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The Medicare[1] and Medicaid[2] programs, created in 1965 by Congress[3] in an effort to make crucial health care services available to those segments of society least able to afford them, have become increasingly expensive to fund due primarily to the precipitously rising cost of health care.[4] Recently, another disturbing inflationary force has been the subject of media coverage[5] and congressional concern—fraud and abuse on the parts of both the providers and the beneficiaries of medical services. After finding substantial evidence demonstrating that health care providers participating in Medicare and Medicaid have frequently and profitably employed a number of fraudulent and abusive practices, Congress passed the Medicare-Medicaid Antifraud and Abuse Amendments[6] in a comprehensive effort to rid the health care delivery system and the federal budget of these wasteful and often unsavory occurrences.[7]

In so doing, Congress placed particular emphasis on the need to monitor the health care services provided by "Medicaid mills"—usually inner-city group practice facilities owned and operated by profit motivated entrepreneurs—to eliminate a number of the fraud-

merger as part of an effort to circumvent a Valhi charter provision inhibiting Valhi's ability to merge with Contran), and Kemp v. Angel, 381 A.2d 241 (Del. Ch. 1977) (short-form merger enjoined because of allegations that parent obtained its over 90% holding in subsidiary as result of false representations in tender offer).

1. 42 U.S.C.A. §§ 1395-1395nn (West 1974 & Cum. Supp. 1978).

2. *Id.* §§ 1396-1396k.

3. Social Security Amendments of 1965, Pub. L. No. 89-97, §§ 102(a), 121(a), 79 Stat. 286.

4. Between 1965 and 1974, the cost of medical care in the United States doubled. Rogers, *The Challenge of Primary Care*, in DOING BETTER AND FEELING WORSE 81, 89 figure 4 (J. Knowles ed. 1977).

5. Two separate editions of the CBS television news show "60 Minutes" presented documentation illustrating such fraudulent practices as the rendering of unnecessary care, over-billing, billing for services never rendered, and bribery and kickback schemes in laboratory-physician relations.

6. Medicare-Medicaid Antifraud and Abuse Amendments of 1977, Pub. L. No. 95-142, 91 Stat. 1175 (codified in scattered sections of 42 U.S.C.A. (West Cum. Supp. 1978)).

7. *See generally* H.R. REP. No. 393, 95th Cong., 1st Sess. (1977).

ulent and abusive practices known to flourish there.[8] The method chosen by Congress to alleviate these problems is elaborate and comprehensive. Professional Standards Review Organizations (PSROs),[9] previously responsible only for monitoring the level of care provided Medicare and Medicaid beneficiaries in institutions,[10] will now be required to review the Medicare- and Medicaid-reimbursed services rendered in all noninstitutional (ambulatory) care settings with respect to the necessity, appropriateness, and quality of the services provided.[11] Requests to the Secretary of Health, Education and Welfare (HEW) by PSROs to review "shared health facilities,"[12] a subset of ambulatory care facilities under the bill and defined to include Medicaid mills,[13] are to be given priority by the Secretary[14] in order to expedite PSRO review of the "mills." This review mechanism is intended to curtail the over-utilization of services for which Medicare or Medicaid reimbursement is sought.

The extension of PSRO review into the publicly funded ambulatory care field effects significant change. Review of the quality and necessity of medical care provided in the publicly funded ambulatory care field has hitherto been carried out on an optional basis only.[15] Generally, ambulatory care providers have been reimbursed on a fee-for-service basis regardless of the medical necessity or quality of the services rendered. While the review that was conducted was sufficient to ensure that flagrant abuse and fraud were not left wholly unde-

8. *See id.* pt. 2, at 45-46.

9. PSROs review the necessity and quality of health care for which Medicare or Medicaid reimbursement is sought. They are composed of members of the local medical profession who apply local standards of quality and necessity in making review determinations. PSROs deny reimbursement for unnecessary services and rectify quality deficiencies. *See* notes 18-33 and accompanying text *infra*.

10. H.R. REP. No. 393, *supra* note 7, pt. 1, at 52.

11. 42 U.S.C.A. § 1320c-4(g)(2) (West Cum. Supp. 1978). Fully operational (designated) PSROs are required by this provision to begin ambulatory care review within two years after becoming designated. *Id. See also* H.R. REP. No. 453, 95th Cong., 1st Sess. 42 (1977) (conference committee report). Though no PSROs have yet been designated, *see* note 17 and accompanying text *infra*, the 108 PSROs with "conditional" designations are required to reach fully designated status within four years by the new law. *See* 42 U.S.C.A. § 1320c-3(b) (West Cum. Supp. 1978). Therefore, a large number of PSROs will be conducting ambulatory care review by 1984.

12. 42 U.S.C.A. § 1301(a)(9) (West Cum. Supp. 1978).

13. H.R. REP. No. 393, *supra* note 7, pt. 1, at 52-53.

14. 42 U.S.C.A. § 1320c-(4)(g)(2) (West Cum. Supp. 1978).

15. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, § 1155(g), 86 Stat. 1329 (amended 1977) (current version codified at 42 U.S.C.A. § 1320c-4(g)(2) (West Cum. Supp. 1978)).

tected,[16] most efforts to monitor the necessity and quality of care were directed toward institutional care. PSRO review of ambulatory care represents a new and pervasive intervention in an area receiving a large percentage of Medicare and Medicaid funds.[17] The opportunity for

16. *See, e.g.*, Kavaler, *People, Providers and Payment—Telling It How It Is*, 59 AM. J. PUB. HEALTH 825 (1969).

17. In view of the unsettled state of ambulatory care review, the basis of congressional belief that PSROs can effect cost reductions and quality control in the ambulatory care sector warrants scrutiny. The most compelling justification Congress could have had for passing the amendments would have been documented success of PSRO review in the institutional care setting—but no such documentation exists. Of the 203 PSRO areas nationwide, there are 108 conditional PSROs and 64 with planning status. In fact, as of October 1977, no PSRO had yet achieved fully operational status. S. Laudicina & A. Schneider, The Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977: Implications for the Poor, n.40 (National Health Law Program, Inc., 1977). Physician cooperation, essential to this voluntary participation program, has been extended only grudgingly at best, *Medicare-Medicaid Anti-fraud and Abuse Amendments: Joint Hearing Before the Subcomm. on Health of the House Comm. on Ways and Means and the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 95th Cong., 1st Sess. 255, 268-69 (1977) (statement of Dr. Edgar T. Beddingfield, Jr., for American Medical Association) [hereinafter cited as *Hearing*], even after significant efforts by HEW to mollify the profession. The primary purpose of the original PSRO legislation was cost containment. J. BLUM, P. GERTMAN & J. RABINOW, PSROs AND THE LAW 20 (1977) [hereinafter cited as J. BLUM]. In a publication aimed at practitioners, however, HEW emphasized that the primary goal was quality control. DEP'T OF HEALTH, EDUCATION AND WELFARE, PUB. NO. (05) 74-50001 (1973), *reprinted in* 2 MEDICARE AND MEDICAID GUIDE (CCH) 5227 (1974). Presumably, this latter goal was more palatable to the profession, which is opposed to regulation of any sort. Experts agree that any attempt at this time to evaluate the effectiveness of PSROs in reducing costs or upgrading quality would be premature. *Hearing, supra* at 418-19 (statement of National Council of State Welfare Administrators, American Public Welfare Association), 321-22 (statement of Dr. Anthony Robbins); *see* J. BLUM, *supra* at 204-05; Price, Katz & Provence, *Advocate's Guide to Utilization Review*, 71 CLEARINGHOUSE REV. 318 (1977). Moreover, Congress at no point expresses sufficient satisfaction with PSRO efforts to date to justify the broad expansion of PSRO utilization effected by the 1977 amendments. The legislative history, however, offers no other reason for their enactment.

The legislative history does evince concern on the part of a number of groups that the traditional PSRO function of cost and quality control would be injudiciously altered by the amendments. *E.g., Hearing, supra* at 5 (statement of Dr. Tim Lee Carter who cosponsored the bill), 382 (statement of Dr. Louis Finney for American Association of Neurological Surgeons), 255, 268 (statement of Dr. Edgar T. Beddingfield, Jr. for AMA Council of Legislation). Indeed, the priority given to shared health facility review, *see* notes 12-14 and accompanying text *supra*, coupled with the requirement that PSROs make data available to federal and state Medicare and Medicaid agencies responsible for controlling fraud and abuse, 42 U.S.C.A. § 1320c-15(b)(1) (West Cum. Supp. 1978), indicates a congressional intent to accord PSROs an investigative aspect foreign to the original PSRO cost control mandate. The report of the House of Representatives accompanying the amendments, however, disclaims any such intent. H.R. REP. NO. 393, *supra* note 7, pt. 1, at 53. More to the point, the extension of mandatory PSRO review to all ambulatory care services, rather than solely to those rendered in the "mills," is not explained by the "investigative arm" hypothesis.

Although PSROs have not been proven effective, the literature on them indicates a consensus among observers that, even before the most recent amendments, it was likely that PSROs would figure instrumentally in Congress' plans for establishing a national health insurance scheme, *e.g.*, Havighurst & Blumstein, *Coping With Quality/Cost Trade-Offs in Medical Care: The Role of PSROs*, 70 NW. U.L. REV. 6, 8 (1975); Kennedy, *Preface: Public Concern and Federal Intervention in the Health Care Industry*, 70 NW. U.L. REV. 1, 5 (1975), possibly becoming the sole program responsible for utilization review and quality assurance in the entire health care sector. *See, e.g.*,

beneficial change, both in the PSRO program and in the nation's health care delivery system, is great. Conversely, however, the potential for serious harm caused by clumsy PSRO intervention in ambulatory care is also substantial.

PSROs were created by the Social Security Amendments of 1972[18] in a congressional effort to contain the spiraling costs of Medicare and Medicaid.[19] The 1972 Act requires the Secretary of HEW to "establish . . . [geographical] areas with respect to which [PSROs] may be designated,"[20] and then to enter into a contract with a "qualified organization"[21] in each area, designating that organization as a "conditional" PSRO.[22] To qualify, an organization seeking PSRO designation from HEW must be nonprofit, composed of a "substantial portion" of the licensed doctors of medicine and osteopathy in the PSRO's designated area, and must submit to HEW a "formal plan for the orderly assumption and implementation" of statutory review responsibilities.[23] After receiving a "conditional" designation, a PSRO is to implement its plan and become fully operational (conducting all required review) within four years,[24] whereupon it can attain "operational" status and be considered a fully designated PSRO.

"In order to promote the effective, efficient, and economical delivery of health care services of proper quality,"[25] PSROs are required to determine whether services for which Medicare or Medicaid reimbursement is sought are medically necessary and conform to pro-

Greenburg, *PSRO—On the Way, But to Where*, 20 NEW ENGLAND J. MED. 1493, 1493 (1974). This would obviously represent a prodigious undertaking presenting formidable transitional and organizational problems. Perhaps, therefore, the 1977 amendments contain a hidden agenda—the gradual implementation of PSRO expansion in an effort to cushion the impact on the health care field and the nation's economy of an ultimately all-inclusive health care review.

18. Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 1155-1170, 86 Stat. 1329. PSROs are regulated by four sources: the statute, U.S.C.A. §§ 1320c to 1320c-22 (West 1974 & Cum. Supp. 1978); regulations, 42 C.F.R. § 101 (1976); the program manual, DEP'T OF HEALTH, EDUCATION AND WELFARE, PSRO PROGRAM MANUAL (1974) [hereinafter cited as PSRO PROGRAM MANUAL]; and transmittal letters issued by the Bureau of Quality Assurance, which is part of HEW. The latter two sources, though not binding on PSROs because they are not promulgated in compliance with the Administrative Procedure Act, 5 U.S.C. §§ 552-553 (1976), are made binding by the PSRO-HEW contract. J. BLUM, *supra* note 17, at 49; *see* note 48 *infra*. *See generally* J. BLUM, *supra* note 17, at 19-53.

19. *See* 42 U.S.C. § 1320c (Supp. V 1975) (declaration of purpose).

20. *Id.* § 1320c-1(a).

21. *Id.*

22. *Id.*

23. 42 U.S.C.A. § 1320c-1(b) (West Cum. Supp. 1978).

24. Originally, the conditional designation period was not to exceed 24 months. Social Security Amendments of 1972, Pub. L. No. 92-603, § 1154(b), 86 Stat. 1329. The new law extends that period to 48 months. 42 U.S.C.A. § 1320c-(3)(b) (West Cum. Supp. 1978).

25. 42 U.S.C. § 1320c (Supp. V 1975).

fessional standards of quality.[26] These decisions are to be made by applying "professionally developed" norms[27] and criteria[28] based upon "typical patterns of practice in [the PSRO] region."[29] If, on the basis of its review, a PSRO finds that some or all of the services rendered or to be rendered to a Medicare or Medicaid beneficiary were or are not medically necessary, it must deny reimbursement.[30] When it finds that the services have been of substandard quality, the PSRO can require the provider to undertake continuing education in order to increase its expertise,[31] or in more serious cases, it may report the violations to HEW, which may then suspend or exclude the provider from participation in the Medicare and Medicaid programs.[32]

It is apparent from this complex body of legislation that a PSRO has two distinct review responsibilities: utilization review, to determine the medical necessity of services; and quality assurance, to monitor and assure compliance with professional standards of quality. Utilization review can be thought of as establishing the maximum level of health care services that may be reimbursed under Medicare and Medicaid by asking: "What procedures and tests were used?" Quality assurance, in contrast, enforces the minimum level of care acceptable to the local members of the medical profession by asking: "What procedures and tests were *not* used?" Together, the two review procedures form a health care public accountability system[33] applying peer-developed norms and criteria to determine the adequacy and necessity of medical services provided.

PSROs are required by the 1972 statute to conduct "concurrent" utilization review of all hospital care for which reimbursement is sought.[34] Concurrent review is conducted while the patient is in the

26. *Id.* PSROs are also required to determine whether institutional care was or is being rendered in the appropriate setting—the least expensive setting consistent with quality care. *Id.*

27. 42 U.S.C. § 1320c-5(a) (Supp. V 1975). Norms are used in evaluating necessity. They represent the typical amount of care delivered to similar patients with similar dysfunctions. *See* notes 40-42 and accompanying text *infra*.

28. PSRO PROGRAM MANUAL, *supra* note 18, § 709. The criteria used in evaluating the quality of care represent either those procedures that local practitioners believe ought to be performed, or the acceptable level of success in patient health improvement. *See* notes 56-63 and accompanying text *infra*.

29. 42 U.S.C. § 1320c-5(a) (Supp. V 1975).

30. *See* 42 U.S.C.A. § 1320c-7 (West Cum. Supp. 1978).

31. J. BLUM, *supra* note 17, at 41.

32. *Id.* at 41-42.

33. *See* Escovitz & Zeleznick, *Health Care Accountability System*, in PSRO UTILIZATION AND AUDIT IN PATIENT CARE 232 (S. Davidson ed. 1976) (comparison and contrast of two types of PSRO review responsibilities).

34. *See* 42 U.S.C. § 1320c-5(d)(1) (Supp. V 1975).

hospital to determine the necessity of his admission to the facility and the necessity of his continued stay there.[35] Prospective review, or preadmission screening, is authorized but optional,[36] and consists of a determination of the necessity for elective admissions before they occur.[37] Retrospective review is conducted after discharge by reviewing the patient's chart or an abstract of it[38] only when concurrent review has not been implemented, or when it has been ineffective.[39]

All utilization review scrutinizes the amount of care rendered a patient. Hospital utilization review by PSROs deals primarily with the length of time spent by a patient in the facility. A norm representing the typical length of stay for previous subjects in a patient's age-sex-diagnosis category is used to determine his permissible length of stay;[40] any stay lasting longer than that norm must be justified to the PSRO by the patient's attending physician.[41]An analogous norm, representing the typical number of doctor visits in a patient's age-sex-diagnosis category, has been used successfully in ambulatory care utilization review to reduce the costs of care without prejudice to professional quality standards.[42] It can therefore be reasonably anticipated that PSROs will undertake review for medical necessity of the number of doctor visits, applying norms analogous to those employed in length of stay hospital review.

It is likely that this review will be concurrent or retrospective, since prospective screening by a doctor to determine if a patient needs to see a doctor would be impractical, wasteful, and quite possibly unconstitutional.[43] Moreover, concurrent review in the ambulatory care setting will likely be the exception and not the rule because of practical limitations. Concurrent review of length of stay in hospitals is achieved by

35. J. BLUM, *supra* note 17, at 6-8. *See generally* Price, Katz & Provence, *supra* note 17.

36. *See* 42 U.S.C. § 1320c-4(a)(2) (Supp. V 1975).

37. J. BLUM, *supra* note 17, at 6.

38. *Id.* at 8.

39. PSRO PROGRAM MANUAL, *supra* note 18, § 707(b).

40. *Id.* § 709.15. See J. BLUM, *supra* note 17, at 316-18, for a discussion of hospital utilization review as performed by in-house utilization review committees. PSRO utilization review is identical in its essentials. *Id.* at 322.

41. J. BLUM, *supra* note 17, at 323. Permissible deviations from the norm are represented by "standards." PSRO PROGRAM MANUAL, *supra* note 18, §§ 705.2, -.24, -.26, 709.14.

42. *See* Sasuly & Hopkins, *A Medical Society-Sponsored Comprehensive Medical Care Plan—The Foundation for Medical Care of San Joaquin County, California*, 5 MED. CARE 234, 247 table 7 (1967).

43. *Cf.* American Med. Ass'n v. Weinberger, 522 F.2d 921 (1975) (pending trial on merits, enforcement of HEW regulations requiring hospitals participating in Medicare or Medicaid to perform review of hospital admissions within 24 hours after they occur enjoined, primarily because they endangered right of patient to receive treatment).

requiring that, in order for a patient to be reimbursed for hospital days beyond the date determined to be the norm for his age-sex-diagnosis group, a reviewer must certify before that date the necessity of an extension.[44] Analogously, when an ambulatory care patient is scheduled for a regular medical appointment with his physician, he could be told before he makes his norm-exceeding visit that Medicare or Medicaid will not pay for it, if that is the PSRO decision. Plainly, however, this can be done only when the patient is expected to return to the same physician in connection with the same illness that prompted his previous visit or visits. Except in the case of chronic or moderately serious illness when return visits to the doctor are expected, the typical illness episode will probably not be so predictable. Thus, quite often, review will of necessity be retrospective.

That being so, a significant shift in the importance given cost of care by PSRO reviewing committees may be forthcoming. In conducting concurrent review of the "necessity" of health care services before they are rendered, doctors quite correctly give considerable weight to the patient's right to receive treatment.[45] Because the PSRO decision will affect the care to be received by a particular patient, reimbursement will often be favored in those borderline cases in which the marginal benefit to the patient is small and the cost of the service great. When retrospective review is conducted, however, treatment has already been given; consequently, only the right to payment is at stake. Freed of the necessity of considering a particular patient's needs, the PSRO may be more prone to take a "macro" view of the costs and benefits of health care—the PSRO can decide the necessity of particular health care services by a dispassionate balancing of their benefits and costs, unencumbered by the natural tendency in a marginal situation to provide a particular patient all beneficial services.[46]

The *PSRO Program Manual* provisions,[47] however, promulgated by HEW as binding[48] "guidelines" for PSRO operation, require that

44. *See* authorities cited note 35 *supra*.

45. Havighurst & Blumstein, *supra* note 17, at 59.

46. The PSRO reimbursement decision may become more akin to a policy decision about whether to relax a building code requirement, and less like the humanitarian decision to spend thousands of dollars to rescue a person trapped in a collapsed building. *See id.* PSROs can adequately safeguard physician expectations of reimbursement by resolving difficult necessity issues of first impression in their favor, while denying reimbursement prospectively to future providers rendering the service in question.

47. PSRO PROGRAM MANUAL, *supra* note 18.

48. The guidelines in the *PSRO Manual* are made binding on the PSROs through the PSRO-HEW contract. J. BLUM, *supra* note 17, at 49. This method of operating a government

retrospective review be conducted only when concurrent review is ineffective or not yet implemented.[49] It can be argued that, given the exigencies of ambulatory care delivery, concurrent review will almost always be ineffective, except in the case of chronic or moderately serious illness when patient visits can be anticipated. In addition, the restriction on retrospective review is based upon the principle that retroactive denial of payment imposes a hardship on beneficiary and provider alike, and is avoidable by use of concurrent review.[50] This consideration, however, is undoubtedly of less weight in the ambulatory care context because the cost of ambulatory care is only a small fraction of the cost of a typical hospital bill. The efficacy of the HEW restriction as applied to ambulatory care review is, therefore, questionable.

In addition to utilization review responsibilities, PSROs are required to monitor the quality of health care billed to Medicare and Medicaid. PSRO review of hospital care quality is accomplished through the use of two forms of "medical audit": profile review and Medical Care Evaluation studies (MCEs).[51] Profile review is mandatory,[52] and entails the maintenance and review of "profiles" which contain records of the covered care rendered by individual providers.[53] MCEs are retrospective reviews of patient charts conducted to determine whether health care practices meet current standards of acceptability.[54] Profile review can be used to identify the specific problems affecting medical quality, which in turn can be addressed by MCEs or concurrent utilization review.[55]

The crucial variables in quality assurance are "criteria," predetermined elements against which the quality of care can be measured.[56] There is an ongoing and far from resolved debate over what form these criteria should assume; in particular, whether they should be process criteria, specifying procedures to be followed by the provider, or out-

program has been severely criticized for its failure to ensure public input into the PSRO regulation process. *See, e.g.*, Willett, *PSRO Today: A Lawyer's Assessment*, 292 NEW ENGLAND J. MED. 340, 340-41 (1975).

49. *See* PSRO PROGRAM MANUAL, *supra* note 18, § 707(b).

50. *See generally* S. LAW, BLUE CROSS: WHAT WENT WRONG? 115-44 (1974).

51. J. BLUM, *supra* note 17, at 29-31; Price, Katz & Provence, *supra* note 17, at 322.

52. 42 U.S.C. § 1320c-4(a)(4) (Supp. V 1975).

53. *Id.*

54. PSRO PROGRAM MANUAL, *supra* note 18, § 705.31.

55. Price, Katz & Provence, *supra* note 17, at 322.

56. PSRO PROGRAM MANUAL, *supra* note 18, § 709; Price, Katz & Provence, *supra* note 17, at 323.

come criteria, measuring the ultimate effect on patients' health of the care rendered.[57]

Process criteria are professionally recognized procedures to be followed in diagnosing and treating specific symptoms or conditions.[58] Their use is justifiable on the assumption that the best way to ensure the health of patients is to require that all the recognized procedures for diagnosis and treatment be followed in each case. Procedures used as process criteria, however, need not be validated by clinical tests or studies establishing their efficacy in improving patients' health.[59] Consequently, process criteria have been formally applied in evaluating the "quality" of care even though the procedures required have not been demonstrated to be efficacious in improving patients' conditions. Process criteria are, however, easy to apply in the hospital setting, where all tests and treatments administered to a patient are recorded

57. This so-called outcome/process debate has carried over to the ambulatory care quality assurance field, there to join a myriad of other problems yet to be resolved by those employing this infant discipline. *See Hearing*, *supra* note 17, at 154 (statement of Dr. John Bussman). *See generally* Christoffel & Loewenthal, *Evaluating the Quality of Ambulatory Health Care: A Review of Emerging Methods*, 15 MED. CARE 877 (1977). For example, care is frequently rendered despite the lack of a specific diagnosis to which procedure-or outcome-oriented criteria may be applied. Physicians lack control over patient adherence to instructions outside the office, thus blurring the correlation between care provided and the health of the patient. Incomplete treatment records hinder medical audit. Finally, there remain significant problems in collecting and standardizing data. *Id.* at 879-82. Existing ambulatory care quality assurance programs have done little toward solving these and other problems, and there is no consensus on what the most efficient, feasible and productive methods are for doing so. 1 N. WHITE, M. RYLAND, G. GIEBINK, D. MCCONATHA & A. TOMAN, AMBULATORY CARE QUALITY ASSURANCE PROJECT 41 (1976). An exhaustive bibliography of the ambulatory care quality assurance literature may be found in 3 *id.*

58. Christoffel & Loewenthal, *supra* note 57, at 885-86. *See generally* Williamson, *Evaluating Quality of Patient Care: A Strategy Relating Outcome and Process Assessment*, 218 J.A.M.A. 564 (1971). For an example of a quality audit employing process criteria exclusively, see B. PAYNE, THE QUALITY OF MEDICAL CARE: EVALUATION AND IMPROVEMENT (1976). A list of items to be checked in patient history was composed by four panels of Hawaii physicians, symptoms to be discovered, and treatment to be rendered for a number of disorders. Each of these criteria was weighted according to its importance to the patient's health, and the weighted sum of the criteria met by a physician or group of physicians yielded a "Physician Performance Index" representing the quality of care provided. *Id.* at 20-28.

59. Indeed, serious impediments to validation testing of many procedures make validation impossible. *See* McDermott, *Evaluating The Physician and His Technology*, in DOING BETTER AND FEELING WORSE, *supra* note 4, at 135, 148-53. The PSRO PROGRAM MANUAL, *supra* note 18, requires that MCE criteria be based first on scientific evidence of a procedure's efficacy and then on expert judgment. *Id.* § 705.35(a). In a study by Brook and Appel, process criteria based on expert judgment were applied to a group of 296 patients with urinary tract infections or ulcerated gastric or duodenal lesions. The results showed that, while only 1.4% of the patients received adequate care under explicit-process scrutiny (and 23.3% under implicit-process scrutiny), 63% experienced satisfactory outcomes of treatment. Brook & Appel, *Quality-of-Care Assessment: Choosing A Method For Peer Review*, 288 NEW ENGLAND J. MED. 1323, 1327 (1973). It has been noted that "many widely accepted therapies have never been subjected to randomized, controlled clinical trials to establish their efficacy in improving patients' health." Havighurst & Blumstein, *supra* note 17, at 29; *accord*, Christoffel & Loewenthal, *supra* note 57, at 884.

using a uniform system.[60]

Outcome criteria, on the other hand, seek to measure the effect on patients' health of the diagnostic and therapeutic procedures employed by measuring the incidence of post-treatment mortality, morbidity, physical and psychological impairment, and ability to function normally.[61] Even with short-term, disease-specific outcome criteria—those that evaluate the effects of care on specific dysfunctions observable within a year after treatment—collection of data must be accomplished by the difficult task of follow-up surveys of former patients. Nevertheless, these outcome criteria are preferable to process criteria due to the paucity of scientific evidence substantiating the efficacy of many routine procedures,[62] and because of the usefulness of outcome criteria in comparing the effectiveness of alternative modes of and settings for treatment of various illnesses.[63] Finally, the logic of outcome criteria—that the best way to assure good results of care is to measure them directly—is persuasive.

Although there may be good reason for preferring the convenience of process- over outcome-oriented criteria in the hospital setting, when concerned with ambulatory care different considerations must come into play to account for the unique circumstances of this latter type of care. (For example, the ease of data collection in the process approach is absent in the ambulatory care setting, in which no uniform system is in widespread use.[64]) In choosing between the two types of criteria, policy-makers at HEW should consider the differences between in-patient and ambulatory care goals and methodologies, the advances which may be expected to be achieved in providing satisfactory ambulatory care, and the role ambulatory care will play in the future of the health care delivery system.

Quality assurance criteria should be sensitive to the effects on patient welfare of all aspects of health care. Nontechnical factors play a crucial role in the effect of care on a patient's health, particularly in the

60. Christoffel & Loewenthal, *supra* note 57, at 881.

61. *See generally* Brook, Davies-Avery, Greenfield, Harris, Lelah, Solomon & Ware, *Assessing the Quality of Medical Care Using Outcome Measures: An Overview of the Method*, 15 MED. CARE, Supp. No. 9, Sept. 1977, at 1, 9 table 9.

62. *See* note 59 and accompanying text *supra*.

63. Process criteria, by which the quality of care is judged according to its conformance to model treatment procedures, are inapplicable for this purpose. PSRO PROGRAM MANUAL, *supra* note 18, mentions process criteria, *id.* § 705.35(a), and outcome criteria, *id.* § 705.35(d) as appropriate methods of quality review, but expresses no preference for either.

64. Christoffel & Loewenthal, *supra* note 57, at 879.

ambulatory care setting.[65] The ability of a physician to establish a rapport with his patient and to gain his confidence and trust is probably as important a factor in inducing a patient to follow a physician's advice after he leaves the office (a problem peculiar to ambulatory care) as is the patient's comprehension of the seriousness of his condition. Without continuity of care, in which the ongoing responsibility for the health of a patient remains with the same physician or group of physicians, this crucial rapport is difficult to establish.[66] Continuity of care is facilitated by the ability of a doctor or health facility to provide a comprehensive array of services. In a survey sample of hospital outpatient facilities, fragmentation of special services into separate departments was cited, along with a lack of continuity of care, as being a primary reason for substandard care.[67] With inpatient treatment, these problems cannot arise.

Process criteria, however, fail to give sufficient weight to this particularly significant aspect of health care effectiveness. If the tests and treatments performed at two different ambulatory care facilities are identical, process criteria would indicate that the facilities are providing care of equal quality. Yet one facility, because of its poor organization or the inability of its doctors to gain the confidence of their patients, might fail dismally to improve or maintain the health of its patients. Outcome criteria, on the other hand, could readily identify the deficient facility as a target for in-depth study and its failings could then be identified and remedied.

Finally, the application of process criteria to a facility excelling in the nontechnical aspects of care could easily result in the institution of "defensive medicine" tactics[68] in an effort to gain for that facility the malpractice immunity offered by the 1972 amendments on condition of adherence to PSRO criteria,[69] and to avoid PSRO rebuke or corrective sanctions.[70] In undertaking such practices the facility would be

65. *Cf.* Rogers, *supra* note 4, at 82 (primary care is concerned with psychological as well as physical aspects of illness). The primary care provider is the point of first contact between the patient and the health care system. Additionally, the majority of ambulatory patients suffer from disorders of lesser physical severity, indicating the greater relative importance of psychological factors in the eventual outcome of care.

66. *See id.* at 81.

67. BIO-DYNAMICS, INC., A STUDY OF SELECTED INNOVATIVE HOSPITAL PROGRAMS IN AMBULATORY CARE 12-28 (1974).

68. *See* McDermott, *supra* note 59, at 139.

69. *See* 42 U.S.C. § 1320c-16(c) (Supp. V 1975). *See generally* Comment, *PSRO: Malpractice Liability and the Impact of the Civil Immunity Clause*, 62 GEO. L.J. 1499 (1974).

70. *See* notes 31 & 32 and accompanying text *supra*.

performing procedures that its experience has shown could be supplanted by less expensive (or more effective) measures. The result would inevitably be a disinclination to adopt innovative techniques of organization or treatment in favor of continued—and perhaps unjustified—reliance on the prescribed procedures.[71]

Research and development in health care delivery methodologies must be fostered by PSROs, not discouraged, if the program is successfully to aid in the development of a satisfactory health care system. In recent years, the ambulatory care sector has assumed a primary role in exploring ways to improve health while cutting costs. Preventive screening can result in a dramatic reduction of the incidence of serious illness and days of hospitalization.[72] Similarly, maternal and infant care treatment centers are invaluable in reducing infant mortality.[73] Further, efforts to employ the learning of the behavioral and social sciences in ambulatory care are soon to be underway.[74] Finally, Health Maintenance Organizations (HMOs), as well as other prepaid group health care plans, are of special concern because they provide an important competitive alternative to fee-for-service providers. Because they are funded on a prepaid basis, they have only a limited amount of funds available for financing health care delivery. HMOs therefore have a strong economic incentive to develop low-cost alternatives to traditional, fee-for-service developed techniques.[75]

All of these innovations hold out the prospect of improving the quality of ambulatory care delivery at reduced cost. More importantly, they offer ways of avoiding costly hospitalization at a time when such alternatives are sorely needed.[76] The PSRO program should

71. This undesirable phenomenon, commonly known as "cookbook medicine," results from rigid application of process criteria without regard to whether the processes are proven efficacious or not. *See* J. BLUM, *supra* note 17, at 77-78. This stifling effect on innovation is manifested in two ways. First, by requiring that certain procedures be used, alternative methods for treating or diagnosing the same condition are discarded, regardless of their outcome effectiveness. Second, the more procedures are required, the less resources are available to fund alternative programs such as preventive screening and maintenance, whose aggregate benefit to the population served by a facility and to the entire health care delivery system may far exceed that of the prescribed practice.

72. Screening of children for rheumatic fever in Baltimore caused a 60% drop in the incidence of that disease. Rogers, *supra* note 4, at 88.

73. In Omaha, Nebraska, these centers accomplished a 60% reduction in infant mortality in a five-year period. *Id.*

74. *Id.* at 102; McDermott, *supra* note 59, at 156.

75. *See* Havighurst & Bovbjerg, *Professional Standards Review Organizations and Health Maintenance Organizations: Are They Compatible?*, 1975 UTAH L. REV. 381.

76. Between 1965 and 1974, the cost of medical care rose approximately 100%. In that same period, the cost of a semiprivate hospital room rose 166%. Rogers, *supra* note 4, at 89 figure 4.

respect these trends,[77] allow them to develop, and where feasible, provide incentives for their proliferation. Excessive or rigid application of process criteria in PSRO quality audits could unwisely divert limited resources from innovative programs as well as hinder the development of alternative technical and nontechnical skills in ambulatory care.[78] Given the significance of the public health care sector,[79] and the magnitude of national health care expenditures,[80] clumsy PSRO activity in the ambulatory care area could have far-reaching negative economic and social effects. Conversely, by careful implementation of a national policy restricting the use of process criteria to appropriate circumstances,[81] and by promotion of the general use of retrospective utilization review,[82] HEW could effect major beneficial changes in the health care delivery system.

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77. "Primary ambulatory care with an emphasis on prevention, diagnostic screening, referral, preventive maintenance, and health education constitutes the wave of the future in medical care delivery." C. OAKES, THE WALKING PATIENT AND THE HEALTH CRISIS 325 (1973).

78. Senator Edward M. Kennedy has warned that PSRO standards, "once defined and articulated, must not become inflexible, thereby constituting barriers to innovation and evolution in the provision of health care." Kennedy, *supra* note 17, at 3.

79. In 1975 public expenditures for health and medical care totalled $50 billion. S. AXELROD, A. DONABEDIAN & D. GENTRY, MEDICAL CARE CHART BOOK 107 (rev. 6th ed. 1976).

80. In 1975, $118.5 billion dollars were spent on health and medical care in the United States. *Id.*

81. One of the primary responsibilities of the ambulatory care provider is to identify those cases that, though innocent in appearance, are in fact very serious and call for immediate treatment. Rogers, *supra* note 4, at 82. A skeletal set of diagnostic process criteria are required to assure that these cases are detected. Additionally, those procedures whose efficacy has been scientifically verified, and whose benefits clearly outweigh the costs engendered by their application, should be used as process criteria. This sensible method of criteria development was first suggested in Williamson, *supra* note 58, at 564. The process criteria thus employed could be referred to as "essential" criteria as opposed to "optimal" criteria. *See* Christoffel & Loewenthal, *supra* note 57, at 887.

82. *See* notes 44-50 and accompanying text *supra*.