CLEARINGHOUSE REV. 434 (Summer 1986).

401. Conversation with Laura Schoenberg, Pennsylvania Public Interest Coalition.

402. AARP, DRAFT OF SURVEY BY MARKETFACTS 5 (1988).

403. In fact, PRO data reveal that the extent of issuance of hospital notices varies significantly from PRO to PRO. New York hospitals had issued 39,726 notices as of June 1988, Washington hospitals only 10. The extent of PRO disagreement with the hospital also varied significantly, from a disagreement rate of 41% in Michigan and 44% in Delaware, to 3% in Minnesota, Montana, and Maine. HEALTH CARE FIN. ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., MONTHLY PEER REVIEW ORGANIZATION (PRO) DATA SUMMARY D3 (Sept. 8, 1988) [hereinafter PRO DATA SUMMARY].

Though hospitals must all disseminate the "Important Message" at admission, they can draft their own notices of noncoverage to give at discharge, and these vary significantly, some not explaining the patient's rights at all.

The most important issues in this area concern whether the beneficiary should always be entitled to a liability-free appeal to the PRO, when the beneficiary should be given a notice of his or her rights, and what the notice should say. As described above, if the hospital notifies the beneficiary that it and the beneficiary's physician concur that the beneficiary should be discharged, and the beneficiary appeals by noon of the next day, the beneficiary cannot be charged for care until the PRO rules on the appropriateness of the discharge. If, however, the hospital and the physician disagree, the hospital requests PRO review, the PRO rules in favor of the hospital, the hospital issues a notice of noncoverage, and the beneficiary requests PRO reconsideration, the beneficiary may end up paying for a day of care while awaiting the PRO decision.

This two-track process is responsible for much of the complexity of the "Important Message" and the confusion of the current process. Surely the cost to the hospitals of the extra day of care in the latter situation, which cannot be too common, does not justify this added confusion and complexity. Alternatively, PROs reviewing beneficiary appeals, when they have already ruled on the disagreement between the doctor and hospital, should be able to reconsider their decision within the two grace days, because they already have the records and have talked to the parties during the prior review. In any event, it should be possible to provide the beneficiary with a liability-free review by the PRO. OBRA '86 only provided a liability-free appeal from notices of noncoverage when the hospital and physician concurred. OBRA '87 appeared to assure a liability-free appeal for all beneficiaries, regardless of physician concurrence or nonconcurrence in the original decision, but a technical correction to OBRA '87, found in the Catastrophic Coverage Act, restored the two-track system.⁴⁰⁴ The statute should be amended to assure that every beneficiary who receives a notice of noncoverage, and who appeals by noon of the next day to the PRO, is entitled to remain in the hospital without additional charge until the PRO decides the appeal.

If it is the intent of HHS to make beneficiaries aware of their rights, it is troubling to rely on information concerning these rights given beneficiaries at the time of admission, when most beneficiaries (and their representatives) are overwhelmed with the anxiety of a hospital admission and other paperwork connected with the hospital stay. Even having the beneficiary or representative sign the notice will help little, as the notice will remain only one more paper to be signed as part of the admission process. Notice of beneficiary rights should, therefore, also be given as part of the discharge planning process.⁴⁰⁵

404. Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, § 4096, 1988 U.S. CODE CONG. & ADMIN. NEWS (102 Stat.) 683, 791 (to be codified at 42 U.S.C. § 1320c-3(e)(3)(A)(i), 1320c-3(e)(2)(B)) (to be amended by a subsequent technical correction striking "before 'paragraph (2)'" in Family Support Act, Pub. L. No. 100-485, § 608, 1988 U.S. CODE CONG. & ADMIN. NEWS (102 Stat.) 2343, 2421 (to be codified at 42 U.S.C. § 1320c-3)).

405. Section 9305(c) of OBRA '86, Pub. L. No. 99-509, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 1874,

At the time a hospital or attending physician determines that a Medicare patient no longer needs hospital care, the patient ought to be given notice of this decision and of his or her rights under the law. This information should be given the patient as soon as possible after it is determined that the patient is ready for discharge and at an early enough point to allow the patient to exercise his or her rights. The notice should be provided to the beneficiary by his or her own physician or by an employee of the hospital responsible for discharge planning. Alternatively, the notice could be posted on the wall near the bed in all patient rooms that are used for Medicare beneficiaries, so that the beneficiary could read it at his or her leisure. While providers may object that this procedure may lead to more appeals, it is hard to sympathize with an argument that beneficiaries should be kept ignorant of their rights to keep them from burdening the system through the exercise of those rights.

The notice given the patient should be as simple as possible.⁴⁰⁶ It need only tell the patient that, even though the hospital has decided that discharge is appropriate, the patient can stay and not be charged for the stay until after the second day following the date of the notice. If the recommendation to merge the two-track system into a single system is adopted, the notice would further state that, should the patient decide to appeal and promptly calls (by noon of the next day) the PRO (whose toll-free number would appear prominently in the notice), the patient could not be discharged or charged for care until the day following the PRO's decision on the case. If a two-track system is retained, the notice just described could be given when the doctor and hospital agree, and a separate, differently worded notice could be given if the hospital has already received review from the PRO. This notice would state that a prompt appeal to the PRO would secure review within three days, with the patient liable for only, at most, one day of care. This is all the beneficiary really needs to know, and further information may be more confusing than helpful. This notice (or notices) should be on forms provided the hospital by HCFA to assure uniformity and accuracy. It should be drafted with ample input from beneficiary organizations to assure that it is comprehensible to beneficiaries.

IX. UTILIZATION REVIEW DENIALS, RECONSIDERATIONS, AND APPEALS

While PROs do not yet have regulatory authority to deny payment for substandard care, they regularly exercise their authority to deny payment for care they determine to have been rendered unnecessarily, or in an inappropriate setting, or to partially deny requested payment by modifying the DRG assigned by a hospital.⁴⁰⁷ When PROs determine that payment should be denied on the basis of lack of necessity, they are required further to determine whether beneficiaries, practitioners, or providers should be excused from liability for the cost of this care because they did

1989, requires hospitals to assist Medicare patients with discharge planning. 42 U.S.C. § 1395x(ee) (1982 & Supp. IV 1986) (implemented by regulations proposed at 53 Fed. Reg. 22,506 (1988)).

406. See Letter, *supra* note 172, at 4.

407. 42 U.S.C. § 1320c-3(a) (1982 & Supp. IV 1986); 42 C.F.R. § 412.60(d) (1987); *id.* pt. 466.

not know, and could not reasonably have known, that Medicare would not pay for the care.⁴⁰⁸

The PRO utilization review denial process is normally initiated when a nurse reviewer, applying screening criteria, kicks out an aberrant medical record. This record is then reviewed by a physician (usually not of the specialty of the physician whose work is being reviewed) who then sends a notice to the attending physician and to the provider requesting an explanation.⁴⁰⁹ The PRO must allow the physician and provider twenty days to respond to the query and must also allow an opportunity to discuss the problem by telephone.⁴¹⁰ The provider and physician response is then reviewed again, and a final initial determination is made by the PRO. In several of the PROs I interviewed, this determination is made by the initial reviewer; in others it is performed by a second reviewer. In only one of the PROs I interviewed was there an attempt to use a matched specialist for this review.⁴¹¹ Notice of this initial determination is sent to the beneficiary, physician, provider, and the fiscal intermediary (which denies payment to the provider).⁴¹²

A beneficiary, provider, or physician affected by an initial denial, unfavorable waiver of liability determination, or DRG change may request a reconsideration by the PRO within sixty days of receipt of notice of the denial.⁴¹³ The case is then reconsidered by a matched board-certified or board-eligible specialist, who cannot be the person who made the initial determination.⁴¹⁴ If a beneficiary requests a reconsideration, the PRO must complete its review within three working days if the beneficiary is an inpatient in a hospital (and the claim relates to the hospitalization) or if the initial determination was a preadmission review and denied admission, or if the patient is an inpatient in a skilled nursing facility, the PRO must complete its review within ten working days.⁴¹⁵ All other PRO reviews must be completed within thirty working days.⁴¹⁶ Some PROs offer an evidentiary hearing at the reconsideration level; others conduct a review on the written record (considering any additional information offered by the requester) or by telephone.⁴¹⁷

If the PRO reconsideration decision is unfavorable, and the amount in controversy involves more than \$200, the beneficiary may appeal the decision to an ALJ.⁴¹⁸ If more than \$2000 is involved, the beneficiary may seek judicial review.⁴¹⁹

408. 42 U.S.C. § 1395pp (1982 & Supp. IV 1986); 42 C.F.R. § 466.86(a)(4) (1987).

409. 42 C.F.R. § 466.93 (1987).

410. THIRD SCOPE OF WORK, *supra* note 3, § III(B), at 2-3.

411. The regulations only require that the determination be made by a physician, 42 C.F.R. § 466.98, though the *PRO Manual* also requires that it be done by a physician who practices in a setting similar to that of the physician whose care is being reviewed. PRO MANUAL, *supra* note 53, § IM2002. The AMA PRO EXECUTIVE SURVEY, *supra* note 136, Table 7, found that 28% of the PROs use specialists for initial medical reviews. More information on this is contained in a recent GAO study. See generally GAO MEDICARE PROs, *supra* note 175.

412. 42 C.F.R. § 466.94(a) (1987).

413. 42 U.S.C. § 1320c-4 (1982); 42 C.F.R. §§ 473.15, .16, .20 (1987); PRO MANUAL, *supra* note 53, § 4082. See generally Wilson, *supra* note 400 (on PRO appeals).

414. 42 C.F.R. § 473.28 (1987); PRO MANUAL, *supra* note 53, § 4084(A).

415. 42 C.F.R. § 473.32 (1987).

416. *Id.*

417. PRO MANUAL, *supra* note 53, § 4086(B).

418. 42 U.S.C. § 1320c-4 (1982).

419. *Id.*

A provider or physician denied payment, however, has no recourse beyond the reconsideration, except the right to appeal unfavorable waiver of liability determinations.⁴²⁰ The provider or practitioner may also request an ALJ hearing if the PRO found it to have inappropriately discharged or transferred a patient in circumvention of the PPS system.⁴²¹ The physician or provider cannot collect from the patient if payment is denied.

As a practical matter, PRO determinations seldom involve large enough sums of money to justify the cost of an appeal to an ALJ or judicial review.⁴²² Moreover, since only the beneficiary can directly appeal a PRO necessity or appropriateness decision, and since the beneficiary is usually excused from payment for denied care under the waiver of liability provisions, there is seldom sufficient incentive for the beneficiary to appeal.

PRO officials with whom I spoke generally felt the utilization review system was working rather well. Beneficiary and provider representatives were less sanguine, though few put revising the utilization review process at the top of their PRO agenda. Several concerns, however, were raised by these representatives.

First, providers and practitioners are concerned that they have no means of directly appealing an adverse PRO utilization review decision to an ALJ. 42 U.S.C. section 1320c-4 only allows beneficiaries the right to appeal PRO decisions to an ALJ. As noted above, providers may directly appeal adverse waiver of liability decisions, but not the underlying decision on necessity or appropriateness (except when the provider has been found to have taken an action to circumvent PPS).⁴²³ Even if a provider wins a waiver of liability appeal and the underlying decision is wrong, the provider will be bound by that decision in future cases, for it will not again be able to argue that it did not have notice of the lack of necessity of the service, a necessary element of a waiver of liability determination.⁴²⁴ Section 9313(a) of OBRA '86 permitted providers and practitioners to represent beneficiaries in Medicare appeals (if they did so without charge and waived any right to payment for the services that were the subject of the appeal),⁴²⁵ thus effectively allowing providers and practitioners direct appeal rights when the beneficiary agreed to allow such representation. This provision, however, expressly does not apply to PRO decisions.⁴²⁶ The Senate version of OBRA '87 extended it to the PRO program, but

420. *Id.* § 1395pp(d) (1982 & Supp. IV 1986). This appeal is only available if the beneficiary does not appeal and if the amount in controversy exceeds \$100 for Part A determinations or \$500 for Part B determinations. Judicial review is available for waiver of liability determinations involving more than \$1000.

421. PRO MANUAL, *supra* note 53, § 4088(A); 53 Fed. Reg. 8,665 (1988) (to be codified at 42 C.F.R. § 466.83) (proposed Mar. 16, 1988). This distinction is often not clear. A PRO could find an inappropriate readmission, for example, to be not medically necessary or to be the result of a premature discharge.

422. Some of course will, such as an admission denial involving a costly medical procedure.

423. PRO MANUAL, *supra* note 53, § 4088(A).

424. 42 U.S.C. § 1395pp(a)(2) (1982).

425. OBRA '86, Pub. L. No. 99-509, 1986 U.S. CODE CONG. & ADMIN. NEWS (100 Stat.) 1874, 2002 (to be codified at 42 U.S.C. § 1395ff(b)(1)).

426. 42 U.S.C. § 1395ff(b)(1)(D) (1982 & Supp. IV 1986).

this amendment was dropped from the conference bill,⁴²⁷ and thus providers and practitioners remain without any means of appealing PRO decisions.

Because few PRO utilization review denials involve large enough sums to justify the cost of an appeal (or even to reach jurisdictional amounts for an appeal), providers and practitioners are much more concerned that utilization review decisions be made correctly in the first place. The data are not encouraging. Nationally as of June 1988 during the second contract cycle, 3.862% of reviewed cases were denied.⁴²⁸ In over 30% of these cases, a reconsideration was requested.⁴²⁹ In nearly 44% of these cases, the initial decision was reversed on reconsideration. Reversal rates of individual PROs ranged from 10% to 71%.⁴³⁰ The SuperPRO has also disagreed with PRO utilization review decisions in a significant proportion of cases.⁴³¹ It is difficult to avoid the impression that PROs are often sending out initial denials without adequate consideration, trusting that if the decision is wrong it can always be changed at the reconsideration level. This is not a defensible approach under any circumstance. Considering that denial notices go to beneficiaries as well as to providers and practitioners, and often leave beneficiaries confused, anxious, and uncertain of their own liability for the denied care, this practice is inexcusable.

Two approaches to improving the quality of utilization review decisions are apparent. First, more contact can be required between the PROs and the providers and practitioners whose records they are reviewing. This approach is taken by OBRA '87, which affords a practitioner or provider an opportunity of discussion and review of a proposed denial before the decision is implemented.⁴³² Although this approach is sensible and is already the practice of many PROs, going further in the direction of requiring the reviewer to justify his or her decision to the practitioner or provider is not without costs. One PRO executive, for example, noted that it is difficult enough to get qualified reviewers, and it will be even more difficult if reviewers are expected to argue face-to-face with other doctors over every review decision.

Second, specialist review can be required at the initial determination level. Currently, final initial decisions are made in most PROs by doctors who are not specialists in the type of medical care under review.⁴³³ Only at the reconsideration level is specialty-matched review required.⁴³⁴ Given the highly specialized nature of modern medicine, this practice is unacceptable and goes far towards explaining the high level of reconsideration reversals.⁴³⁵ It may not be practical to assign initial

427. H.R. CONF. REP. No. 495, 100th Cong., 1st Sess. 666, *reprinted in* 1988 U.S. CODE CONG. & ADMIN. NEWS 2313-1245, 2313-1412.

428. PRO DATA SUMMARY, *supra* note 403, Table D11.

429. *Id.*

430. *Id.* See Whalen, Schmitt, & Rossetti, *Early Experience with Peer Review Organizations*, 3 J. GEN. INTERNAL MED. 59 (Jan.-Feb. 1988) (describing the PRO reconsideration process from a reviewer's perspective).

431. OIG EFFECTIVENESS REPORT, *supra* note 9, at 12, 61.

432. OBRA '87, Pub. L. No. 100-203, § 4093, 1987 U.S. CODE CONG. & ADMIN. NEWS (101 Stat.) 1330, 1330-136. See 53 Fed. Reg. 8,865 (1988) (to be codified at 42 C.F.R. § 466.93) (proposed Mar. 16, 1988).

433. See 42 C.F.R. § 466.98 (1987).

434. See *id.* § 473.28; 53 Fed. Reg. 8,666 (1988) (to be codified at 42 C.F.R. § 473.28) (proposed Mar. 16, 1988); PRO MANUAL, *supra* note 53, § 4084.

435. See Whalen, Schmitt, & Rossetti, *supra* note 430, at 61.

reviews and the drafting of proposed decisions to matched specialists. Indeed, if the review is done on-site, it is probably not possible. But the final initial decision, made after the provider or practitioner has had an opportunity to review and respond to the proposed decision, should be made by a specialist.

A final issue that is beyond the scope of this Article should be noted because it was mentioned so often by the provider representatives that I interviewed. The direct consequence of a PRO utilization review denial is that the fiscal intermediary is notified, which then denies reimbursement to the hospital under Part A for the unnecessary or inappropriate care. The intermediary should notify the carrier, which should deny payment to the physician who ordered the inappropriate care.⁴³⁶ Hospitals firmly believe, however, that this A-B link has not been made, and carriers are not denying payment to doctors. Hospitals are exceedingly annoyed that they are routinely denied payment for unnecessary care, but the doctors who ordered the care are not penalized by Medicare in any way. Their annoyance seems justified, and taxpayers, who are financing the unnecessary care, should be equally upset.

X. PRO DATA CONFIDENTIALITY AND DISCLOSURE

One of the primary functions of the PROs is to assemble data. Not surprisingly, therefore, they possess vast quantities of data on Medicare providers, practitioners, and beneficiaries. PROs are not subject to the requirements of the Freedom of Information Act.⁴³⁷ Rather, disclosure and maintenance of confidentiality of PRO data are governed by the PRO statute⁴³⁸ and regulations.⁴³⁹ The general effect of these provisions is to protect data that identifies patients, providers, and practitioners against disclosure, except insofar as this information is required by federal or state regulatory and law enforcement agencies to carry out their responsibilities.

The PRO confidentiality and disclosure provisions are generally consistent with recommendations made by the Institute of Medicine after a thorough study in 1981.⁴⁴⁰ This study thoughtfully weighed the considerations in favor of disclosure and of confidentiality and reached conclusions that continue to be on the whole acceptable. I would favor greater disclosure of health care quality data to assist in creating a smoother functioning market for health care services,⁴⁴¹ but this preference is grounded on health care policy rather than administrative law considerations.⁴⁴²

Several confidentiality and disclosure issues have been discussed earlier in this

436. Part B Carrier's Manual, § 4169; Gosfield, *Utilization Management and Quality Assurance*, 2 MED. STAFF COUNS. 15, 16 (Spring 1988).

437. 42 U.S.C. § 1320c-9(a) (1982 & Supp. IV 1986).

438. *Id.* § 1320c-9.

439. 42 C.F.R. pt. 476 (1987); *see also* 53 Fed. Reg. 8,654, 8,666-67 (1988) (to be codified at 42 C.F.R. pt. 476) (proposed Mar. 16, 1988).

440. *See* INSTITUTE OF MEDICINE, ACCESS TO MEDICAL REVIEW DATA: DISCLOSURE POLICY FOR PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS (1981), summarized in *Searches for A Balance in Medical Data Disclosure: Report of a Study*, 1 HEALTH AFF. 62, 62 (Spring 1982).

441. *See* Jost, *The Necessary and Proper Role of Regulation to Assure the Quality of Health Care*, 25 Hous. L. REV. 525, 594-97 (1988).

442. Greater disclosure is favored also by beneficiary groups. *See* Letter, *supra* note 172, at 5-6; Letter from Sidney Wolfe to HCFA (July 5, 1984) (commenting on proposed PRO confidentiality and disclosure regulations).

Article.⁴⁴³ There are two additional areas, however, in which PRO policy should be clarified to assist in effectuating the PRO mission. First, PRO sharing of data with state medical boards should be improved. The OIG study on PRO quality assurance activities found that 67% of the PRO CEOs interviewed believed that the relationship between their PRO and state medical board was relatively poor, and 27% felt that greater clarification was needed as to federal restrictions on sharing information with the medical board.⁴⁴⁴ This is consistent with my own discussions with the twelve PROs I interviewed, most of whom exchanged little data with the state medical boards.

Section 9353(d) of OBRA '86 requires PROs to share data with state regulatory authorities. Regulations implementing this provision have been proposed by HHS.⁴⁴⁵ HHS should promptly promulgate regulations, issue *Manual* provisions implementing these regulations, and amend its *Scope of Work* to require the PROs to formulate a plan for sharing data with state medical boards.⁴⁴⁶

The second issue involves PRO notification of hospitals of problems involving physicians on the staff of those hospitals. The PRO confidentiality regulations require PROs to disclose to an institution, on request, information regarding the practice and performance of practitioners in that institution.⁴⁴⁷ Some PROs with which I spoke have interpreted this provision liberally, notifying hospitals immediately whenever they identify quality problems involving physicians on their staffs and fully involving the hospital in the corrective action plan.⁴⁴⁸ Others have refused to release any information to hospitals about a practitioner without the consent of that practitioner, which is seldom given. The California Medical Association, recognizing the valuable role that hospital medical staffs can play in assisting physicians with practice problems, has urged HCFA to clarify the responsibilities of PROs to involve hospital medical staffs in resolving physician quality problems.⁴⁴⁹ The AMA has debated taking a position favoring disclosure of physician problems to hospital medical staffs, but it stopped short of doing so.⁴⁵⁰ The AHA has also asked that hospitals be notified

443. See *supra* text at notes 278–81, 371–77.

444. OIG QUALITY REPORT, *supra* note 167, at 18; see also OIG LICENSURE & DISCIPLINE REPORT, *supra* note 337, at 15, 17 (faulting the state medical boards for their poor relationship with the PROs). See also GAO MEDICARE PROs, *supra* note 175, at 30 (57% of PROs reported no contact with state medical boards in the fourth year of the program; only 27% reported more than one contact).

445. 53 Fed. Reg. 8,654, 8,666–67 (1988) (to be codified at 42 C.F.R. pt. 476) (proposed Mar. 16, 1988). HCFA should also alter its proposed regulations to conform to the law. 42 U.S.C. § 1320c-9(b)(2), as amended by OBRA '86, requires disclosure on request to state licensure bodies of data or information "relating to a specific case or to a possible pattern of substandard care." The proposed regulation requires disclosure on request of information "relating to a specific case of a possible pattern of substandard care." 53 Fed. Reg. 8,654, 8,667 (to be codified at 42 C.F.R. § 476.138(a)(1)) (proposed Mar. 16, 1988) (emphasis added). As the rule would seem to require a pattern of substandard care before information regarding a specific case could be disclosed, it would permit sharing of much less information than the statute. I am informed that this is a misprint, which will be corrected by HHS in the final rule.

446. See OIG QUALITY REPORT, *supra* note 167, at iii; current requirements in the *Scope of Work* require this only obliquely (see THIRD SCOPE OF WORK, *supra* note 3, §§ XVIII(G), XX, at 41–42).

447. 42 C.F.R. § 476.133(a)(2) (1987).

448. See AMA PRO EXECUTIVE SURVEY, *supra* note 136, Table 15 (85% of the PROs report meeting with medical staff to share corrective action plans).

449. See Letter from Laurens White, CMA, to Thomas Morford, HSQB, at 3 (Mar. 30, 1988).

450. PROs Draw Fire from AMA House, MED. WORLD NEWS, Jan. 12, 1987, at 26.

whenever a quality problem is identified by the PRO involving a physician on their medical staffs.⁴⁵¹

Several HCFA memos issued in 1988 have further muddied the waters as to the PROs' responsibilities in this respect. A Regional Medical Review Letter issued in January 1988 informed the PROs that absent permission from a physician they could not disclose information concerning quality problems to a hospital medical staff unless the PRO identified a "pattern" of poor practice (involving more than one confirmed problem) and then only if the hospital requested the information. A subsequent Regional Medical Review Letter, dated June 1988, informed PROs that HCFA had reconsidered and that they could inform hospitals of any confirmed quality problems involving physicians on that hospital's staff, with or without a request. This reconsideration was based on the realization that any quality problem involving a physician potentially involved the provider as well. The June 1988 letter, however, prohibited PROs from divulging to hospitals corrective action plans they were considering. This left the PROs in a quandary, as most physician corrective action plans involve hospital oversight. A memo from HSQB, dated July 22, 1988, addresses this situation by permitting PROs to notify hospitals of corrective action plans when the hospital's participation is necessary to implement the plan or if the plan will affect the hospital. Otherwise, notification to the hospital is still prohibited.⁴⁵²

HHS should amend its confidentiality regulations to allow PROs to disclose to hospital medical staffs information regarding any confirmed quality problems involving practitioners on the staffs of those hospitals and any corrective action plans involving those practitioners. Hospitals already have a pretty good idea of who on their staff is in trouble with the PROs because they know whose records the PROs are requesting. Explicit sharing of PRO information with the hospitals would help them to better focus their efforts in assisting these problem doctors to improve their practices. Such sharing is certainly consistent with the PRO statute, which permits disclosure of confidential information "to the extent that may be necessary to carry out the purposes of this part" and when the Secretary permits disclosure by regulation.⁴⁵³ This change would assist PROs in carrying out their quality assurance role, assist hospitals in dealing with problem doctors, and, ultimately, assist doctors in addressing quality problems before beneficiaries are harmed and sanctions become necessary.

451. See Letter from Jack Owen to William Roper (May 16, 1988) (commenting on proposed PRO regulations). See also Remarks of Buetel, Dedic, and Weit on the role of a hospital PRO committee in assisting physicians, Transcript, Conference on Understanding the Federal P.R.O., 95-107 (Feb. 28, 1987) (sponsored by Loyola University Health Law Institute, Chicago Academy of Medicine, and Resurrection Hospital, Chicago).

452. Memo from Richard Husk, Director Office of Peer Review, to John L. Setman, Associate Regional Administrator, HSQB, Region VII.

453. 42 U.S.C. § 1320c-9(a)(1)-(2) (1982 & Supp. IV 1986).

XI. CONCLUSION

The PRO program is still very young—a person its age would still be in kindergarten. During its short life it has undergone frequent and dramatic change. Not surprisingly, the beneficiaries, providers, and practitioners affected by the program have frequently found it frustrating and almost always confusing. Among those I interviewed, however, there seemed to be an emerging consensus that the program is worth keeping and that it is maturing. The recommendations delineated in this Article are offered to assist in that maturing process, to fine-tune rather than to radically change the program. They will undoubtedly not be accepted by consensus. The parties affected by the program too often have already staked out positions too sharply at odds to make consensus possible. These suggestions are offered, however, with good will towards the program and to all those affected by it. It is hoped that those with the power to implement these recommendations will consider them carefully as a means towards improving the PRO program to better serve the Medicare program and its beneficiaries.

