NEW YORK LAW SCHOOL

NYLS Journal of International and Comparative Law

Volume 20 | Number 2 Article 4

2000

HEALTH CARE REFORM AND THE CHANGING STANDARD OF CARE IN THE UNITED STATES AND GERMANY

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I. INTRODUCTION

If the practice of medicine had not changed in 100 years, today we would spend no more than one percent of our current health care budget.[1] Modern medicine prolongs life on the average, but our societies have become sicker: in the past, cancer or Alzheimer's disease, for example, were rare occurrences because individuals died of more acute causes at a much younger age. Furthermore, the availability and sophistication of treatments and medical technology have exploded and, as a consequence, so have our expectations for care, as well as the content of our classification of diseases.[2] As one author observed, "Whoever used to have a VW Beetle but now drives

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*. J.D. candidate (2000), The Columbus School of Law, Catholic University, Washington, D.C. I would like to thank my German support system: Justice Dr. Thomas Clemens and Ms. Heidi Welsch at the Supreme Social Court, Kassel; Mr. Klaus Schuler, Bonn/Berlin; Dr. med. Klaus Schnetzer, Rastatt; Mr. Herbert Schuster (Oertel), Mr. Karl Goßmann, and Mr. Wolf-Rüdiger Schultze, Esq., Bad Hersfeld. Without their generosity and unending willingness to help in Germany and their indefatigable efforts to supply information across the Atlantic, this article could not have been written. I am also grateful to Professor William F. Fox, Columbus School of Law, The Catholic University of America, Washington, D.C., for his expertise in bridging the gap between American and German administrative law.

1. OFFICE OF HEALTH ECONOMICS, TRENDS IN EUROPEAN HEALTH SPENDING (OHE Briefing No. 14, May 1981), *quoted in* Walter Krämer, *Medizin muß rationiert werden [Medical Care Must be Rationed]*. 1 MEDIZINRECHT 1 (1996) [hereinafter MEDR].

2. "Before, if you were born lisping, stuttering, cross-eyed or had crooked teeth, you would take these conditions with you to your grave without ever being bothered nor considered afflicted with illness." WALTER KRAMER, WIR KURIEREN UNS ZU TODE [WE ARE HEALING OURSELVES TO DEATH] 29, 30 (Ullstein Buchverlage, Berlin, 1997).

a Cadillac, should not complain that the vehicle has increased in price."[3] In addition, as a consequence of demographic changes, fewer individuals support a growing elderly segment of the population.[4]

American health care expenditures have risen over the past several years to almost 15% of GDP[5] (up from 6.5% in 1965) while German expenditures (3.5% of GDP in 1965) have been stable at around 10.5% (they declined from 10.5% in 1996 to 10.3% in 1998).[6] Members[7] and their families, however, have had to shoulder an increasing share of the burden through copayments and deductibles in order to help achieve premium stability[8], one of the basic principles of the statutory health insurance system.[9] In the United States, managed care helped to stabilize health care expenditures temporarily, but premiums and costs are moving upward again.[10] In both

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3. *See* KRÄMER, *id.* at 2.

4. In Germany, 20% of health care expenditures are occasioned by the five most common age-related disease complexes: dementias (including Alzheimer's), stroke, motor control disorders (such as Parkinson's), geriatric depression and chronic pain. *Der Alterungsprozess ist uns immer noch ein Rätsel [The Enduring Enigma of the Aging Process]*, SÜDDEUTSCHE ZEITUNG, Nov. 6, 1998, at 14.

5. Gross Domestic Product.

6. *Kassen zwischen Rationierung und Rationalisierung [Sickness Funds Between Rationing and Rationalizing]*, FRANKFURTER RUNDSCHAU, Sept. 9, 1999. This number combines public health care expenditures for 90% of the population (8% of GDP) and the privately insured sector (2% of GDP).

7. The terms "members" and "patients" are used interchangeably. The common German term is "patient" since most of the population receives cradle-to-grave coverage by the statutory health care system, making everyone a patient as of the first day of life.

8. *Beitragssatzstabilität.* SGB V, Arts. 71, 86. Premiums have remained stable at around 13% and can be adjusted up or down, depending on annual funding requirements. Sickness fund administrative expenditures fluctuate between 2 to 6% while managed care organizations spend 30% of the premium dollar on administration. Only 70% remain for the "medical loss component."

9. In 1999, cost containment measures resulted in a surplus of one billion Deutschmarks ($500 million at the current exchange rate). Andreas Hoffmann, *Die Kostenpille [The Cost Containment Pill]*, SÜDDEUTSCHE ZEITUNG, March 7, 2000, at 19.

10. An average cost increase of 12 percent for large employers' health plans is expected for 2000. *More evidence of rising plan costs.* 5(3) ON MANAGED CARE 3 (Panel Publishers, March 2000) (quoting 1999 TOWERS PERRIN HEALTH CARE COST SURVEY).

countries, legislators and courts are working on finding acceptable solutions out of the demographic and "medical progress" traps.[11]

As a consequence, the allocation of health care funds has become a heatedly debated issue by public opinion and lawmakers in the United States and Germany. In both countries, there is agreement that unlimited fee-for-service medicine is no longer financially viable, and a number of cost containment approaches have been developed. But every resource allocation measure impacts on medical decision-making and the standard of care. In the United States, where health care reform has been left mainly to the market, the standard of care for a majority of the employed population is determined by managed care organizations (MCOs)[12] through the macro and micro-allocation of health care funds; in Germany, with its tradition of universal access/universal coverage social health insurance,[13] macro-allocation and some macro-level standard of care determinations rest with legislators and corporate entities established under public law[14] to represent

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11. *Die Fortschrittsfalle.* As one author observed, "Whatever the Germans have done with their health care system, they must have "managed" something very well." German health care expenditures in 1997 amounted to $2,339 per capita compared to $4,090 in the United States without any correspondingly superior "health status" of its population; the United States will reach the current German percentage of individuals 65 years or older in 2018-2020 when the baby-boomers retire; and the increased demand for health care since German unification in 1990 could be roughly compared to the United States absorbing Mexico. Uwe Reinhardt, *'Mangled Competition' And 'Managed Whatever.'* 18 HEALTH AFFAIRS 92 (May/June 1999).

12. Managed Care Organizations (MCOs) are defined here as a prepaid system of health care, combining insurance with the delivery of medical services. Common examples are Health Maintenance Organizations (H.M.O.s) integrating all aspects of the delivery of health care, and Preferred Provider Organizations (PPOs), offering members a limited network of providers, hospitals included, which have accepted an array of arrangements for reduced fees in exchange for access to a larger patient base.

13. *Gesetzliche Krankenversicherung (GKV).* The German health care system with mandatory membership up to a predetermined level of personal income, spreading risk among 90% of the population, developed out of a communitarian approach to society in the 19th century. It is designed to protect individuals as members of a solidarity-based community. Premiums are shared at 50% between employees and employers through a type of payroll tax. Social law provides for uniform, comprehensive coverage. For a detailed description of the German health care system, *see* Ursula Weide, *A Comparison of American and German Cost Containment in Health Care: Tort Liability of U.S. Managed Care Organizations vs. German Health Care Reform Legislation,* 13 TUL. EUR & CIV. L. F. 47, 58 (1998).

14. *Körperschaften des öffentlichen Rechts.* The rights and duties of all participants (providers and patients) in the health care system are codified in Title 5 of the German Social

providers and health insurers. Micro-level care decisions are still left to providers. But the paternalistic comprehensive German system limits individual choice while the market-dominated American approach has resulted in a large number of uninsured and underinsured individuals and the loss of much of physician autonomy. In both countries, the current system of health care delivery is questioned as the practice of medicine is moving from "advocacy to allocation."[15]

II. SETTING THE STANDARD OF CARE

A. The United States

The Constitution does not guarantee certain minimum rights of treatment nor "otherwise impose an affirmative obligation on the state to ensure that life, liberty or property do not come to harm through other means."[16] This excludes a right to health care and, hence, any basic standards for its provision. From the end of the 19th century roughly until 1960, health law was focused primarily on protecting physician autonomy, and the quality of care depended on local communities of private practitioners.[17] Beginning in the fifties and sixties, more socially oriented attitudes developed, recognizing society's responsibility to protect the rights and interests of all of its members, and to achieve a greater degree of equity. Law was seen as an instrument to balance the unequal relationships among patients, providers, and health insurers. This "modestly egalitarian social contract" lead to the creation of Medicare and Medicaid for two of the most vulnerable segments of society, the elderly and the poor. Beginning in the seventies, however, the emphasis shifted to market competition, away from

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Code (SGB V).

15. John K. Iglehart, *Health Policy Report: The American Health Care System,* NEW ENG. J. MED. 327 (1992). Adolf Laufs, *Immer weniger Freiheit ärztlichen Handelns [Restricting Independent Clinical Judgment],* 37 NEUE JURISTISCHE WOCHENSCHRIFT 2717, 2718 (1999) [hereinafter NJW].

16. Collins v. Harker Heights, 503 U.S. 115, 117 (1992), *citing* DeShaney v. Winnebago County Dep't of Social Servs., 489 U.S. 189, 196 (1989). The Supreme Court ruled that substantive due process under the Due Process Clause of the Fourteenth Amendment does not extend to a fundamental right to health care, but that this Clause was intended to limit the State's power to act. The Court cites the doctrine of judicial self-restraint whenever asked to "expand the concept of substantive due process."

17. This section is based on RAND E. ROSENBLATT ET AL., LAW AND THE AMERICAN HEALTH CARE SYSTEM, (The Foundation Press Inc., 1997) [hereinafter ROSENBLATT ET AL.].

the strictures of both government regulation and common law remedies. As a result, the power of insurance companies, including managed care organizations, contractually determining standards of care and benefits, was greatly strengthened. In the nineties, with health care delivery mainly dominated by large corporations striving to minimize the "medical loss component" of each premium dollar by limiting coverage and "medically necessary" benefits, many states have resorted to mandating minimum benefits to protect patients and providers alike.

1. Tort Liability

a. Which Standard of Care?

In the absence of comprehensive national or state legislation addressing quality of care and provider qualifications, tort law has helped to define physicians' duty to exercise "reasonable care." Initially, the "locality rule" reflected a community-based standard of care. In the sixties and early seventies, again under the influence of the modestly egalitarian social contract (and accompanying the civil rights movement), the impact of tort liability expanded, and judicial decisions protective of patients paved the way from the locality rule to national standards. Allowances are made for facilities and practitioners in rural areas without top-of-the-line resources.[18] But reliance on local or prevailing standards is not permitted whenever the physician knows or has reason to know that a procedure has been questioned as potentially harmful. Practitioners then must exercise their "best judgment."[19] In this instance, informed consent is required.[20]

Already in 1914, Judge Cardozo stated that "the patient is an autonomous person with the right to determine what shall be done with his own body." Without consent, defined as no objection to an announced intervention, a physician was liable for assault or battery. Today, patients must be informed of risks they would reasonably consider relevant in order to be able to participate in decisions regarding their health care.[21] "The patient's right of self-decision shapes the boundaries of the duty to reveal."

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18. Hall v. Hillburn, 466 So.2d 856, 871 (Miss. 1985). German courts have adopted the identical stance.

19. Toth v. Community Hosp. at Glen Cove, 239 N.E.2d 368 (N.Y. 1968).

20. Burton v. Brooklyn Doctors Hosp., 452 N.Y. 2d 875 (1982). In Germany, a large body of case law addressing informed consent has developed, strengthening patients' rights under the statutory health insurance system. For further discussion, *see infra* section II.B.5.e.

21. *See* ROSENBLATT ET AL., *supra* note 17, at 900.

Such ruled the judge in *Canterbury v. Spence*,[22] holding a physician liable for having violated his duty to warn of a one percent chance of paralysis following a laminectomy. In this case, a nineteen-year old complaining of severe back pain was disabled for life. The physician had felt that revealing risks was not good medical practice as it might deter patients from submitting to needed surgery.

In the ever-changing world of medical technology, what is to be considered the applicable standard of care? A case from 1932 established the foundation for "reasonable prudence" taking precedence over lower industry or professional standards. Judge Learned Hand in the *T.J. Hooper* case[23] ruled that whenever protective equipment is available at affordable cost (here, radios for communications between tug boats to avoid collisions), a carrier is required to use reasonable prudence by installing the device even if the industry on the whole does not yet rely on it.[24] The prevailing industry or professional standard was also held to be inadequate in *United Blood Services v. Quintana*.[25] The court found that had the blood bank exercised reasonable prudence (or ordinary and reasonable care), taking into consideration available scientific knowledge, the plaintiff's infection with the AIDS virus would have been prevented. If donors had been screened adequately concerning their lifestyle, supplemented by physical examinations and surrogate blood testing, contaminated samples would not have been obtained nor processed. In *Washington v. Washington Hospital Center*,[26] a patient undergoing anesthesia suffered catastrophic brain damage because the hospital had not installed a carbon dioxide monitor to detect an inadequate supply of oxygen. Rejecting the locality rule, the court applied the "reasonably prudent professional" standard, finding that enough scientific evidence was available at the time of the incident for the hospital to know that this new device would prevent injuries as sustained in this case. As a matter of fact, the chief anesthesiologist had submitted a request for such a

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22. 464 F.2d 772 (D.C. Cir. 1972).

23. 60 F.2d 737 (2d Cir. 1932).

24. A comparable contemporary case is the installation of defibrillators on commercial aircraft. They are available at $3,000 a piece, and airlines have kept statistics for years reflecting the regular occurrence of heart attacks in the air. Until recently, only the Australian airline Qantas routinely equipped its aircraft with this easy–to-use, life-saving device until many American carriers were forced to do likewise by the increasing number of wrongful death claims against them.

25. 827 P.2d 509 (Colo. 1992).

26. 579 A.2d 177 (D.C. 1990).

monitor almost a year earlier stating that the hospital otherwise would "fail to meet the national standard of care."

These cases underscore that if "the natural risk of death or injury is transformed into potential legal liability; the function of tort liability would then be to assure the rapid diffusion of new technology."[27] How are practitioners to provide care faced with competing standards in case of a "respectable minority" or "two schools of thought"? The court in *Jones v. Chidester*[28] considered the existence of two schools an absolute defense against medical negligence, and to be determined by the trier of fact relying on expert testimony.[29] Prevailing or customary practices depend on a quantitative analysis while the acceptance of a procedure by a respectable minority relies on both quantitative and qualitative considerations. In this case, a tourniquet was used during surgery to stop the blood flow, and the plaintiff had complained that this "unacceptable" practice had caused nerve damage.

b. The Role of Clinical Practice Guidelines

Clearly, ordinary prudence standards depend on the availability and access to adequate information about ever-changing medical practices. Clinical practice guidelines (CPGs) are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[30] Guidelines, developed by recognized scientific organizations and professional medical societies[31] according to a scientifically valid methodology, provide such information. "They improve the standard of care by restraining risky experimentation by individual

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27. *See* ROSENBLATT ET AL., *supra* note 17, at 862.

28. 610 A.2d 964, 969 (PA. 1992).

29. German law allows for "respectable minority" practices as well.

30. INSTITUTE OF MEDICINE, COMMITTEE ON CLINICAL PRACTICE GUIDELINES, CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM (M.J. Field, Kathleen N. Lohr, eds., Washington, D.C., National Academy Press, 1990).

31. "In the absence of a national policy-making body, professional medical societies are presently the best authority for promulgating judicially cognizable practice guidelines." Richard A. Leahy, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines.* 77 CAL. L. REV. 1483, 1510 (1989). Under the German social health insurance code, a quasi-regulatory entity cooperating with the medical societies is currently preparing to develop additional guidelines. For further discussion, *see* section II.B.2.B.a and II.B.4.e.

providers and by systematizing and operationalizing collective knowledge."[32] Practice guidelines, indicating a certain range of clinical options, may be used to assist practitioners in determining how health conditions can most effectively be prevented, diagnosed, treated and managed clinically.[33] By 1996, more than 2,000 guidelines had been presented by approximately 75 organizations such as medical societies, the American Medical Association, and private research organizations.[34] A workgroup was created by the Agency for Health Care Policy and Research (a division of the Public Health Service) to decide on a methodology for guideline development and their application to the evaluation of quality of care.[35] Guidelines are to be based on available medical evidence or professional judgment in case of insufficient empirical data. Some regional adjustments may be needed to reflect local population differences. The Institute Of Medicine (chartered by the National Academy of Sciences) warned, however, that such adaptations may not be valid if done for self-serving purposes such as perpetuating unacceptable practices, to promote economic interests, or to exclude certain categories of practitioners. Furthermore, managed care organizations, "with their commitment to the bottom line, may make modifications to guidelines to achieve their best interests and not those of the patients."[36]

Courts can resort to CPGs to determine the applicable standard of care. Under the Maine demonstration project for the establishment of practice parameters and risk management protocols,[37] such guidelines would serve as an affirmative defense for the physician abiding by them. The burden of proof of compliance rests with the provider.[38] Guidelines have evidentiary relevance but are not legally binding and can be challenged. In *Bragdon v.*

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32. *See* ROSENBLATT ET AL., *supra* note 17, at 856.

33. AGENCY FOR HEALTH CARE POLICY AND RESEARCH, USING CLINICAL PRACTICE GUIDELINES TO EVALUATE QUALITY OF CARE (AHCPR Publication No. 95-0045, Rockville, Md., March 1995). Vol. 1 contains a "List of attributes of good practice guidelines" and a 12-point checklist for guideline development, similar to the approach developed by the German workgroup *ÄZQ*. For further discussion, *see infra* section II.B.2.B.b.

34. GENERAL ACCOUNTING OFFICE, PRACTICE GUIDELINES: MANAGED CARE PLANS CUSTOMIZE GUIDELINES TO MEET LOCAL INTERESTS 3 (GAO/HEHS-96-95, Washington, D.C., May 1996).

35. Vol. 2. AHCPR Publication No. 95-0046, *supra* note 33.

36. *See* GAO, *supra* note 34, at 12 (quoting an anonymous expert source on guidelines).

37. GENERAL ACCOUNTING OFFICE, MEDICAL MALPRACTICE: MAINE'S USE OF PRACTICE GUIDELINES TO REDUCE COSTS (GAO/HRD-94-8, Oct. 1993).

38. Such a reversal of the burden of proof is hotly contested in Germany.

Abbott,[39] the Supreme Court, ruling that AIDS was covered by the Americans with Disabilities Act definition of disability, examined the 1993 Center for Disease Control Dentistry Guidelines outlining the Recommended Infection Control Practices for Dentistry in order to determine the safety of treating HIV infected patients in private dental offices. The American Dental Association had issued a policy statement that such infection control procedures provided adequate protection for patients and dental personnel. The Court considered neither the CDC guideline nor the ADA policy statement to be definitive and objective evidence. It felt that both set out recommendations without assessing statistical risk, and that the ADA, even though a professional association and a respected source of information, may have included considerations of professional responsibility in its policy statement.

In spite of the considerable efforts of the AHCPR, for example, to lay out a scientifically sound methodology for developing practice guidelines and translating them into guidelines for quality of care evaluations, they do not seem to have had much of an impact on actual standards. One reason may be that such guidelines can serve two very different purposes: to assist practitioner's clinical decision-making, and to serve as criteria for quality and utilization review purposes by entities outside the physician-patient relationship. Hence, they are often associated with cost control efforts "de-legitimating" individual physicians by giving more weight to "established" sources of statistical medical and scientific data.[40]

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39. 524 U.S. 624, 651 (1998).

40. RAND E. ROSENBLATT, SYLVIA A. LAW, SARA ROSENBAUM, LAW AND THE AMERICAN HEALTH CARE SYSTEM, 1999-2000 SUPPLEMENT 57 (Foundation Press, 1999). A telling comment may have been that of a respondent to an informal survey conducted among managed care organizations about their use of practice guidelines who felt that the AHCPR guidelines "did not seem to fit his circumstances." MCOs use internal guidelines to deny benefits for individual patients according to corporation-specific utilization review data while AHCPR guidelines rely on scientific evidence reflecting prevailing standards of care in order to support clinically appropriate decision making and do not include economic considerations. Jane Sisk, *How are Health Care Organizations Using Clinical Guidelines?* HEALTH AFFAIRS 90 (Sept./Oct. 1999).

c. Hospital Liability

Under the doctrine of charitable immunity laid down in *McDonald v. Massachusetts General Hospital*,[41] hospitals as "public charities" (wealthy individuals received medical treatment at home) were largely immune from malpractice liability because accepting free care was considered an implied waiver by patients of their rights under tort law.[42] (This principle was extended to paying patients as well, one of the doctrinal flaws of charitable immunity contributing to its eventual failure.) Hospitals were only held to exercise due care when selecting medical staff as their agents. Beginning in the 1940s, and following the analysis in *President of Georgetown College v. Hughes*,[43] heavily critiquing the inconsistencies of the doctrine, most of the states eventually eliminated charitable immunity. After a period during which hospitals were seen as merely providing the required facilities for physicians and as such held liable only for administrative but not medical negligence, the theory of *respondeat superior* began to govern malpractice actions. Again influenced by the modestly egalitarian social contract developing in the fifties and sixties, courts increasingly found hospitals liable for negligence on the part of their agents, including physicians as independent contractors with hospital privileges as well as employed technicians and nurses.

Under theories of agency, hospitals are vicariously liable for negligence on the part of their employees acting within the scope of employment. Apparent agency is assumed, for example, for physicians working as independent contractors in emergency rooms. Hospitals, now commercial ventures instead of charitable institutions—and often advertising their services—hold physicians out as their providers, and patients look to the hospital for competent care. Numerous courts have extended this doctrine to other specialists as well. The Alaska Supreme Court even attributed a non-delegable duty to a hospital. In *Jackson v. Power*,[44] the Court ruled that an acute care hospital had a non-delegable duty to staff its emergency room with physicians and therefore was not shielded from liability claims when one of them performed negligent diagnostic services, causing an accident victim to lose both kidneys. The court compared the duty to provide

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41. 120 Mass. 432 (1876).

42. This section is based on Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System.* 108 HARV. L. REV. 381 (1994), and on ROSENBLATT ET AL., *supra* note 17.

43. 130 F.2d 810 (D.C. Cir. 1942).

44. 743 P. 2d 1376 (Alaska 1987).

competent emergency room physicians to that of airlines to assure the safety of their passengers.

Corporate liability, adopted by at least twenty-two states,[45] encompasses not only malpractice by those physicians selected by and under contract with the hospital, but also surgeons and obstetricians, for example, selected by patients. Hospitals are held liable for negligent credentialing, i.e. improperly selecting, verifying the credentials, and supervising the quality of care of those physicians permitted to practice on their premises. *Darling v. Charleston Community Memorial Hospital*[46] is often cited as the leading case paving the way for corporate liability. The court, quoting licensing regulations, accreditation standards, and hospital bylaws as indicators of custom and, hence, the standard of care, ruled that the jury reasonably could have concluded that the hospital had certain responsibilities to ensure adequate treatment. In this case, neither the operating orthopedic surgeon nor the nursing staff had prevented the necrosis of a broken leg, leading to amputation. In addition, the current standards of the Joint Commission on the Accreditation of Healthcare Organizations and state licensing regulations require hospitals to check physicians' qualifications before granting them privileges, and to periodically review their performance.

2. Accreditation

a. Hospitals

Around the turn of the century, physicians commonly received hospital staff privileges.[47] As the number of hospitals and physicians expanded, hospitals were faced with the necessity of practitioner selection, especially for surgery. In 1919, the American College of Surgeons (ACS) published standards for hospitals including adequate staffing of labs and x-ray departments, also requiring careful selection of physicians and peer review of the quality of care they provided. Hospitals were considered to owe adequate service to the community. Without an enforcement mechanism, however, compliance was entirely voluntary. The Hill-Burton Act, passed by Congress in 1946, made state licensing of hospitals the prerequisite for the disbursement of federal funds for hospital construction. State legislation

45. Carol P. Michael, *Credentialing Liability in the Managed Care Arena,* 35 TORT. & INS. L. J. 137 (Fall 1999).

46. 211 N.E.2d 253 (Ill. 1965).

47. This section is based in part on ROSENBLATT ET AL., *supra* note 17.

adopted many elements of the ACS standards, but enforcement remained mostly theoretical for lack of resources.

In 1951, a private organization, the Joint Commission on Accreditation of Hospitals (JCAH) succeeded the ACS standards program. Its board was composed of representatives of the American Medical Association, the American Hospital Association, and several specialized professional organizations.[48] Again, compliance with ACS standards was voluntary, giving this "private regulatory apparatus an often illusory quality"[49] since almost any physician with a degree from an approved school could be admitted to practice at a hospital. As some authors have observed, "the structure of accreditation standards, control committees, and legal requirements derive from our commitment to unsupervised, private practice in hospitals."[50] Current JCAHO standards hold hospital governing bodies, including elected and appointed leaders of the medical staff, the clinical departments, and the nurse executive and other senior nursing leaders, responsible for coordinating, providing and improving quality health care services.[51]

Recently, a major hospital in the Washington, D.C. area lost its accreditation, an indication that JCAHO does act at least in extreme cases. This decision by "a group that has often been criticized as a rubber-stamp for the hospital industry" was considered a serious blow, potentially leading to the loss of the state license and Medicare and Medicaid funding.[52] (Of more than 9,000 hospitals and other health care organizations reviewed, similar action was taken in 60 instances last year.) In light of the generally observed resistance of medical staff to submit to some administrative supervision and control, the impact of corporate liability and the JCAHO standards on quality of care is questioned. Judicial determinations of the extent to which

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48. Today, these members of the now called Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are the American College of Physicians, the American College of Surgeons, and the American Dental Association.

49. *See* ROSENBLATT ET AL., *supra* note 17, at 918.

50. *See id.* (quoting Milton Roemer, Jay Friedman, *Doctors in Hospitals* (1971)).

51. JOINT COMMISSION FOR THE ACCREDITATION OF HEALTHCARE ORGANIZATIONS, 1999 HOSPITAL ACCREDITATION STANDARDS 105 (JCAHO, 1999).

52. Avram Goldstein, *Md. Hospital Facing Loss of Accreditation,* WASH. POST, Nov. 16, 1999, at A1. Apparently, the agency was unaware of the conditions at Shady Grove Hospital—biopsy samples were lost, and one intensive care patient died after having been left without supervision in another part of the hospital—until the Washington Post publicized them in an article on October 17. Five days later, JCAHO conducted a surprise on-site inspection.

accreditation standards should also be considered legal standards are needed. "Seriously pursuing the goals of the corporate liability doctrine and the industry's own JCAHO standards will be a long-term and complex process, in which malpractice law has played and will continue to play an important role, both in its own right, and as a stimulus to other regulatory efforts."[53]

b. Managed Care Organizations

JCAHO, in accordance with its stated mission "to improve the quality of care provided to the public through the provision of health care accreditation and related services that support performance improvement in health care organizations," also accredits managed care organizations. "It is a natural progression, as health care has evolved to a network structure, to evaluate delivery systems to ensure that appropriate attention is directed to patient care.... Accredited networks demonstrate a commitment to the highest industry standards; the integration of care and services; a comprehensive review of their administrative and clinical services; the protection of member/patients rights; the development and use of outcome data; and continuous quality improvement."[54] The overall approach is similar to that for the accreditation of hospitals and involves: fostering an ethical and mutually respectful relationship between the network and its members; maximizing the coordination of care; health promotion and disease prevention; network leadership (relying on the leaders of the governing body, the chief executive officer and other senior officers, the leaders of the licensed independent practitioners within the network) to ensure the provision of quality health care services which meet the needs of the community; appropriate and qualified staffing to meet members' needs; information management to support member care and governance; and improving network performance through improved clinical and governance processes. One of the JCAHO publications offered to accredited MCOs is the "Abstracts of Clinical Care Guidelines", selected from peer-review journals, specialty and government agency reports, and covering prevention and screening, diagnosis, therapy, new technologies, and patient management.[55] This indicates the recognition that a MCO is a provider of medical services and not just an insurer or corporate entity.

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53. *See* ROSENBLATT ET AL., *supra* note 17, at 934.

54. JOINT COMMISSION FOR THE ACCREDITATION OF HEALTHCARE ORGANIZATIONS, 1998-2000 STANDARDS FOR HEALTHCARE NETWORKS 1 (JCAHO, 1998).

55. *See id.* at 332. Recent subjects included Alzheimer's Disease, HIV-1-protease inhibitors, and the management of patients with acute myocardial infarction.

But the major instrument for the accreditation and evaluation of MCOs is the Health Plan Employer Data and Information Set (HEDIS), first developed in 1993 by a committee of health plan representatives and corporate purchasers,[56] then released as version 3.0 in January 1997[57] and succeeded by HEDIS 2000 in 1999.[58] Its purpose is to collect and make available information to assist both private (employers) and public (such as the Health Care Financing Administration for Medicare and Medicaid) purchasers in selecting high-quality plans. Specifications for 63 indicators addressing quality of clinical performance (such as childhood immunization rates and breast cancer screening), patient access and satisfaction, membership and utilization, finance, and health plan management are provided.[59]

By holding plans accountable, competition may raise the quality of care[60] since "efficient economic markets require good information."[61] One major shortcoming of the measures, however, is their reliance on self-reporting. The phenomenon of "social desirability" is well-established in the field of social psychology as a tendency among test or survey respondents to self-report only information they believe is socially acceptable. For managed care organizations, this may be dubbed "economic desirability", potentially leading them to misrepresent quality-related information in order to become more attractive to potential purchasers.[62] The questionable reliability of the data obtained, further weakened by variations of the data acquisition methodology among reporting health care systems, is recognized in the literature and has led to calls for outside audits, a costly proposition.[63] In addition, the quality of care measures themselves can also be questioned

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56. *See* GAO, *supra* note 34.

57. In October 1997, data for more than 300 capitated health care systems, covering over 37 million individuals, were published. The most prominent result obtained was the considerable variation among plan performance. JOSEPH W. THOMPSON, JAMES BOST, ET AL., *The NCQA's Quality Compass: Evaluating Managed Care in the United States,* 17 HEALTH AFFAIRS 153 (Jan./Feb. 1998).

58. NATIONAL COMMITTEE FOR QUALITY ASSURANCE, HEDIS 2000 (NCQA, Washington, D.C., 1999).

59. *See* GAO, *supra* note 34, at 5.

60. *See* THOMPSON ET AL., *supra* note 56.

61. William L. Roper & Charles M. Cutler, *Health Plan Accountability and Reporting: Issues and Challenges,* 17 HEALTH AFFAIRS 153 (March/Apr. 1998).

62. *See* THOMPSON ET AL., *supra* note 56, at 155.

63. *See* Roper, *supra* note 60.

because they may not reflect prevailing medical standards, but instead rely on statistical "evidence" without taking individual needs or circumstances into consideration.[64] This raises serious liability issues.

3. Managed Care Organizations: From Vicarious to Direct Liability

For decades, medical care was provided mostly on a fee-for-service basis and health insurers processed and paid claims retrospectively. The Health Maintenance Organization Act was passed in 1973 by President Nixon to promote managed care organizations (MCOs) as a cost-effective alternative to the fee-for-service system. After the failed health care reform efforts of the Clinton Administration, managed care corporations began a consolidation process which has left the country with a limited number of managed care giants. Today, 170 million Americans receive their medical services through some form of managed care, the most prevalent system of health care delivery.

Inherent in the managed care approach to health care cost containment is the intertwining of medical and coverage decision-making. Since any resource allocation has medical consequences, MCO cost control strategies impact on the standard of care and limit or eliminate physician autonomy.[65] MCOs sell medical services to private (employers) or public (such as HCFA) buyers, limiting care both on a contractual basis (macro-allocation through the "plan" and its coverage provisions) to a particular group and on an ad-hoc basis (micro-allocation through prospective or concurrent "medical necessity" determinations) to individual patients. Often, specific services and conditions are excluded from the contract: "elective" surgery, in vitro fertilization, preexisting conditions, and the so-called "experimental treatments" such as bone marrow transplants and high dose chemotherapy for cancer. Of particular relevance on a micro-level is "utilization review", a system of pre-authorization of treatment or diagnostic procedures. Such decisions are often based on hypothetical "average case" corporate practice

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64. *See* ROSENBLATT ET AL., *supra* note 17, at 571-572, citing the HEDIS quality measure for eye exams for diabetics. Since diabetes is the leading cause of adult blindness and can lead to a rapid deterioration of eyesight, the American Diabetes Association recommends annual exams. The HEDIS measure asserts that biannual exams are adequate but that patients need to determine the appropriate interval themselves.

65. "Doctors already face liability, but often their decisions are forced upon them by an insurance plan. It is only fair that insurance plans be held to the same accountability." Rep. Merrill Cook, *quoted in:* Robert Pear, House Passes Bill to Expand Rights on Medical Care, WASH. POST, Oct. 8, 1999, at A1. Many German physicians share this view. *See* Schmidt—De Caluwe, *infra* note 305.

guidelines, frequently applied to an individual patient's symptoms by off-site clerical staff, using a computerized system.

Additional managed care cost containment measures include financial incentive programs for physicians to refrain from ordering "unnecessary referrals and diagnostic tests" which shift some of the financial risks to the providers. "Capitation" is the payment of a flat fee per patient, independent of treatment, and excluding reimbursement for the cost of procedures beyond the preset amount. Through "withholds", the MCO retains some of the physician's income, which is paid out only if certain limits on referrals, diagnostic tests, or treatment procedures are not exceeded. Bonus or penalty programs reward or penalize providers according to utilization rates. All of these mechanisms have the same effect: they provide incentives to under-treat in order to lower costs. The considerable number of lawsuits against MCOs attests to the detrimental impact on patients.[66] Only recently have injured patients or their survivors been increasingly successful in holding managed care organizations liable for the consequences of their allocation decisions.

a. The ERISA Preemption For Health Care

For many years, ERISA, the Employee Retirement Benefit Act, was an effective shield from liability for managed care organizations because of its preemption of state law provisions regulating health care and insurance through its Sections 514 and 502(a).[67] ERISA was passed by Congress in

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66. Many other industrialized nations contain health care expenditures through the national macro-allocation of health care funds, preserving most of their physicians' autonomy of medical decision making. Physicians may also participate through their organizations in setting the standard of care on a regulatory level. For further discussion, *see infra* sections II.B.2.A.b and c; and II.B.2.B.a.

67. 29 U.S.C. 1001 seq. §514(a) preempts all state tort law claims against employee benefit plans "relating to" ERISA plans ("conflict preemption"). The expansive interpretation of the term "relate to" was limited by the Supreme Court in three separate cases: New York State Conference of Blue Cross & Blue Shield v. Travelers Insurance Co., 514 S.Ct. 1671 (1995); DeBuono v. New York Commissioner of Health, 117 S.Ct. 1747 (1997); California Division of Labor Standards Enforcement Division v. Dillingham Construction, 117 S.Ct. 832 (1997). §514(b), the saving clause, saves from preemption any state law regulating insurance while §514(c), the deemer clause, exempts all self-insured employee benefit plans from state insurance regulations (for "insurance bad faith", for example) by deeming them not to be insurers. §502(a), ERISA's civil enforcement section, only allows actions for benefit recovery and the clarification of current and future rights under the plan. It is often raised as a defense by managed care companies as it preempts all alternative state enforcement mechanisms (such

1974 to insure the nationwide uniform administration of employer-provided pension plans and to curb pension plan mismanagement and abuses. Its stated purpose was "to promote the interests of employees and their beneficiaries in employee benefit plans including ... any plan, fund or program for the purpose of providing medical, surgical or hospital care or benefits." From the beginning, all ERISA health care cases have been plagued with semantic difficulties since the Supreme Court never construed the terms "plan" and "benefit." Is the benefit the payment for the medical care, or is the benefit the care itself, the membership in the plan, or the plan itself? The Court ruled in *Travelers*, one of the three recent Supreme Court decisions narrowing the term "relate to",[68] that only those state laws should be exempted which have an effect on the administration of an ERISA plan. Unfortunately, "administration" has also not been construed: does it refer to purely business decisions by corporate management, or is every act on the part of an employee an "administrative decision?" Increasingly, however, ERISA §514(a) has lost much of its importance as a hurdle to state law claims by plaintiffs injured by managed care malpractice.[69]

Today, most litigation focuses on §502(a), ERISA's civil enforcement provision. This section was regularly and successfully raised as a defense by MCOs to achieve the preemption of state law claims for compensatory and punitive damages in cases of malpractice resulting from "benefit denial." In *Pilot Life Ins. Co. v. Dedeaux*,[70] the Supreme Court held that all claims for "improper processing of benefits" were preempted by §502(a). As a consequence, state tort claims for the recovery of damages incurred due to

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as state tort law claims for malpractice) and authorizes removal to Federal Court ("complete preemption").

On April 20, 1999, in Unum Life Ins. Co. v. Ward, 119 S.Ct. 1380, another landmark decision weakening the ERISA preemption, the Supreme Court restricted the scope of the saving clause by ruling that California's "notice prejudice rule" regulates insurance and thus falls outside of §514(b). The Court specified that not all of the three factors enumerated in the McCarran-Ferguson Act must be met by a business to be considered an insurance company but that these factors are merely "checking points or guideposts." Managed care companies can now be found more easily to be "insurance companies," and plaintiffs have access to remedies formerly not available.

68. *See Travelers Insurance*, 514 S.Ct. 1671; *see also Dillingham Construction*, 117 S.Ct. 832; *see also De Buono*, 117 S.Ct. 1747 (effect on plan administration).

69. Malpractice claims not preempted under §502(a) and remanded by federal courts may still have to survive a §514 challenge in state court.

70. 481 U.S. 41 (1987). In the course of three years, *Pilot Life* reinstated and terminated Mr. Dedeaux's disability benefits several times.

prospectively denied medical care ("benefits") were dismissed. The Fifth Circuit in *Corcoran v. United Health Care*[71] took this approach to its extreme by ruling that MCOs make medical decisions as part of coverage determinations and, thus, cannot be held liable for lowering the standard of care when they "deny benefits" through the "administrative" process of utilization review. This case underlined the fundamental flaw of the managed care system: the merger of resource allocation with treatment decisions.

b. The Quality vs. Quantity of Care Distinction

Absent any Supreme Court construction of the terms plan, plan administration and benefits, courts have been left to their own devices when applying the ERISA preemption to managed care malpractice. In 1995, the Court of Appeals of the Third Circuit in *Dukes v. U.S. Healthcare*[72] in a groundbreaking analysis distinguished between the quality (standard of health care) and quantity (benefits or coverage) of care. Mr. Dukes, suffering from several ailments, visited his primary care physician who referred him to a hospital which refused to perform the recommended diagnostic test. Even though the test was conducted one day later at another facility, Mr. Dukes died within three days. The Court concluded that no claims were made for refusal of care due to USH's refusal to pay (which would correspond to "improper claims processing" under *Pilot Life* and concern the quantity of care) but that all counts exclusively attacked the inadequate quality of medical treatment as arranged for by USH. Construing ERISA §502(a), the *Dukes* Court emphasized that this section simply does not address the quality of care and that the legislative history is void of any federal intent to control health care regulation traditionally left to the states. Medical decisions are, therefore, not preempted by the Act. "Patients enjoy the right to be free from medical malpractice regardless of whether or not their medical care is provided through an ERISA plan."

The Court added, however, that "the difference between the 'utilization review' and the 'arranging for medical treatment' roles is crucial for the

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71. 965 F.2d 1321 (5th Cir. 1992). Ms. Corcoran, during her second high-risk pregnancy, was refused the physician-requested hospitalization (which had saved her first baby's life) by a plan utilization review nurse and received only home care instead. While the nurse was not on duty, the full-term fetus went into distress and died. All the Corcoran's state law claims including malpractice and wrongful death were held to be "related" to the plaintiffs' ERISA plan and thus preempted, leaving the couple without a remedy.

72. 57 F3d 350 (3d Cir. June 1995).

purposes of §502(a) because only in a utilization-review role is an entity in the position to deny benefits due under an ERISA plan." Therefore, lawsuits based on state law alleging that the organization itself in its utilization review role refused to authorize and/or pay for treatment are completely preempted and only the limited remedies and damages provided under §502(a) apply. But (malpractice and vicarious liability) state law claims addressing treatment and negligent medical decisions made by physicians affiliated with MCOs covered by ERISA fall outside the scope of §502(a) and can be pursued in state court. The *Dukes* court also addressed a third, increasingly important issue—the applicable standard of care. It found that in the case at bar, there was no agreement to replace the common law standard of care with a contractual one and declined to express a view whether a managed care organization may "by contract opt out of state tort law."

Within four years, the above analysis of the ERISA preemption changed the terrain of managed care liability litigation. A solid consensus has developed among the districts,[73] especially over the past two years, that properly pleaded medical malpractice and negligence claims against MCOs attack only the quality of care, not the provision of benefits or the enforcement of rights under the plan and thus escape preemption.[74] But even *Dukes* did not deliver a definitive resolution: when do managed care decisions amount to benefit denials, or when are they imposing medical decisions violating the standard of care?

c. Theories of Liability

Today, many courts agree to call a spade a spade: negligent medical services arranged for or provided by the managed care industry constitute a breach of the standard of care. MCOs violate the tort standard by implementing a contractual standard of managed care based on coverage exclusions and corporate practice guidelines defining "medical necessity" criteria. Common strategies are the exclusion of preexisting conditions and "experimental" treatments, primary care gate-keeper refusal to refer to a specialist, denial of the appropriate treatment setting (home care instead of hospitalization, for example) or the appropriate provider (a nurse instead of a physician), denial or delay of diagnostic and treatment procedures, and

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73. Herrera v. Lovelace Health Systems, 35 F. Supp.2d 1327, 1332 (D. N. M. 1999).

74. In most of the unsuccessful cases, the claims language tied the court's hand: actions were not filed as medical malpractice but as benefit denial and left the court no choice other than to preempt the claims under §502(a) in accordance with *Pilot Life*, *supra* note 70.

phone diagnosis over an emergency hotline before admission to an emergency room may be authorized.[75]

Judges in successful cases focus on what the claims are really challenging and, often looking beyond the claims language employed, conduct a functional analysis of Congressional intent when adopting ERISA, thus favoring "function" over "form."[76] Quality of care cases against MCOs are based on theories of both vicarious and direct liability. Managed care organizations are held vicariously liable for provider (hospital or physician) negligence or malpractice according to agency or apparent (ostensible) agency principles ("holding providers out" as their agents either through literature or corporate conduct). They are also held directly liable for making medical decisions, negligent provider credentialing, negligently designed policies and procedures, and substandard supervision and management of treatment and medication. Recent cases have also successfully attacked plan design and the duties of ERISA fiduciaries.

i. Vicarious Liability

In *Howard v. Sasson*,[77] the plaintiffs' baby was born with vascular malformations in his legs, known to the treating providers. The mother contacted her pediatrician's office when the child developed a high fever, was advised to administer Tylenol and give the boy a tepid bath, but not to come to the office or take him to an emergency room. After additional fruitless calls to the physician's office, the baby began having convulsions. The mother was now allowed to bring the boy to the office where he was first examined by a nurse who then called in the physician. He arranged for an ambulance but an hour and a half after hospital admission, the child was dead. The court granted the vicarious liability claims against the MCO and

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75. German law requires physicians to examine and diagnose patients in person, and phone diagnosis is expressly prohibited. *See infra* note 284.

76. Peter D. Jacobson, Scott D. Pomfret, *Form, Function and Managed Care Torts: Achieving Fairness and Equity in ERISA Jurisprudence.* 35 HOUS. L. REV. 985 (1998). The authors argue that a "plain language" approach (a "formal" analysis, as espoused so far by the Supreme Court) to the ambiguous language of ERISA fails and that a "functional" analysis, centered on the purpose of the act and legislative intent, is more appropriate since judges should focus on the functions of health care delivery in the ever-changing environment of managed care. *Id.* at 993, 994. "Formal" analysis is also considered the cause of the remaining inconsistency and unpredictability of case outcomes.

77. Howard v. Sasson, M.D., U.S. Healthcare, et al., No. 95-0068, 1995 U.S. Dist. LEXIS 14373 (E.D. Pa. Oct. 3, 1995).

emphasized that they were only based on substandard quality of care allegations, not on any refusal to authorize and/or pay for treatment under utilization review procedures.

For almost five years, a girl—eleven years old initially—was treated by Kaiser's primary care physicians for recurrent headaches, vomiting and blood-shot eyes with adult-strength pain medication.[78] Only once a school psychologist concerned with Paige Lancaster's deteriorating performance intervened with the physicians were an EEG and an MRI conducted. The tests revealed a tumor mass covering 40% of the child's brain. In spite of several surgical interventions, the tumor could not be completely removed. The court held that §514 did not preempt state law medical malpractice claims against the physicians and the corresponding claims for vicarious liability against the MCO because they did not sufficiently "relate to" ERISA's underlying purpose. The same claims were also not preempted under §502(a) because attacks on the quality of care were held to fall outside the scope of this provision. Even though the plaintiff alleged that Kaiser's financial incentive program for physicians providing bonuses for "avoiding excessive treatments and tests" motivated the provider to refrain from investigating the cause of the child's symptoms, the court held that such claims do not convert attacks on the soundness of medical decisions into claims of "administrative benefit denial" for purposes of an ERISA preemption.

After the managed care company had denied his discharge to a rehabilitation hospital following an amputation, Mr. Hoose, cared for at home and receiving improper wound dressing, required a second amputation, this time above the knee.[79] The court refused to preempt vicarious and direct liability claims against the MCO for malpractice, inadequate selection, oversight and supervision of medical personnel, and allowed a claim against a case manager for "inadequate monitoring" of Mr. Hoose's condition. It rejected the defendant's invitation to label the case manager's denial to transfer the patient to a rehabilitation hospital as "utilization review." Instead, the court stressed that the plaintiff had alleged managed care negligence for "arranging inadequate treatment" and nowhere referred to improper care because of a refusal to pay.

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78. Lancaster v. Kaiser Foundation Health Plan, 958 F.Supp. 1137 (E.D. Va. 1997).

79. Hoose v. Jefferson Home Health Care, Inc. No. 97-7568, 1998 U.S. Dist. LEXIS 1369 (E.D. Pa. Feb. 6, 1998).

In *Crum v. Health Alliance Mid-West*,[80] the federal court ruled that the plaintiff's claim for vicarious liability against Health Alliance was based on the quality of medical care, and that the "faulty medical advice" by the phone nurses was a medical decision. The decedent, 42 years young, had a family history of heart disease. When he experienced chest pain and vomiting, his wife called the plan emergency line several times, beginning at 10.50 p.m. The nurse on duty, having been made aware of Mr. Crum's family history, insisted that he was just suffering from gastric problems, should drink milk, would be fine in the morning and did not require emergency intervention. Mrs. Crum eventually drove her husband to the hospital ER where he was pronounced dead of acute myocardial infarction at 11.34 p.m.

ii. Direct Liability

MCOs Make Medical Decisions.[81] Courts increasingly put the blame where it often belongs: with the managed care industry and its service components making medical decisions. In such instances, a malpractice claim by the injured plaintiff against an individual provider is no longer the prerequisite for a successful lawsuit. The only issue in *Roessert v. Health Net*,[82] as the court saw it, was whether the plaintiffs' direct liability state law claims alleging medical negligence and infliction of emotional distress by Health Net, the MCO, were based on purely medical decisions, or whether they related to benefit determinations. The court decided that the MCO was giving purely medical advice, unrelated to its administrative role of coordinating benefits and services under the plan. The court referred to *Dukes* and ruled that Health Net's alleged decision to commit Ms. Roessert to a mental institution was a clear medical decision, analogous to the hospital's decision in *Dukes* not to perform a blood test.[83] In *Moscovitch v.*

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80. Crum v. Health Alliance Midwest, No. 98-CV-2241, 1999 U.S. Dist. LEXIS 6469 (C.D. Ill. May 6, 1999).

81. In Germany, where budgets administered by the sickness funds increasingly require physicians to micro-allocate benefits, some authors feel that liability should rest with the insurers. *See infra* note 270. This opinion is shared by American commentators as well. "Doctors can be sued when they make an incorrect medical decision. So should the insurance company that, for example, denies essential access to a specialist." *Battle Lines on Managed Care*, N.Y. TIMES, July 17, 1998, at A20.

82. Roessert v. Health Net, 929 F.Supp. 343 (N.D. Cal. 1996).

83. *See Dukes*, 57 F3d 350.

Danbury Hospital[84] and *Plocica v. NYLCare of Texas*,[85] both mental health cases involving suicide, the courts found that the plaintiffs were challenging the "appropriateness of the medical and psychiatric care decisions by the MCO." Consistent with *Dukes*, the claims were held to attack only the quality of the benefits received.

The *Snow v. Burden*[86] court ruled that the action for the MCO's alleged failure to timely "approve and authorize diagnostic tests and studies recommended by the attending physicians" for renal cancer, in spite of the decedent's extreme symptomatology, was exclusively one of inadequate medical treatment. Since the plan was directly involved in arranging the patient's entire substandard medical care (including the control of referrals to specialists), it was therefore directly liable for the patient's death as a consequence. The court in *Blaine v. Community Health Plan*[87] called the absence of a physician for diagnosis and treatment a "unilateral determination of medical treatment" by the MCO. Furthermore, no MRI or a CT-scan were conducted to determine the nature and extent of Ms. Blaine's back condition, and she was not advised against a pregnancy. When she did become pregnant, a discectomy in an attempt to alleviate some of her chronic pain was required, and future treatment included the surgical fusion of vertebrae. The court also made a point highly relevant to all managed care efforts to lower the standard of care: patients such as Ms. Blaine do not know that they are being denied appropriate care until they have already suffered an injury.[88]

Ruling in *Nascimento v. Harvard Community Health Care Plan*,[89] the court emphasized that the only issue of relevance in this case was whether the treatment provided (failure to properly diagnose and treat the plaintiff's

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84. 25 F.Supp.2d 74 (D. Conn. 1998).

85. 43 F. Supp.2d 658 (N.D. Tex.1999). This action was brought under the Medicare Act stipulating preemption provisions similar to ERISA. It was the first case under the new Texas Senate Bill 386, allowing for claims against MCOs in cases of negligent benefits decisions. "It is not surprising that the first lawsuit would be a psychiatric case. Psychiatric care has always been the stepchild in terms of benefits and coverage. The patients have always been discriminated against, and managed care has continued this trend." Bernard Gerber, *quoted in* Michael Jonathan Grinfeld, *H.M.O. Liability: Legal Barriers Are Finally Breaking Down,* PSYCHIATRIC TIMES (January 1999) *at* http://www.mhsource.com/pt/p990110.html.

86. Snow v. Burden, No. 99-1874, 1999 U.S. Dist. LEXIS 6932 (E.D. Pa. May 6, 1999).

87. 687 N.Y.S.2d 854 (N.Y. Sup. Ct. 1998).

88. The court reasoned appropriately that such plaintiffs can not be criticized for failing to "follow any ERISA mandated process for obtaining the medical treatment."

89. 2 Mass. L. Rptr. 568 (1997).

breast cancer for three years) was consistent with the applicable standard of care. The plan had promised all "medically necessary treatment" but went back on the decision for an autologous bone marrow transplant and provided chemotherapy instead. The court commented that the term "medically necessary" does not replace the common law standard of care with a contractual one. It quoted *Dukes* at length and concluded that, in spite of the plaintiff's allegation that the ABMT was withheld by the MCO because of financial considerations, defendant's motives for lowering the treatment standard were irrelevant and did not convert this malpractice case into one of "benefit denial." In *Newton v. Tavani*,[90] the plaintiff's direct liability claims of negligent medical care against U.S. Healthcare were considered quality of care issues and not preempted under §502(a). Mr. Newton, deceased, was given a FOBT kit (fecal occult blood test) as a screening device for colorectal cancer by U.S. Healthcare. He never returned the kit and the MCO did not follow up nor inform the family physician.

iii. Negligent Policies and Procedures

In *Kampmeier v. Sacred Heart Hospital*,[91] a physician-ordered prenatal ultrasound was delayed "due to MCO regulations," and the baby was born with severe injuries. The court upheld all counts of direct liability arising from "faulty policy in arranging for timely medical treatment" and refused to characterize the test delay as the "benefit denial" claimed by the defendant. None of the counts for direct liability in *Herrera v. Lovelace*[92] (failure to enforce adequate rules and policies to ensure quality medical care and to properly select and retain competent physicians, corporate negligence for improperly overseeing the treatment of patients, asserted violations of a state statute setting standards of care in medical facilities, and intentional infliction of emotional distress) were held preempted by §502(a). The court ruled that the issues in this case concerned exclusively the quality of medical services provided but not the "administration" of the H.M.O. plan nor any benefit-related procedures. Without citing any facts, the court in *Moreno v. Health Partners Plan*[93] concluded that claims for direct managed care liability for the negligent creation of a substandard care plan (designing and delivering a procedure which resulted in injury) were not preempted by

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90. 962 F.Supp. 45 (D. N.J. 1997).

91. Kampmeier v. Sacred Heart Hosp., No. CIV.A. 95-7816, 1996 U.S. Dist. LEXIS 5739 (E.D. Pa. May 1996).

92. 35 F.Supp.2d 1327 (D. N. M. 1999).

93. 4 F. Supp.2d 888 (D. Ariz. 1998).

§§514 and 502(a), and no "benefit denial" defense was available because "who paid for the procedure [was] inconsequential" as the claims only challenged the quality of care.

The court in *DeLucia v. St. Luke's Hospital*[94] refused to preempt the direct liability claims against Aetna/U.S. Healthcare based on the "adoption/enforcement of rules, regulations and procedures which established disincentives to doctors to provide complete and proper medical care under the circumstances of this case." Keith DeLucia was born two months premature and diagnosed with respiratory distress. After one month of hospitalization, he was discharged and his mother was advised by a physician that her child did not meet Aetna's criterion for discharging a newborn on a breathing monitor. Keith suffered blue spells on a daily basis, often accompanied by apnea. He died four months later of SIDS (Sudden Infant Death Syndrome), most likely due to respiratory arrest.

The plaintiff in *Ouellette v. Christ Hospital*[95] was discharged after removal of her ovaries, even though suffering from severe pain and fever. Her MCO's policy limited hospital stays as she was told by the nurse on duty who never informed a physician of the patient's deteriorating condition. In one of her direct liability counts, Ms. Ouellette alleged that the MCO breached its duty by "limiting the hospital stays of its subscribers and enforcing those limitations." The court agreed and ruled that the plaintiff's claim was not challenging the quantity of benefits, but the quality of service received.

In *McDonald v. Damian*,[96] the court upheld direct liability claims for the failure to adopt and enforce adequate rules and policies to ensure quality control for medical services, to adequately monitor the implementation of corporate policies for standards of care, to provide after-care quality assurance, and to disclose financial incentives and arrangements with providers and facilities. Left without proper diagnostic and follow-up procedures, the plaintiff had been belatedly diagnosed with metastasized melanoma, requiring invasive and intensive cancer treatment. The *Kapka v. Hornstein*[97] court held that claims of direct liability because of improper supervision and management of plaintiff's medical and dental treatment by the MCO were not completely preempted by §502(a) and remanded this

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94. DeLucia v. St. Luke's Hosp., No. CIV.A. 98-6446, 1999 U.S. Dist. LEXIS 8124 (E.D. Pa. May 1999).

95. 942 F.Supp. 1160 (S.D. Ohio 1996).

96. 56 F. Supp.2d 574 (E.D. Pa. 1999).

97. Kapka v. Hornstein, M.D., No. CIV.A. 97-1261, 1997 WL 381762 (E.D. Pa. June 1997).

"qualitative" action for malpractice to state court. Following *Dukes*, the judge concluded that ERISA was not intended to regulate the quality of benefits received because health care regulation is a traditional area of state concern.

d. Outlook

The above representative cases elucidate the increasingly refined distinction drawn between quality and quantity of care introduced by the Third Circuit in *Dukes* in 1995. Ruling in *In re: U.S. Healthcare*,[98] the Court of Appeals seized the opportunity to further clarify when a managed care organization arranges for medical treatment (not preempted), and when it engages in administrative activities unrelated to care. The original action, *Bauman v. U.S. Healthcare*,[99] arose from a "drive-through" delivery with tragic consequences: the newborn Michelina died the day after her 24-hour hospitalization of an undiagnosed infection resulting in meningitis. The District Court had held that the counts alleging negligent and recklessly indifferent MCO policies concerning hospital utilization (discouraging physicians from re-hospitalizing a sick new-born) fell outside of the scope of §502(a). Furthermore, the Court refused to preempt the count challenging the 24 hour-limit to hospitalization after delivery, ruling it to be a quality of care issue. Since this decision went directly to a plan "coverage limitation," the court clearly rejected the MCO approach to resource allocation replacing the common law standard with its own contractual standard. The Court of Appeals of the Third Circuit affirmed and thus addressed the applicable standard of care issue it had sidelined in *Dukes*.

The Third Circuit, however, reversed one holding by the lower court. The plaintiffs had charged U.S. Healthcare with negligence for the denial of a home visit requested when their daughter fell ill. This service was covered under the plaintiffs' policy. The District Court had dismissed the claim, applying the "administrative benefit denial" construction of the ERISA preemption, and relying on the considerable body of case law preempting under §502 state law claims for damages by patients injured by the denial of covered services. The Court of Appeals concluded that this claim only attacked the adequacy of care the child had received by the MCO acting "in its capacity as medical provider.... If U.S. Healthcare failed to meet the standard of care required of health care providers by failing to arrange for a pediatric nurse in a timely manner, [this count] sets forth an ordinary state-

98. 193 F.3d 151 (3rd Cir. 1999).

99. 1 F.Supp.2d 420 (D. N.J. 1998).

law tort claim for medical malpractice." This case will further change the terrain of managed care malpractice litigation because injured patients may now recover for damages resulting from the denial of covered treatment and negligent plan design. The Supreme Court denied certiorari on June 19, 2000.[100]

But without Supreme Court construction of the key terms of the preemption provisions, every ERISA case equals a semantic balancing act. Commentators have observed that there is some "confusion as to whether the tautological ERISA [plan] definition ("any plan, fund, or program established or maintained by an employer for the purpose of providing its participants and beneficiaries, through the purchase of insurance or otherwise medical, surgical, or hospital care or benefits") encompasses H.M.O.s and other managed care organizations."[101] In *Washington Physicians Service v. Gregoire*,[102] the court distinguished between the health insurance carrier, the MCO, offering the "health plan" which was held subject to the state "Alternative Provider Act" regulating insurance, and the "benefit plan" offered by the employer, which was not. According to Washington State insurance law, "A 'health plan' is defined as any policy, contract, or agreement offered by the health carrier to provide, arrange, reimburse, or pay for health care service."[103] Therefore, the state law was not preempted under the ERISA saving clause and the MCO was treated like an insurer.

Furthermore, if managed care organizations were ruled to be health care "products" or "service providers" to employers independent of the ERISA plan (the contract between the employer and the MCO), they could be held directly liable for the negligent provision of medical services and for insurance bad faith. Any benefits or medical decisions, impacting on the quality of care, made by MCOs or any of their components as health care suppliers to an ERISA plan, would then be subject to the same relevant state laws and standards applicable to other "suppliers" of medical services as well. The court in *American Drug Stores v. Harvard Pilgrim Health Care*[104] ruled that a state law regulating vendors (drug store chains, in this instance) offering a service to an ERISA plan was not preempted by the act. The court reasoned that such a sweeping interpretation of the federal preemption could easily be read to cover state laws regulating the quality of health care which

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100. U.S. Healthcare Inc. v. Bauman, 193 F.3d 151 (3d Cir. 1999), *cert. denied,* No. 99-1383, 68 U.S.L.W. 3552 (U.S. June 19, 2000).

101. *See* P. D. Jacobson & S.D. Pomfret, *supra* note 76.

102. 147 F.3d 1039 (9th Cir. 1998).

103. Alternative Provider Act. RCW 48.43.005(9).

104. 973 F.Supp. 60 (D. Mass. Aug. 1997).

the Supreme Court has held to be a "traditional area of state concern," and which should be left to the states. As one forward-looking judge recently observed in *Nealy v. U.S.Healthcare*[105] "We leave for another day the issue whether [the] U.S. Healthcare [H.M.O.] was even a 'plan' within the meaning of the ERISA preemption provision. The Secretary of Labor ... notes that the U.S. Healthcare H.M.O at issue here is not an ERISA plan at all, but rather a service provider to the ERISA plan established by the [employer]."

Currently, MCOs also continue to be shielded from liability for treatment denied through negligent plan "administration," another term left unconstrued by the Supreme Court but often applied to utilization review procedures such as treatment preauthorization. Doris Huss, the mother of a clinically depressed and suicidal sixteen-year old, was covered by Green Spring, a mental health services administrator under contract with a managed care company.[106] On December 16, 1996, Ms. Huss called for a psychiatric referral but was turned down as "unknown" to the company. Three days later, she requested an emergency referral which was refused for the same reason. Her son committed suicide on December 23, a few hours before Green Spring finally "found" the proper file and called with an appointment. Ms. Huss was left without any remedy.

All of the central issues still clouding managed care liability could have been resolved had the Supreme Court taken a broad approach in *Pegram v. Herdrich*,[107] argued on February 23, 2000. Ms. Herdrich was diagnosed with a sizeable inflamed abdominal mass, but an ultra-sound was delayed by a total of fourteen days so that she could be examined at an in-network facility 50 miles away. Her appendix ruptured, resulting in peritonitis, a life-threatening condition. A jury awarded $35,000 for malpractice but the trial court dismissed her breach of fiduciary duty claim under §502(a)(3) against the managed care organization. The Seventh Circuit reversed in *Herdrich v. Pegram*,[108] basing its ruling on the ERISA provision that a "plan fiduciary shall discharge his duties with respect to a plan solely in the interests of the participants and beneficiaries." Since the managed care plan was owned and managed by the treating physicians, they were considered the plan fiduciaries. The Court assumed that the physicians were acting in their own financial interests when making medical decisions because their year-end bonuses depended on delaying or denying care, a

105. 93 N.Y.2d 209 (1999).

106. Huss v. Green Spring, No. 98-6055, 1999 WL 2225885 (E.D. Pa.) In mental health, many of the dead patients are children.

107. 120 S. Ct. 2143 (June 12, 2000).

108. 154 F.3d 362 (7th Cir. 1998).

violation of their fiduciary duties. Citing numerous sources from the literature and the media, the Court concluded that "market forces are insufficient to cure the deleterious effects of managed care on the health industry."

The dissent, however, felt that market forces should be trusted and that the majority ruling challenging financial incentives as one of the managed care cost containment features would jeopardize the cost-saving goals of managed care. A petition for a rehearing *en banc*[109] was denied but the dissent delivered an unusual second opinion: if the above plan design including financial incentives for providers to contain cost was held to violate ERISA, all of managed care, the health care delivery system for a majority of Americans, would be at risk. Since MCOs are already regulated by federal law, courts should not improperly interpret ERISA and subject them to state regulation.

During oral argument, the Supreme Court focused mostly on the issue of fiduciary duty and financial incentives for physicians[110] as elements of managed care plan design, presaging a narrow ruling sidestepping the construction of terms turning any ERISA case into a semantic minefield. Counsel for respondent argued that financial gains from withholding care unduly influence physician/owners' clinical judgment, equaling a breach of fiduciary duty under ERISA. Counsel for petitioner expounded on much of the dissent's reasoning, arguing for cost containment measures as integral elements of managed care plan structure (not preempted), but not of plan administration, and whose implementation would not violate fiduciary duty. Interestingly, petitioners also considered medical decisions as separate from plan administration and subject to state law, thus arguing against the ERISA preemption of state regulation of health care. Petitioners cited recent

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109. Herdrich v. Pegram, 170 F.3d 683 (7th Cir. 1998), *rehearing denied.*

110. Courts are split whether the non-disclosure to patients of physician financial incentives to limit care violates H.M.O. fiduciary duty under ERISA. Shea v. Esensten, 107 F.3d 625 (8th Cir. 1997) *cert. denied*, 118 S.Ct. 297 (1997) (non-disclosure violates fiduciary duty); Ehlmann v. Kaiser Foundation Health Plan, WL No. 98-11020 (5th Cir. 2000), *petition for cert. filed*, 68 U.S.L.W. 3726 (May 15, 2000) (No. 99-1828); Weiss v. Cigna Health Care Inc., 972 F.Supp. 748 (S.D. N.Y. 1997) (rejecting fiduciary duty under ERISA to disclose financial incentives). Interestingly, Judge Flaum in his dissent in Herdrich v. Pegram, 154 F.3d 362 (7th Cir. 1998), argued for the fiduciary duty to disclose.

Supreme Court rulings[111] as well as *Dukes* and progeny narrowing the scope of the ERISA preemption.

In its judgment of June 12, 2000,[112] the Court expanded the reasoning of the Court of Appeal's dissent, arguing that Congress had intended H.M.O.s from their inception to be profit-making, that financial incentives were an indispensable method of cost containment to achieve the "rationing" of health care, and that to decide otherwise would possibly "portend the end" of managed care, nonprofit H.M.O.s included.[113] Furthermore, since treatment and eligibility (coverage) decisions were held "inseparably mixed," neither H.M.O.s acting through their physicians nor the latter could be considered ERISA fiduciaries.[114] To impose such a fiduciary duty would convert every claim of breach of fiduciary duty by an H.M.O. physician making a "mixed decision" into a claim for malpractice, "and the fiduciary standard would be nothing but the malpractice standard traditionally applied."[115] The Supreme Court thus chose not to "broaden" the reach of federal law by subjecting mixed eligibility decisions to ERISA preemption and, in the perceived absence of a "clear manifestation of congressional purpose" to the contrary, preserved the traditional state law regulation of health care and state court jurisdiction over malpractice claims by injured MCO patients.[116] Footnote eight (at p.2154) refers to the potential fiduciary duty of MCOs to disclose "characteristics of the plan and of those who provide services to the plan, if that information affects beneficiaries' material interests," in particular plan aspects subscribers have no control over.[117] But, as the Court added, the case before it did not actually address this issue, and since the petition for certiorari in *Ehlmann*[118] has been withdrawn, the outcome of future cases claiming a fiduciary duty to disclose remains uncertain.

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111. New York State Conference of Blue Cross & Blue Shield v. Travelers Insurance Co., 514 S.Ct. 1671 (1995); DeBuono v. New York Commissioner of Health, 117 S.Ct. 1747 (1997); California Division of Labor Standards Enforcement Division v. Dillingham Construction, 117 S.Ct. 832 (1997).

112. *See supra* note 107.

113. *See id.* at 2156 & n.11.

114. *See id.*

115. *See id.*

116. *See id.*

117. *See id.* at 2154 & n.11.

118. *See supra* note 112.

On June 19, 2000, shortly after the Pegram judgment was handed down, the Supreme Court vacated the Pennsylvania Supreme Court ruling in *Pappas v. Asbel.*[119] Basile Pappas was admitted as a neurological emergency due to an epidural abscess but the emergency room physician concluded that more adequate treatment could be provided at a university hospital. U.S. Healthcare's transfer denial delayed the patient's transportation to an appropriate facility by four-and-a-half hours. As a consequence, Mr. Pappas became permanently paraplegic. His claims against the attending physicians were settled but the Pennsylvania Supreme Court ruled that the claims by one of the physician's liability insurers against the MCO were not preempted by ERISA §514. This ruling was vacated by the Supreme Court and remanded for further consideration to the Pennsylvania high court in light of *Pegram v. Herdrich.*[120] Pappas turned on a "mixed eligibility and treatment decision" by a utilization review physician at U.S. Healthcare not engaged in the practice of medicine, and who refused to speak to the attending ER physician despite repeated entreaties, and after having been made aware that Mr. Pappas' condition could worsen or become permanent. The remand may indicate that, for the time being, the Supreme Court is delegating to a lower court the difficult task of beginning to square the preempted "pure eligibility," coverage, and utilization review decisions with the application of state law to negligence claims under the *Dukes* quality vs. quantity distinction.

Are emergency treatment delays as in Pappas, occasioned by someone acting in an "administrative" capacity, pure coverage decisions protected by the legal vacuum of the ERISA preemption? Are they mixed eligibility decision because they concern the delay or denial of needed treatment and hence subject to state malpractice law under Pegram? Are they quality of health care decisions regulated by the state, thus implicating direct MCO liability for negligent treatment decisions? And is it of relevance whether such decisions are made by physicians or ancillary, possibly non-medical staff? By denying certiorari in *Bauman*, with its attack on plan design and the extension of quality of care standards to covered treatment denials hitherto shielded by ERISA §502, by vacating the holding in Pappas that ERISA does not preempt the application of state law to managed care malpractice, and by fashioning the term "mixed eligibility decisions" subject to state malpractice law, the Supreme Court has amplified the legal enigmas

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119. 724 A.2d 889 (Pa. 1998), *rehearing denied* (Feb. 12, 1999).

120. U.S. Healthcare Sys. of Pa., Inc. v. Pennsy lvania Hosp. Ins. Co., 120 S.Ct. 2686 (2000).

of the American system of health care delivery—while resoundingly ratifying its domination by private industry.

4. The Managed Care Reform Debate

a. Federal Managed Care Legislation

As managed care organizations continue to control the health care system and the number of enrollees increases, so do the complaints by both providers and beneficiaries. On October 7, 1999, the House of Representatives passed the Bipartisan Managed Care Improvement Act (H.R. 2990) by a majority of 275 votes to 151, including 68 Republicans who had defected to support the Democratic bill.[121] It guarantees access to and coverage of emergency room treatment whenever a "prudent lay person" would consider it necessary, prompt access to specialists, prompt access to obstetrical and gynecological care as well as to pediatric care without primary care gate-keeping. It also creates internal and external review procedures for benefit denials, eliminates "gag clauses" prohibiting providers from advising patients of treatments not covered by their plan, and grants patients the right to sue MCOs and other health plans by amending ERISA §514.

> **Sec. 302. ERISA PREEMPTION NOT TO APPLY TO CERTAIN ACTIONS INVOLVING HEALTH INSURANCE POLICYHOLDERS.**[122]
>
> IN GENERAL. Section 514 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144) is amended by adding at the end the following subsection:
>
> "(c) PREEMPTION NOT TO APPLY TO CERTAIN ACTIONS ARISING OUT OF PROVISION OF HEALTH BENEFITS.
>
> "(1) NONPREEMPTION OF CERTAIN CAUSES OF ACTION.

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121. Robert Pear, *House Passes Bill to Expand Rights on Medical Care*, N.Y. TIMES, Oct. 8, 1999, at A1.

122. H.R. 2723, 106th Congress, at 59 (introduced Aug. 5, 1999) (the "Norwood" bill).

> "(A) IN GENERAL. Except as provided in this subsection, nothing in this title shall be construed to invalidate, impair, or supersede any cause of action by a participant of beneficiary (or the estate of the beneficiary) under State law to recover damages resulting from personal injury or for wrongful death against any person –
>
> "(i) in connection with the provision of insurance, administrative services, or medical services by such person to or for a group health plan as defined in section 733, or
>
> "(ii) that arises out of the arrangement by such person for the provision of such insurance, administrative services, or medical services by other persons."

With one stroke of the magic wand, this section would preclude any future damage by a badly written law[123] which has wreaked havoc on American health care for 25 years. It also would eliminate the virtual deregulation of employee benefit health plans by subjecting all medical, administrative and insurance services to state regulation. Members or their survivors could sue for malpractice[124] under state tort law, claiming compensatory and punitive damages.

Alas, one day before its adoption, another health care bill creating tax breaks for medical savings accounts[125] and individuals purchasing health insurance independent of employment was yoked to the Bipartisan Managed Care Act by the Republicans in order to hobble the Act's progress. Intended to help those without any medical insurance, it would have a price tag of more than $47 billion over ten years while the above bill would cost $7 billion over five years. In addition, on November 3, Republican leaders in the House appointed to the conference committee ten Republican members who had voted against H.R. 2990, one who had voted for it, and one who had been absent. Members of the House, in an uproar, called this maneuver

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123. As one Supreme Court Justice put it, "The ERISA preemption provisions are perhaps not a model of legislative drafting." Metropolitan Life Ins. Co. v. Massachusetts, 471 U.S. 724, at 739 (1987).

124. The section of H.R. 2990 defines "personal injury" as physical injury and "including an injury arising out of the treatment (or failure to treat) a mental illness or disease."

125. *A Managed Care Debate.* WASH. POST, July 12, 1999. Medical savings accounts are criticized as favoring healthier, wealthier individuals who can opt out of the insurance pool, leaving behind the sick and less well-off.

unprecedented and stacking the deck.[126] The Senate conferees consisted exclusively of a majority of Republicans (and a minority of Democrats favoring the House bill) who had voted for the limited Senate bill (S. 1344) in July which applied to no more than 48 million individuals insured by government plans (the House bill covered 161 million insureds across the board), regulated few MCOs, and rejected any attempt at allowing patients to bring legal action in state court. In early December, after "frantic" lobbying, the "health industry saw its wish list made into law" when the budget bill, "packed with provisions sought by lobbyists for drug companies, hospitals, H.M.O.s and nursing homes" was passed and signed by the president.[127] (Even the Medicare law had been tinkered with, raising payments to managed care organizations.) Democrats complained that "this is no way to run a Congress,"[128] and none of this boded well for the House Bipartisan Managed Care Improvement Act to be taken up in conference at the beginning of 2000.

But on March 2, after the first meeting of the conference committee, chaired by a Republican, both camps seemed to be closer than expected. Perhaps spurred by patients' rights "becoming hotter as this fall's elections approach," Republicans expressed a new willingness to consider holding MCOs liable in state courts for injuries due to the delay or denial of care. Both House and Senate bills would introduce independent review procedures for benefit denials. Republicans in the Senate, by limiting the original scope of their bill, did not want to "usurp the states' authority to regulate health insurance [since] in general, states have done a good job of regulating."[129]

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126. David Rosenbaum, *Not Quite Business as Usual in House on Managed Care.*, N.Y. TIMES, Nov. 4, 1999, at A1.

127. A recent attempt by the Secretary of Health and Human Services to cut Medicare payments for blood glucose strips for diabetics was thwarted, eliminating the Secretary's authority and subjecting her decisions to congressional review. The new Medicare law also obliges the Secretary to raise payments to MCOs. *See* Robert Pear, *supra* note 121. The budget bill, passed at the same time as the Bipartisan Act and already signed by the president, earmarked funds for numerous specific medical projects and institutions in the districts of influential members of Congress. *See* Robert Pear, *Health Industry Sees Wish List Made Into Law*, N.Y. TIMES, Dec. 6, 1999, at A1.

128. *See id.*

129. *See* Robert Pear, *Negotiations Begin on a Health Care Bill,* N.Y. TIMES, March 3, 2000, at A17. Quoting Senator Don Nickles, chairman of the conference committee, stating, "My objective is to complete this conference this month and have a bill passed by both houses of Congress by Easter. We have a much better chance of passing good legislation that's not so partisan, not so political, if we work sooner rather than later."

Unfortunately, this seemingly developing rapprochement quickly ran aground, weighted down by disputes over how many Americans should benefit from new federal standards,[130] the details of a potential appeals process in case of MCO benefit denial, and whether patients should be able to sue MCOs under federal law for injuries resulting from treatment delay or denial.[131] President Clinton invited ten members of Congress to the White House to impress upon them his preference for the House bill[132] but congressional negotiations stalled over the issues of legal liability[133] and the "fine print" of the appeals process.[134] Finally, the Senate adopted a new Republican bill, granting patients a limited right to sue, which was rejected by the Democrats as a "total sham" since it offered too little to too few people. Democrats then submitted their own proposal for patient protection, covering all insured individuals, which was quickly defeated by the Republican majority.[135] With both parties accusing each other of "shunning the compromises" needed to make progress in the legislative arena,[136] prospects for any type of federal managed care legislation before the elections are dim. Since the Supreme Court in *Pegram* called upon and deferred to a stalemated Congress, patients continue to depend for protection from managed care abuse on lower courts and the states.

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130. *See* Robert Pear, *Compromise Is Offered to Break Deadlock over Patients' Rights,* N.Y. TIMES, March 23, 2000, at A18.

131. *See* Robert Pear, *House and Senate Agree On Patients' Rights Plan,* N.Y. TIMES, April 15, 2000, at A7.

132. *See* Robert Pear, *Clinton Sets Meeting to Spur Progress on Patients' Rights,* N.Y. TIMES, May 8, 2000, at A21.

133. *See* Robert Pear, *Negotiators Stall on Patients' Rights Bill,* N.Y. TIMES, May 26, 2000, at A15.

134. *The Managed Care Deadlock,* Editorial, WASH. POST, June 15, 2000, at A32.

135. *See* Helen Dewar, *Senate Passes Patients' Rights Bill,* WASH. POST, June 30, 2000, at A4.

136. *See* Helen Dewar, *In Congress, It's Politics Over Progress,* WASH. POST, May 6, 2000, at A12.

b. State Regulation of Managed Care

The federal H.M.O. Act of 1973[137] mandates standards for roughly those two-thirds of managed care plans which are federally qualified.[138] The remainder is not subject to federal regulation, and setting standards for such plans through licensing laws, for example, is left to the states. In the absence of comprehensive federal legislation, states have also passed statutes mandating minimum benefits and prohibiting certain managed care practices. Today, thirty-four states require direct access to ob/gyn services without primary care gate keeping; thirty-seven states mandate reimbursement for ER services and thirty-six apply the prudent lay person standard; fourty-two states mandate inpatient care after childbirth, nineteen after a mastectomy; fourty-eight states prohibit gag clauses, disallowing physicians to inform their patients of alternative (potentially more effective but more costly) procedures not covered under the plan; and twenty-five states ban the use of financial incentives to providers to lower utilization rates.[139]

But the most contentious issue has been MCO liability for the quality, denial, or delay of medical services rendered. Only three states so far have adopted laws incorporating the liability provisions which to date have doomed comprehensive federal managed care legislation. The remaining states leave managed care malpractice determinations to the courts, as discussed above. The first state to enact legislation allowing beneficiaries to sue MCOs for malpractice was Texas in 1997.[140] The act imposes "the duty of ordinary care when making health care treatment decisions on employees, agents, ostensible agents or representatives acting on its behalf, and over whom it has the right to exercise influence or control."[141] An MCO is defined as "any entity which delivers, administers, or assumes risk for health care services with systems or techniques to control and influence accessibility, quality, utilization, or costs but does not include an employer."[142] The law thus applies to insurance companies as well. It instituted an appeals procedure for adverse benefit determinations but exempts beneficiaries who had already been harmed by an MCO and those for whom the review would not be beneficial. Needless to say, large

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137. *See* The Health Maintenance Organization Act of 1973, 42 U.S.C.A. §300 et seq.

138. *See* ROSENBLATT ET AL., *supra* note 17, at 631.

139. PANEL PUBLISHERS, 2000 STATE GUIDE TO MANAGED CARE LAW (Aspen Publishers, New York, 2000) [hereinafter 2000 STATE GUIDE].

140. Tex. Civ. Prac. & Rem. Code Ann. § 88. 002 (Vernon 2000).

141. *See* 2000 STATE GUIDE, *supra* note 139, at 5-30, 31.

142. *See id.*

managed care corporations almost immediately challenged the act as preempted by ERISA.[143] The court, however, struck down the appeals procedure while preserving the patients' right to sue whenever claims are attacking the quality of care, not benefit determinations.

On June 20, 2000, the Fifth Circuit saved the Texas law from ERISA preemption,[144] allowing patients to sue their MCO vicariously for negligence by the treating physician. But it refused to read the act as encompassing claims based on the denial of treatment as not covered, considering coverage disputes specifically excluded and referring to ERISA §502 as the proper federally mandated enforcement mechanism for such claims. Any external review or appeals procedure for adverse benefit determinations was held preempted for the same reason.[145] Provisions prohibiting MCOs from deselecting physicians for advocating medically necessary treatments, and indemnification clauses in provider contracts holding the MCO harmless for its own acts were held to fall outside the scope of ERISA.[146] Many states may have been waiting for the outcome of this appeal to be better able to avoid ERISA problems when formulating their own managed care statutes. "If the Texas statute survives, 'there will be a bandwagon effect.'"[147] Since the law was passed two years ago, few actions have been filed, and the dire predictions of the managed care industry that premiums would rise, triggered by an avalanche of law suits, have not come true.[148]

Georgia, the second state adopting a managed care liability law[149] in July 1999, mandates ordinary diligence and benefit administration in accordance with health care provider standards. Injuries due to negligence are considered torts. California followed suit on September 28, when the

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143. *See* Corporate Health Insurance Inc.; Aetna v. The Texas Department of Insurance, 12 F.Supp. 597 (S.D.Tex. 1998).

144. *See* Corporate Health Ins., Inc.; Aetna v. The Texas Department of Insurance, 2000 WL 792345 (5th Cir. Tex. June 2000).

145. *See id.* This decision does not serve to elucidate the meaning of the Supreme Court's "mixed eligibility decisions" as created in the Pegram ruling, and seems to afford the managed care industry an easy retreat behind the intractable overlap between treatment and coverage determinations.

146. Since they do not "mandate the structure or administration of an ERISA plan", these clauses were held not preempted under ERISA §514.

147. *See* Michael Higgins, *Second Opinion on H.M.O.s,* 85 A. B. A. J. 60, 65 (1999).

148. *See* Amy Goldstein, *Patients' Rights' Case Study: So Far, Benign; In Texas, Ability to Sue HMOs Has Prompted Little Litigation,* WASH. POST, Sept. 28, 1999, at A1.

149. *See* 2000 STATE GUIDE, *supra* note 141, at 5-39 (Amendment to Official Code of Ga. Relating to general provisions regarding torts, Ch. 1, Title 51, Sec. 1, 1999 Ga. Laws 281.

governor signed Senate Bill No. 21 granting managed care patients numerous new rights and allowing claims for compensatory and punitive damages when the duty of ordinary care has been breached.[150] The Georgia law has not yet been challenged in court, and the California acts attempt to avoid potential ERISA preemption by basing the right to sue on attacks on the quality of care.[151] "The enactment of [these] new health care reforms shows that state leaders are well ahead of Congress in addressing the need for managed care regulation....[But] "Americans elsewhere need Congress to enact basic protections to insure that patients [can] get the care they need."[152]

c. Physicians Unite!

By May 1999, more than 35,000 of the 700,000 physicians in the United States had become union members.[153] Labor experts expect this number to rise by 15% each year, and more than half a dozen unions are conducting organizing campaigns. Physicians are growing "angrier over managed care,"[154] curtailing their autonomy to make independent clinical decisions and exerting financial pressures, often with the purpose of lowering the standard of care. "Medicine has gone from a mom-and-pop operation to corporatization, which has left the provider, the doctor, out of medical decision-making."[155] With increasing numbers of patients covered by managed care plans, physicians are often told by MCOs to "take it or leave it." Alone, they feel "they don't have a say."[156] Many of the recently unionized doctors are employed by hospitals, for example. However, physicians in private practice under contract with MCOs (roughly 90 %) have joined their ranks, often pushing the unions to negotiate with MCOs for large groups of providers. "The way medicine is going right now and the way patients are being treated by managed care is just terrible, and someone has

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150. Managed Health Care Insurance Accountability Act of 1999, Ch. 536, Sec. 2, 1999 Cal. Adv. Legis. Serv. 536 (Deering).

151. *Health Care Reforms in California,* WASH. POST, Oct. 1, 1999, at A24.

152. *See id.*

153. *See* Steven Greenhouse, *Board Denies Doctor's Bid to Unionize at H.M.O,* N. Y. TIMES, May 25, 1999, at B8.

154. *See* Steven Greenhouse, *Angered by H.M.O.'s Treatment, More Doctors Are Joining Unions,* N. Y. TIMES Feb. 4, 1999, at A1.

155. *See id.* (quoting Barry Liebowitz, president of the Doctors Council, a union representing 3,400 members).

156. Ginger Thompson, *Feeling the Push of Managed Care: In Syracuse, Doctors and Patients Adjust as H.M.O.s Start to Take Hold,* WASH. POST, Feb. 12, 1999, at A23.

to stand up for proper health care." Physicians' unions ... "primarily [serve] to get the message out that we have to improve health care."[157] In June 1999, the American Medical Association voted to form a national negotiating organization, Physicians for Responsible Negotiation, in order to give physicians "the leverage they now lack to guarantee that patient care is not compromised or neglected for the sake of profits"[158] when negotiating with managed care plans and insurers. It began its activities in November 1999. However, the AMA has ruled out strikes, and many physicians consider the withholding of essential services violations of the Hippocratic oath. German physicians, in spite of the rhetoric, have not resorted to strikes, contrary to their French colleagues repeatedly protesting working conditions and additional demands on the exercise of their profession. However, union executives—and certainly some physicians as well—feel that it is rather the working conditions created by MCOs which force physicians to violate their oath by denying procedures and preventing them from providing the standard of care they consider appropriate.[159] Psychologists are joining as well. The New York State Psychological Association is affiliating with the American Federation of Teachers because, as its president commented, "We want to maintain professionalism and patients' rights against the inroads of managed care."[160]

Diminishing the power of managed care would restore to physicians some of their former influence on the provision of medical services. Another way to regain control has been the creation of Independent Practice Associations, strengthening physicians' bargaining power while not restricting them individually to a collectively negotiated agreement they may disagree with. As one physician commented, "We don't need a middleman to manage health care. We are smart enough to do it ourselves."[161] Managed care organizations are fighting back by claiming that many of the salaried physicians voting on unionization are supervisors and, thus, not entitled to

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157. *See* Greenhouse, *supra* note 154 (quoting Brian J. Moore, *Angered by H.M.O.'s Treatment, More Doctors Are Joining Unions,* N.Y. TIMES, Feb. 4, 1999, at A1.) For eloquent examples of managed care malpractice, *see supra* section II.A.3.

158. *See* Fitzhugh Mullan, *I Joined Once, Now I'm Not So Sure,* WASH. POST, July 18, 1999, at B3.

159. *See* Greenhouse, *supra* note 154.

160. Joe Volz, *Angered by Managed Care, Practitioners Look to Unions.* 30(8) THE AMERICAN PSYCHOLOGICAL ASSOCIATION MONITOR 1 (Sept. 1999) (quoting Marianne Jackson, President, New York State Psychological Association).

161. *See* Thompson, *supra* note 156.

join (as at Lincoln Hospital in the Bronx in October 1998)[162] or by claiming that physicians are independent contractors. On May 24, 1999, the National Labor Relations Board's regional office in Philadelphia rejected the attempt of 500 physicians in New Jersey to form a union.[163] The physicians had argued that the Amerihealth Corporation of New Jersey, an H.M.O., exerted so much control over the details of their work that they should be considered employees and allowed to unionize. The NLRB rejected this argument and found that the doctors in question were independent contractors, hence, forming a union would violate antitrust principles.

Antitrust law, together with the deregulation of employer-provided health insurance and, therefore, of the quality of medical care under ERISA, has been the driving force behind the transformation of American health care.[164] Over the past years, medicine, increasingly controlled by large corporations and turned into an industry, has been subjected to unfettered market forces. Antitrust law supports this development by favoring the vertical integration of providers in managed care corporations over the horizontal integration of independent suppliers of medical services. Physicians traditionally operated small businesses and acted together to have some influence on fees and the practice of medicine. Antitrust law, however, mainly seeks to preserve price competition and hence prohibits any such horizontal arrangements. The Supreme Court in *Arizona v. Maricopa County Medical Society*[165] applied the full force of the Sherman Act to physicians, focusing exclusively on "horizontal price setting." As the chairman of the Federal Trade Commission opined in July 1999, "The decision of the American Medical Association to endorse creation of a bargaining unit that will allow doctors in the future to bargain collectively with H.M.O.s is the wrong answer" [to the] "serious problem of H.M.O. interjection into every detail of medical practice."[166] Instead, he supported the adoption by Congress of a strong Patient Bill of Rights in order to return to doctors control over their professional lives without "giving them a license to do little more than increase their incomes by engaging in price fixing." In keeping with this attitude, the Justice Department in August 1998 charged Delaware orthopedic surgeons with an "illegal boycott and conspiring to raise health care prices" after they left Blue Cross/Blue Shield and joined a union, protesting reduced reimbursements. However, its executive director

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162. *See* Greenhouse, *supra* note 153.

163. *See* Greenhouse, *supra* note 154.

164. *See* ROSENBLATT ET AL., *supra* note 17, at 647, 662.

165. 457 U.S. 332 (1982).

166. *See* Robert Pitofsky, *Doctors Unite?* WASH. POST, July 18, 1999, at B7.

observed, "Here you have an antitrust law that was passed to control the Rockefellers and Carnegies, but is being used against doctors trying to hold on to their practices."[167]

Doctors in private practice have appealed to Congress to pass an exemption to antitrust law,[168] granting them the same rights as truck driving entrepreneurs owning their vehicles while allowed to entrust their union with bargaining for working conditions and salaries. In October 1999, the Republican Speaker of the House postponed "indefinitely" a committee vote on H.R. 1304 (Quality Health Care Act), thus temporarily preventing the full House from debating the proposed antitrust exemption for physicians.[169] After a change of heart, however, the House, by a vote of 276 to 136 on June 29, 2000, finally approved the bill, sponsored by a Republican member from California and supported by the American Medical Association.[170] So far, no senator has introduced similar legislation in the Senate, and the leader of the Republican majority has vowed to oppose any attempts: "I don't think we need more labor unions in America."[171] Both the Federal Trade Commission and the antitrust division of the Department of Justice continue to object to any bill which would permit physicians to negotiate collectively with insurers over working conditions and payment. Both have filed cases against physicians accusing them of "conspiring" to thwart the cost containment measures of MCOs and "engaging in price fixing."[172]

However, there is another aspect to blindly applying the antitrust provisions to the medical profession. Physicians, similar to other "independent competing entrepreneurs," self-regulate their profession through a code of ethics issued by their associations. The indiscriminate enforcement of antitrust principles destroys or diminishes these efforts to

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167. *See* Greenhouse, *supra* note 153 (quoting Jack Seddon, Executive Director of the Federation of Physicians and Dentists).

168. *See id.*

169. *Hot Doc Topic: Unions, Liability*, 5(1) ON MANAGED CARE 2, (Jan. 2000).

170. *See* Robert Pear, *After Doctor's Antitrust Triumph, Lott Puts Up Roadblock in Senate.* N.Y. TIMES, July 1, 2000, at A1. (The bill is also opposed by nurses, nurse practitioners and midwives who fear a diminished role if doctors negotiated with insurers.)

171. Matthew Vita, *House Approves AMA-Backed Bill,* WASH. POST, June 30, 2000.

172. *See* Robert Pear, *supra* note 170. Hence, both the administration and the Senate oppose the right of physicians to exercise some control over their profession through appropriate representation, a right German physicians have had since 1913. *Infra* section B.2.A.a.

protect the public.[173] Assume, for example, that a physician association issued the rule that surgery should only be performed in the presence of two surgeons in order to guarantee a certain standard of care. This would be challenged as a horizontal agreement to raise the demand for surgeons and thus their fees. But if a MCO, as a cost-control mechanism, issued a "practice guideline" limiting the number of attending surgeons to one, antitrust law would remain silent.[174]

173. On this basis, the Federal Trade Commission over the past ten years has attacked associations such as the American Medical Association, the American Dental Association, the American Psychological Association, and the International Conference Interpreters Association (AIIC), which is based in Geneva and has a total of 80 members in the United States. Several U.S. associations were forced to sign consent decrees, often including the elimination of provisions in their code of ethics designed to protect consumers. The American Psychological Association, for example, was compelled to delete a clause prohibiting fear-inducing advertising claims that, unless you came in for treatment of your depression, you might suffer serious consequences including suicide. The FTC argued that this provision prevented the public from adequate access to information. The only association resisting the FTC attacks on the self-regulation and consumer-protection efforts of an independent profession was AIIC which pursued its case by successfully appealing the ALJ's ruling to the full Commission.

174. *See* ROSENBLATT ET AL., *supra* note 17, at 664 (quoting Professor David Frankford).

B. Germany[175]

German providers of medical care and the standards of their conduct are subject to four different bodies of law: the Federal Constitution, and social, civil and criminal law. The Constitution and social law protect the standard of care. Civil and criminal law establish the standard for physician liability. Conflicts of relevance in malpractice actions may arise between social law and civil law which overlap, but may result in diverging standards of care.[176]

1. The Constitution and the Standard of Care

Contrary to the U.S. Constitution, the German Federal Constitution of May 23, 1949, formally recognizes a State duty of care for its citizens.[177] How this duty is to be exercised may be determined by the legislator, free to choose among different means while bound by the principles of social

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175. In spite of numerous common problems and avenues pursued to find solutions in both countries, one of the difficulties when comparing the two health care systems is language. On both sides of the Atlantic, similar terms and concepts are used but often their similarity is superficial only because of the diverging underlying philosophies. The American approach of market-dominated private sector insurance, apart from programs such as Medicare, Medicaid and health care plans for government employees, grew out of the historical defense of individual rights and an interpretation of the constitution aimed at protecting "the right to be let alone", as phrased by Judge Brandeis in Olmstead v. United States, 277 U.S. 438 (1928). The German universal access/universal coverage social health insurance system with mandatory membership for most of the population developed as part of a communitarian approach to society, emphasizing solidarity, and dating back to the 19th century. Because of these differing philosophies, some of the German definitions of concepts familiar in the United States as well may sound like euphemisms or sophistry, especially in an era of cynicism triggered by terms such as medical necessity, "experimental" treatments and utilization review, commonly used in the world of managed care. Even though both systems of health care delivery have slowly begun to converge, fundamental attitudes are still sufficiently diverse to make language a complex and treacherous element when attempting to transpose the search for solutions to similar problems from one mentality to another.

176. Klaus Engelmann, *Ärztliche Berufspflichten im Konfliktfeld zwischen Artzhaftung and Sozialrecht [Conflicts between Medical Liability and Social Law: Physicians' Professional Duties]*. RICHTERWOCHE, BUNDESSOZIALGERICHT [Presentation on the occasion of the annual Justices' Seminar at the Supreme Social Court] (Oct. 1996).

177. BVerfG E 15, 121 [133], June 18, 1975. Ruling of the Federal Constitutional Court *(Bundesverfassungsgericht. BVG)*.

justice.[178] Article 1(1) of the Federal Constitution[179] (human dignity is inviolable and to be preserved and protected by the State) in conjunction with Article 20(1) (the Federal Republic of Germany is a democratic and socially responsible federal state) imposes on the State the duty to provide the material minimum for a dignified existence of its citizens.[180] To leave those who have the right to vote and thus participate in the power of the State without entitlement to support would violate the Constitution.[181] Citizens, as members of the community, have obligations towards each other as well as rights, such as the right to life and health, embodied in Art. 2(2).[182] This includes the preservation of health, the control of pain, and the restoration of health in case of illness.[183] Article 104(1) protects individual physical and psychological integrity. The statutory system of health care could thus be considered synonymous with the socially responsible State.[184] The Federal Constitutional Court has emphasized the constitutional mandate for an effective statutory health care system.[185] Since this implies an outcome-oriented approach, the effectiveness of procedures is given high priority.[186] Furthermore, the Constitution recognizes the self-determination of individuals[187] and, thus, their autonomy as patients. It also guarantees the

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178. *See id.* at 133, 134.

179. GRUNDGESETZ FÜR DIE BUNDESREPUBLIK DEUTSCHLAND [CONSTITUTION OF THE FEDERAL REPUBLIC OF GERMANY] (Bundeszentrale für politische Bildung, Bonn, July 1998) [hereinafter Constitution].

180. BVerfG E 7, 187 [228], June 21, 1977. BVerfG E 40, 121 (133); 45, 187 (228); 82, 60 (80, 85).

181. BverwGE 1, 159 [161], June 24, 1954. Ruling of the Federal Administrative Court *(Bundesverwaltungsgericht. BVwG).*

182. *See id.* at 162.

183. Erwin Deutsch, *Ärztliche Berufspflichten im Konfliktfeld zwischen Artzhaftung and Sozialrecht [Conflicts between Medical Liability and Social Law: Physicians' Professional Duties].* RICHTERWOCHE, BUNDESSOZIALGERICHT (Oct. 1996).

184. Gudrun Eberle, *Die Entwicklung der GKV zum heutigen Stand [The History of the Statutory Health Care System].* 47(3) SOZIALER FORTSCHRITT 53 (March 1998).

185. BVerfG E 70, 1, 30.

186. MANFRED KOHLER, SOZIALRECHTLICH GESTEUERTE GESUNDHEITSFÖRDERUNG IN DER KASSENÄRZTLICHEN VERSORGUNG [HEALTH PROMOTION AND THE DELIVERY OF MEDICAL CARE UNDER SOCIAL LAW] 51 (Erich Schmidt Verlag, Berlin, 1989).

187. *See* Constitution, *supra* note 179, at Art. 2 (the right to self-determination, self-development, physical inviolability).

free choice and practice of a profession,[188] limiting the legislator's options to restrict physicians' access to[189] and exercise of their profession, including their right to independent clinical decision making.[190]

2. Social Law: The SGB V

a. The Legal Foundations of the Health Care Delivery System

Title V of the Social Code (SGB V), passed in 1988, embodies the statutory health care system. It was amended in 1992 and 1997[191] and is the most recent successor to the National Health Insurance Act, adopted in 1883[192] under Chancellor Otto von Bismarck which was followed by the Insurance Code of 1914 (RVO).[193] Since 1883, membership in originally six plans (the "sickness funds"[194]) has been mandatory. The currently over 600 sickness funds are decentralized and remain subdivided into the six traditional categories according to profession, industry or locality[195] plus the "substitute funds" for workers and employees choosing not to belong to any

188. *See id.* at Art. 12 (the right to freely choose and exercise a profession).

189. According to the SGB V, Arts. 99-105, physician and sickness fund associations, in cooperation with state agencies, must determine the number of physicians required to ensure the uniform availability of quality medical care by region. *(Bedarfsplanung)* This has led to some restrictions on the number of new practices especially in metropolitan areas. The constitutionality of this quantitative element of the SGB V is currently contested. SOZIALGESETZBUCH - FÜNFTES BUCH, SGB V. BGBL. S. 2477, Bonn, 20. Dezember 1988 [SOCIAL CODE, TITLE V, published in the GERMAN CODE 2477] (Dec. 20, 1988) [hereinafter SGB V].

190. *Therapiefreiheit.* Constitution, Art. 12, *supra* note 179. *Also* BSG 14a Rka 7/92, Sept. 8, 1993. "The Amalgam Ruling," leaving the choice of filling with the dentist [hereinafter BSG 14a Rka].

191. For a detailed discussion of the Act, including benefits and its revisions in 1992 and 1997, *see* Weide, *supra* note 12.

192. *Krankenversicherungsgesetz*, May 6, 1883.

193. *Reichsversicherungsordnung,* Jan. 1, 1914 (Imperial Insurance Code).

194. *Krankenkassen.*

195. *Betriebskassen* (corporate plans). *Innungskassen* (plans by trade). *Landwirtschaftliche Krankenkasse* (agricultural workers plan). *See-Krankenkasse* (merchant marine plan). *Bundesknappschaft* (mine workers plan). *Ortskassen* (local funds by municipality or county).

of the other plans.[196] All funds offer identical coverage by law and, beginning in 1883, have been self-governed, providing benefits on a prepaid basis. Premiums are assessed at a universal rate (currently 13.6%) up to a predetermined maximum level of income,[197] and shared equally between employer and employee through a type of payroll tax. Dependants are covered free of charge. This statutory health care system is an all-payer,[198] not-for-profit, universal access/universal coverage system of social insurance. It covers 90 percent of the population[199] and provides comprehensive care, including prescription drugs, fertility treatment, home care and sick pay, without lifetime limits or limits for any category of benefits. The sickness funds are the insurers cooperating with the providers to ensure uniform access to and delivery of care as stipulated by the SGB V for all members, independently of geographic location.[200] The main chapters of the act are: (I) foundations of the solidarity-based social insurance, (II) universal access, (III) universal coverage, (IV) services by and the self-governance of plan providers, and (VI and VII) organizational structure and self-governance of the sickness funds.

Patients (or "members") have a substantive right under social law to receive the comprehensive benefits listed in the SGB V[201] according to the following standard of care:

> "The quality and efficacy of the benefits to be provided by the sickness funds must correspond to the generally accepted

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196. This reflects the historical development of the funds during the 19th century. Under a 1997 open-enrollment amendment to the SGB V, members can now elect to join any of the funds and switch on an annual basis.

197. *Beitragsbemessungsgrenze.* At the current exchange rate, roughly $35,000. Assessing individuals beyond this level is considered to yield a negative cost/benefit ratio.

198. Uwe Reinhardt, *West Germany's Health Care and Health Insurance System: Combining Universal Access with Cost Control.* Report prepared for the United States Bipartisan Commission on Comprehensive Health Care, August 30, 1989. Revised June 25, 1990.

199. The remaining 10 percent have opted out of the public system, buying private insurance, because their incomes exceed the statutory income level for mandatory membership. Benefits by law, however, must be at least equal to the comprehensive coverage provided by the sickness funds, creating little incentive even for wealthier individuals, who may become voluntary members of the public plan, to obtain private coverage.

200. *See* SGB V at Art. 72. *Sicherstellungsauftrag.*

201. *See id.* at Art. 27.

> medical standard of care and must be in accordance with the progress of medical science."[202]

> "Medical treatment is defined as all adequate and appropriate procedures performed by a physician as needed for the prevention, early diagnosis and treatment of illness in accordance with the current standard of care. Medical treatment includes procedures performed by providers other than physicians which were ordered by a physician and performed under her/his supervision."[203]

Cost containment is to be achieved through the cost-effectiveness[204] of all care: "Benefits must be adequate, appropriate and cost-effective; they may not exceed whatever is necessary. Members may not claim unnecessary or not cost-effective treatment, providers must refuse it and sickness funds must deny reimbursement."[205]

Physicians' independent clinical judgment is protected by the Constitution but clinical decision-making is not an entirely autonomous process. Patient self-determination is a protected right as well, and today's physician-patient relationship has become less paternalistic and more of a dialogue. In addition, nationally and regionally negotiated budgets macro-allocate health care funds while national benefit guidelines (social law)[206] and clinical practice guidelines (civil law) set a framework for the quality of care. Increasingly, the SGB V will not only serve to guarantee benefits and the quality of medical services but also update the coverage of customary and innovative procedures by subjecting them to cost/benefit evaluations.

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202. *See id.* at Art. 2.

203. *See id.* at Art. 28.

204. *See id.* at Art. 12. *Wirtschaftlichkeitsgebot* (Cost-effectiveness mandate).

205. Preauthorization of benefits is not required. There are, however, retrospective economic reviews of the claims filed by individual providers. For further discussion, *see infra* section II.B.4.a.

206. *Richtlinien.* Benefit guidelines are adopted by the Joint Federal Committee of Physician and Sickness Fund Associations (*Bundesausschüsse)* and approved by the Ministry of Health. For further discussion, *see infra* section II.B.2.B.a.

i. Sickness Funds and Their Associations

According to the SGB V, the sickness funds are autonomous, self-governed corporate entities under public law.[207] As statutory insurers, they provide coverage in accordance with the SGB V and contract with provider associations for medical services.[208] Under the National Health Insurance Act of 1883, sickness fund associations were as of yet nonexistent. In 1894, however, the first voluntary national association[209] was founded in Frankfurt by "local funds," able to exert considerable political influence since a majority of funds joined. Other sickness fund categories followed suit. With the approval of employers and employees, jointly funding the health care system, the Insurance Code of 1914 (RVO) first recognized these associations under private law and by 1933, legislators had transferred to them the responsibility for the contracts concluded with the physicians. The RVO was revised in 1936, turning the sickness fund associations into corporate entities under public law and making sickness fund membership mandatory. It also established a "Working Group of Sickness Fund Associations,"[210] a national umbrella organization representing all categories of sickness funds. Its mission was to handle all sickness fund related issues, and decisions had to be unanimous. After the end of World War II, when Germany was divided into five occupied zones, regional health insurance systems were introduced by the allied powers. Sickness funds, once again voluntarily and under private law, reestablished their regional and national associations. After the Federal Republic of Germany was founded in 1949, sickness fund self-governance was restored through legislation in 1951.[211] In 1955, sickness fund associations, both regional and federal, once again became corporate entities under public law.[212]

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207. *See* SGB V at Art. 4. *Körperschaften des öffentlichen Rechts mit Selbstverwaltung.*

208. *See id.* at Art. 2.

209. *Centralverband der Ortkrankenkasssen im deutschen Reich [Central Association of Local Funds in Imperial Germany].*

210. *Arbeitsgemeinschaft der Reichsverbände.*

211. *Gesetz über die Selbstverwaltung [Sickness Fund Self-Governance Act].*

212. *Gesetz über die Verbände der gesetzlichen Krankenkassen und Ersatzkassen [Statutory Sickness Fund Associations and Substitute Fund Associations Act].* BGBl. I S. 524, 1955 (1 GERMAN CODE 524) (1955).

ii. Physicians and Their Associations

The National Health Insurance Act of 1883 did not yet codify the relationship between the sickness funds and the providers.[213] The funds were free to contract with or dismiss individual physicians, replacing the patient-physician relationship with a civil law contractual relationship between plans and providers. Since this amounted to almost total physician dependency on the sickness funds, frequent friction between the parties ensued, and a number of physician associations, resembling unions, were created. In 1900, the private "Hartmann Bund," comparable to the American Medical Association, was founded. Physicians demanded patient choice of providers, sickness fund contracting with licensed physicians only, collective agreements to guarantee adequate compensation, and a self-regulated system of quality control.

The Berlin Agreement of 1913 established a joint committee of physicians and sickness funds as equal partners and laid the foundation for self-governance. Compensation and physician licensing agreements were jointly negotiated and an arbitration procedure was introduced. The sickness funds made lump-sum payments, calculated according to per capita health care costs, to the physician associations which compensated individual physicians on a capitated basis.[214] The agreement limited the admission of physicians to practice within the public system based on a ratio of 1,350 insured individuals per physician. But since the RVO of 1914 did not regulate the contractual relationship between physicians and sickness funds, frictions continued, culminating in threats of general strikes by physicians and the potential collapse of health care delivery.

Considering the varied history of the relationship between sickness funds and physicians, without government intervention, the system would have been disabled at numerous stages of its development.[215] Legislators

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213. This section is based on KOHLER, *supra* note 186. HEINRICH REITER, ENTSTEHUNGSGESCHICHTE, AUFGABEN UND ORGANISATION DER SPITZENVERBANDE DER KRANKENKASSEN NACH DEM SGB V [DEVELOPMENT, TASKS AND ORGANIZATION OF THE NATIONAL ASSOCIATIONS OF SICKNESS FUNDS UNDER THE SGB V] (Hartung-Gorre Verlag, Konstanz, 1996). HERMANN PLAGEMANN, VERTRAGSARZTRECHT—PSYCHOTHERAPEUTENGESETZ [SGB V: PLAN PHYSICIAN SECTIONS—PSYCHOTHERAPY SECTIONS] (Fachholschulverlag, Frankfurt, Sept. 1998).

214. *Kopfpauschale.* Today, capitated payments are only one element of physician compensation.

215. *See* KOHLER, *supra* note 186 (quoting a contemporary observer when strikes were likely in 1913: "This strike could have been organized either by the physicians or the sickness

increasingly accepted government responsibility and acted whenever the situation required rectification of the organizational framework needed to ensure adequate care. After a four-week strike over New Years of 1923/1924, the government issued an order for the creation of a plan physician association[216] responsible for physician licensing, contracts with the sickness funds, compensation and the determination of the number of physicians required to provide comprehensive care to all member-patients. Many of the Berlin Agreement institutions and provisions thus became components of the RVO and received their status under public law. Physicians were free to conclude either individual or collective contracts with their local physician associations and choose between case-based or fee-for-service compensation (the latter subject to some limitations.)

The government also established a National Joint Committee of Physician and Sickness Fund Associations which issued normative standards for provider licensing, the cost-effective prescription of medication, and, for example, the use of "electro-physical" treatments. The latter two were the precursors of today's SGB V coverage guidelines and, thus, the first attempts at setting a statutory standard of care. In 1932, these standards were incorporated into the RVO and became national law. Regional physician associations responsible for the access to and the provision of medical care were established, and the contractual provider-sickness fund relationship was regulated by public law. A mandatory dispute-settlement procedure for physicians and sickness funds guaranteed the uninterrupted delivery of health care.

Following the self-governance act of 1951, the Plan Physician Act[217] was adopted in 1955 in tandem with the corresponding sickness funds act, awarding the physician associations their definitive status under public law. Membership for physicians practicing within the statutory health care system (about 90%) is mandatory, but it is voluntary for the remaining physicians. There are twenty-three regional physicians organizations,[218] each run by an assembly elected by the physicians and a board elected by the assembly.[219]

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funds. But the hapless victims would have been the patients—an unacceptable situation for any responsible government." (at 18)).

216. *Kassenarztverein.*

217. *Gesetz über das Kassenarztrecht.* The act also provided for additional methods of physician compensation such as fee-for-service and diagnosis-related payment. BGBl. I S. 513, 1955 [1 GERMAN CODE 513] (1955).

218. *Kassenärztliche Vereinigungen. See* SGB V at Art. 70(1).

219. *See id.* at Art. 79.

All are represented by the Federal Association of Physician Associations.[220] The regional associations must guarantee patient access to adequate medical care in accordance with the prevailing standard of care, its preservation through physician licensing and continuing education,[221] correct claims processing (physicians file on a quarterly basis, not patients), and cost-effective care.[222] Clinical decision making, however, rests solely with the providers.

Physicians, once licensed to practice within the statutory system, have a contractual obligation under civil law to provide medical care for patients covered by the sickness funds and entitled to such treatment in accordance with the SGB V. Physicians may refuse to treat (emergencies excepted) in case of disputes with the patient, repeated patient non-compliance, practice overload (patient selection is not permitted), and home visits to geographically distant locations. Even under any of these circumstances, services must be rendered if no other physician is available.[223] If treatment is denied without a valid reason, civil and criminal procedures can be initiated.[224]

iii. The System of Self-Governance

Since 1955, the main players of the current German health care system have been the regional and federal physician and sickness fund associations. The SGB V of 1988, following in the tradition of earlier health care legislation, stipulates their obligation to autonomously but jointly safeguard the organizational structures required for the implementation of their mandate as defined by the SGB V: the provision of "adequate, appropriate

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220. *Kassenärztliche Bundesvereinigung (KBV).*

221. *See* SGB V at Arts. 95, 95(a). The regional physician associations also license physicians for practice within the statutory system.

222. *See id.* at Art. 106. *Wirtschaftlichkeitsprüfung.* Physicians' claims are reviewed retrospectively according to standardized economic criteria.

223. Laws such as EMTALA (The Emergency Medical Treatment And Active Labor Act) and the hospital "charity care" requirement (for accreditation as Medicare/Medicaid provider or tax exempt status under the I.R.S. code) are rendered superfluous since all SGB V providers, hospitals included, have the same contractual obligation to deliver appropriate and adequate care. For hospitals, this is defined as comprehensive care according to patient need, including physicians' services. *See* SGB V at Art. 39.

224. In a medical negligence case, both civil and criminal charges can be filed. Duty, breach, causation and damage requirements are identical but damages for pain and suffering are available only in criminal actions.

and cost-effective treatment corresponding to the generally accepted standard of medical care"[225] in keeping with the "progress of medical science."[226] Physician associations assume a dual role. They ensure appropriate provider compensation while preserving the health care delivery system. The regional physician associations negotiate collective regional agreements[227] with the regional sickness fund associations, detailing the fundamental conditions for the delivery of health care, quality control and claims processing procedures, and the fees for individual physician services. These agreements implement the provisions of the national agreement[228] negotiated on the federal level between the Federal Association of Physician Associations and the Federal Associations of Sickness Funds.[229] Currently, physicians and dentists receive a combination of fee-for-service compensation for specialized procedures, capitated payments for basic procedures, and indemnity payments for some dental procedures.

All methods of payment are renegotiated annually and entered into the national fee schedule based on relative value units (RVUs).[230] The regional physician associations compensate their members with assets received from the sickness funds, and any disputes over reimbursement are resolved by physicians and sickness funds. The regional sickness fund associations[231] (assembly members are elected by plan subscribers) also contract with other providers such as hospitals. In addition, the federal physician and sickness fund associations sit on a Joint Federal Committee[232] composed of one independent chairperson, two independent members, and nine members each representing the physicians and the sickness funds. This Committee adopts the national coverage guidelines discussed below.

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225. *See* SGB V at Arts. 70(1), 72(2).

226. *See id.* at Art. 2(1).

227. *See id.* at Art. 83. *Gesamtverträge.*

228. *See id.* at Art. 82. *Bundesmantelvertrag.*

229. *See id. Kassenärztliche Bundesvereinigungen. Spitzenverbände der Krankenkassen.*

230. *See id.* at Art. 87. *Einheitlicher Bewertunsmaßstab.*

231. *See id.* at Art. 207. *Landesverbände der Krankenkassen.*

232. *See id.* at Art. 91. *Bundesausschuß der Ärzte und Krankenkassen.*

b. Setting the Standard of Care

Coverage is comprehensive, and Chapter III of the SGB V entitles all members to the prevailing standard of care.[233] One normative and one informal mechanism contribute to the definition of this standard: the national coverage guidelines of the SGB V,[234] and the clinical practice guidelines (generally accepted treatment procedures) developed by the different medical specialty societies.[235] Originally, the national coverage guidelines were conceived to guarantee a high standard of care, but the current thirteen guidelines increasingly serve the macro-allocation of health care resources by specifying and updating covered benefits. The clinical practice guidelines are not normative, even though often considered the prevailing standard of care in malpractice cases, but designed to provide a "corridor" for accepted clinical decision making, leaving treatment decisions implying "medical necessity"[236] to the physicians. The standard for both coverage guidelines and clinical practice guidelines is determined by scientific evidence, clinical expertise, and generally accepted preventive, diagnostic, and therapeutic practices. The standard changes over time, and adjustments are permissible whenever required in a patient's individual circumstances.[237]

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233. *Leistungsrecht. See* SGB V at Arts. 11-66.

234. *See id.* at Art. 92. *Richtlinien der Bundesausschüsse [Coverage Guidelines adopted by the Joint Federal Committee].* The Medicare term "coverage determination" is not used here to underscore the differences between the two systems even though both are "social insurances."

235. *Leitlinien.* For further discussion, *see infra* section II.B.2.B.b. Since SGB V, Art. 76(4), entitles patients to the customary care standard applicable to all service contracts under the Civil Code, clinical practice guidelines help to determine civil law malpractice liability.

236. "Medical necessity" has differing connotation in both countries. In the United States, it is best known as one of the managed care concepts used in the micro-allocation of health care funds through mandatory preauthorization of care for individual patients. (Several states have also adopted a macro-level statutory definition of medical necessity.) In Germany, the term is only now becoming popular and may, depending on the context, refer to either the macro-level standard of care to be guaranteed by social law or treatment decisions in a micro-allocation context.

237. Dieter Hart, *Ärztliche Leitlinien - Definitionen, Funktionen, rechtliche Bewertungen [Clinical Practice Guidelines - Definitions, Functions, Legal Implications],* 1 MEDR 8, 1998.

i. National Coverage Guidelines

SGB V, Art. 92, authorizes the Joint Federal Committee of Physician and Sickness Fund Associations to adopt the national coverage guidelines which become binding under the SGB V, once approved by the Federal Minister of Health and published in the Federal Register.[238] Two major coverage guidelines predate the SGB V of 1988: the so-called "Children's Guideline"[239] of 1976 and the "Maternity Care Guideline"[240] of 1985, which is so detailed that it is also considered a clinical practice guideline, both amended in 1998. After the adoption of the SGB V, several coverage guidelines were added because of the recognition that the cost-effectiveness mandate of Art. 12 may conflict with clinical decisions and the prevailing standard of care stipulated by Arts. 2 and 72: "Care must be adequate, appropriate, correspond to generally accepted practices, and be in keeping with the progress of medical science."[241] Therefore, guidelines have also been interpreted as practical implementations of the "cost-effectiveness

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238. *Bundesanzeiger.*

239. *Richtlinien des Bundesausschusses der Ärzte und Krankenkassen über die Früherkennung von Krankheiten bei Kindern bis zur Vollendung des 6. Lebensjahres ("Kinderrichtlinien").* Bundesanzeiger Nr. 159, Aug. 27, 1998 [*Guidelines of the Joint Federal Committee of Physicians and Sickness Funds for the Screening of Childhood Disorders Until Age Six*] Fed. Register No. 159. *See* SGB V at Art. 26.

240. *Richtlinien des Bundesausschusses der Ärzte und Krankenkassen über die ärztliche Betreuung während der Schwangerschaft und nach der Entbinding ("Mutterschaftsrichtlinie").* Bundesanzeiger Nr. 136, July 25, 1998 [*Guidelines of the Joint Federal Committee of Physicians and Sickness Funds for Maternity Care*] Fed. Register No. 136. Incorporated into the SGB V as RVO, Art. 196.

241. KARL HAUCK, SGB V: GESETZLICHE KRANKENVERSICHERUNG, KOMMENTAR [SGB V ANNOTATED] (Sept. 1999) [hereinafter HAUCK]. (This loose-leaf edition is continuously updated.) "Adequate" procedures are defined as corresponding to a minimum standard, and "appropriate" procedures must be adequately effective for their diagnostic or therapeutic purpose. Wolfgang Kemmnitz, *Empirische Untersuchungen medizinischer Normsetzungsprozesse durch ärztliche Leitlinien in medizinischen Instituten [Empirical Evaluation of Normative Procedures Based on Medical Guidelines Developed by Medical Institutions],* at 5 (e-mail edition). In ÄRZTLICHE LEITLINIEN: EMPIRIE UND RECHT PROFESSIONELLER NORMSETZUNG [MEDICAL GUIDELINES: EMPIRICAL AND LEGAL FOUNDATIONS FOR SETTING PROFESSIONAL NORMS] (Dieter Hart, ed., Nomos-Verlag, Baden-Baden, 2000) [hereinafter MEDICAL GUIDELINES].

mandate."[242] The main more recent coverage guidelines address the following benefit categories:[243]

1. Disability determination.[244]
2. Screening for early diagnosis[245] of:
   a. cancer of the reproductive system (beginning at age 20)
   b. skin and breast cancer (age 30)
   c. colorectal cancer (age 30).
3. Prescription Medication.[246]
4. Medical Supplies and Equipment; Adjunct Therapies.[247]
5. Innovative Procedures.[248]
6. Psychotherapy.[249]
7. Fertility treatment.[250]

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242. *See* PLAGEMANN, *supra* note 213. Cost-effectiveness, among other things, also implies limiting therapy to what is necessary in a particular case when two different treatments are available. Kemmnitz, *id.*

243. *See* HAUCK, *supra* note 241.

244. *Arbeitsunfähigkeitsrichtlinie.* BABl. Nr. 11, Oct. 31, 1991 (Federal Labor Law Code No. 11).

245. *Gesundheitsuntersuchungsrichtlinie.* BABl. 1989/10 S. 44, Aug. 24, 1989 (Federal Labor Law Code 1989/10 p. 44). *See* SGB V at Art. 25.

246. *Arzneimittelrichtlinie.* Bundesanzeiger Nr. 246, Dec. 31, 1993; amended Bundesanzeiger Nr. 182, Sept. 29, 1998 (Fed. Register No. 246, 182). *See* SGB V at Art. 84 (global budget for pharmaceuticals), and Art. 35 (reference prices for prescription drugs).

247. *Hilfs- und Heilmittel-Richtlinien.* Bundesanzeiger Nr. 183b, June 17, 199; amended Feb. 19, 1998 (Fed. Register No. 183b). *See* SGB V at Arts. 32-34.

248. *Richtlinie des Bundesausschusses der Ärzte und Krankenkassen über die Einführung neuer Untersuchungs- und Behandlungsmethoden [Coverage Guideline for Innovative Diagnostic and Treatment Procedures Issued by The Joint Federal Committee of Physicians and Sickness Funds].* Bundesanzeiger Nr. 2/91, Jan. 31, 1991 (Fed. Register No. 2/91). *See* SGB V at Art. 135. HAUCK, *supra* note 241, at C-450, p.1

249. *Psychotherapie-Richtlinie.* Oct. 23, 1998, in HAUCK, C 470, *supra* note 241. *See also* SGB V at Art. 95(10-13). The psychotherapy coverage guideline is unusual in that it introduces psychotherapy as a covered benefit (psychologists fought for years to be recognized as providers), both enumerating covered schools of psychotherapy, and stipulating the professional qualifications of providers. From an American perspective, it combines the coverage limitations of health care plans and some elements of licensing laws.

250. *Richtlinien über künstliche Befruchtung.* Bundesarbeitsblatt Nr. 12, Nov. 30, 1990; amended Bundesanzeiger Nr. 243, Jan.1, 1998 (Fed. Register No. 243). *See* SGB V at Art. 27(a).

Coverage guidelines are "norms addressing acts or omissions, issued by a rule-making body as mandated by the SGB V, and violations are sanctioned."[251] Sanctions can range from administrative notice to suspension. Some guidelines specifically permit adjustments when justified by individual circumstances, and sickness funds may make more liberal reimbursement decisions. But the guidelines for fertility treatment, screening for childhood disorders, and covered schools of psychotherapy have the force of law, potentially creating conflicts between physicians' constitutional right to freely practice their profession, and their civil (contract and tort) and social law duties under the SGB V.[252] Furthermore, the Constitution protects individuals' right to health care, and the Supreme Social Court has ruled that coverage guidelines may not hinder the provision of "adequate and appropriate medical care" by the treating physician.[253] Hence, the medical indication must receive priority and the physician may, whenever required by a patient's individual circumstances, ignore the coverage guidelines,[254] which, according to the Supreme Social Court, may also not impinge on the patient's constitutional right of self-determination.[255] Since guidelines can not include all potentially acceptable exceptions, physicians, having provided additional treatment in individual cases, may be required to justify their clinical decisions. Understandably, physicians—and scholars—contest the above inconsistencies which so far have been addressed only on a case-by-case basis, and which are amplified by the ongoing health care reform efforts.

Developing the National Coverage Guidelines. All coverage guidelines must conform to the "generally accepted standard of clinical practice and be in keeping with the progress of medical science."[256]

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251. *See* Hart, *supra* note 237, at 11.

252. Civil courts, in case of malpractice claims, hear experts to determine whether the standard of care was violated. Providing care according to a social law coverage guideline does not immunize from tort liability. Courts should, however, first determine whether a physician was practicing privately or within the statutory health care system, and if a coverage guideline applied. Thomas Clemens, *personal communication by fax* (Nov. 17, 1999).

253. *See id.* BSG 6 Rka 27/87, May 5, 1988.

254. Rainer Pitschas, *Beziehungen zwischen Leistungserbringern und Krankenkassen [The Relationship Between Providers and Sickness Funds] in* JAHRBUCH DES SOZIALRECHTS DER GEGENWART, BD. 17 [17 ANNUAL SOCIAL LAW REVIEW] 267 (Georg Wannagat, Wolfgang Gitter, eds., 1995).

255. *See* BSG 14a Rka, *supra* note 165.

256. *See* HAUCK, K§92 at 3, *supra* note 241. *See* SGB V at Art. 2. According to the SGB V Annotated, only the field of medicine itself "is qualified to define, evaluate and assure the provision of care, not agencies or the courts." *Id.* K§2, at 21. *See also* BSGE rulings 73, 271,

"Generally accepted clinical practice" comprises quantitative, qualitative, and practical aspects.[257] Quantitatively, it is defined as representing the opinion of a clear majority of practitioners.[258] Qualitatively, the opinion of few but renowned experts may actually outweigh the quantitative element such as the recommendation of a prestigious research institute. On a practical level, a procedure is generally accepted when it has become the subject of a clinical practice guideline (CPG). But coverage guidelines are independent of CPGs because they address the "what" not the "how" of treatment. Ideally, both should be in agreement, and the SGB V has established a working group for quality control and harmonization of guidelines, representing all national associations of physicians, sickness funds and hospitals.[259]

The "progress of medical science" criterion recognizes empirical evidence,[260] expert consensus, and clinical acceptance based on "experience or intuition."[261] For "innovative procedures" coverage evaluations under SGB V, Art. 135,[262] the process outlined in Art. 92 relies on scientific

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288; 81, 64, 72 (pointing out that medicine is an empirical science). In addition, Art. 5(3) of the Constitution guarantees the freedom of science and State neutrality in scientific matters. The State, however, does exert "subtle" normative control, for example, through the SGB V sections regulating the practice of physicians within the statutory system of health care. Ruling of the Supreme Constitutional Court (BVerfG E 11, 30, 40). *Vertragsarztrecht.*

257. *See* HAUCK, *supra* note 241, K§2 at 23.

258. Ruling of the Supreme Administrative Court (BverwG ZBR, 1996).

259. *See* SGB V at Art. 137. Harmonization so far has been difficult because of disagreement between the different groups whether clinical practice guidelines should include economic considerations. The participating national physician and sickness fund associations recently approved their integration into the CPGs. But whether quality-related research should be subject to economic considerations is questioned, for example, by numerous medical societies arguing that this would limit a priori the scope of the investigation of the quality of future medical care. *See also* Hart, *supra* note 237, at 12, fn. 32.

260. The SGB V Annotated cites the customary three phases of clinical trials.

261. *See* HAUCK, *supra* note 241, K§2 at 24.

262. *See* SGB V at Art. 135, extends Art. 92 to coverage determinations for "innovative diagnostic and treatment procedures" not yet listed in the national (outpatient) fee schedule, and procedures whose indications have changed. The term "innovative" implies that quality has not yet been shown or is only assumed based on the sickness fund physicians' practices. Wolfgang Dreher, Thomas Clemens, *Zur Leistungspflicht der Krankenkassen für alternative Heilmethoden (hier: Akupunktur bei Neurodermitis) [Sickness Funds' Obligation of Coverage of Alternative Treatments (Here: Acupunture for Neurodermitis)].* 5 MEDR 230 (1998).

evidence indicating effectiveness. Acceptable evidence levels are: (I) at least one randomized, controlled clinical study, (IIa) evidence derived from other prospective clinical studies, (IIb) well-designed cohort or case-controlled studies, preferably involving several groups, (IIc) time-series comparisons with or without clinical intervention, and (III) expert opinions derived from clinical experience reports by committees of experts and consensus-conferences.[263] For reevaluations of already covered procedures under Art. 135,[264] the Joint Federal Committee accepts the clinical practice guideline standard since, as the SGB V Annotated points out, according to U.S. surveys, only 4% of all treatments have been proven to be effective subject to rigorous experimental protocols. Furthermore, the WHO estimates that only 20% of all common procedures have actually been evaluated.[265]

Subjects under consideration by the Joint Federal Committee are published, and comments by any interested party are invited.[266] The Committee can establish working groups which submit recommendations to the plenary. Since not all members of such groups must have professional familiarity with each procedure to be evaluated, they may consult experts, studies and published literature. The working groups must then hear representatives of professional associations and expert opinions. In the case of prescription drug coverage guidelines, only medical and pharmacology experts, pharmacists, experts on drugs for specific treatment approaches, and representatives of pharmaceutical manufacturers may be heard.[267] New coverage guidelines are adopted by a simple majority vote in the plenary. Deliberations are not public. Contrary to the Art. 92 process, Art. 135 does not provide for hearings or the participation of interested parties, only for the consultation of experts. This has been met with criticism because the decisions of the Federal Committee under this article, potentially leading to

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263. *See* HAUCK, *supra* note 241. SGB V, Art. 135. Examples of recently covered innovative methods include LDL-elimination through hemotherapy, methadone substitution, treatment of sleep apnea, and bladder calculus lithotripsy. Coverage was denied for transurethral prostate laser treatment, bioresonance diagnosis and therapy, autologous target cytokine treatment according to Klehr, hyperbaric and oxygen therapy.

264. In addition, the SGB V revision of 1997 authorized the Committee to reevaluate already covered, customary procedures. *2. Neuordnungsgesetz NOG.* BGBl. S. 1520; Bonn, 30. Juni 1997 (Health Care Code Revision Act II, GERMAN CODE 1520). SGB V, Art. 135.

265. *See* HAUCK, *supra* note 241, K§2 at 25.

266. This section is largely based on Kemmnitz, *supra note* 241. Contributions are distributed to all Committee members. How to handle the sheer volume of comments and how to factor them into the decision making process has not yet been resolved.

267. *See id.*

coverage exclusions, have a much greater impact on providers and patients than the coverage guidelines under Art. 92 which rarely exclude benefits.[268]

Some authors have questioned this standard-setting procedure and the democratic legitimacy of the Joint Federal Committee itself. First, the Committee must rely on outside expert testimony when deciding on a new guideline since it is not composed of experts representing all medical specialties.[269] Second, the statutory health care system is self-governed by democratically elected corporate entities under public law. The members (physicians, sickness funds and insured individuals), however, only elect the local and/or regional assemblies, which in turn elect the members of the national assemblies, which then elect the members of the Joint Federal Committee. At this point, democratic legitimacy may be present only in a "homeopathic dosage."[270]

Depending on the type of guideline issued by the Committee, the constitutional, or "legitimacy," implications may differ. Guidelines for internal administrative purposes may be constitutional, coverage guidelines, however, touching upon the constitutionally mandated "protection of the citizen's life and health by the state." For as long as coverage guidelines do not at least correspond to regulations (one normative level above the decisions taken by the Joint Federal Committee which is not an agency), certain treatment decisions may best be left to the informed patient.[271] Even more problematic may be the constitutionality of the innovative diagnostic and treatment procedures guidelines. The SGB V outlines general approval methods but delegates the development of coverage guidelines to the Joint Federal Committee. Its decisions are normative in nature but may conflict with Art. 80(1) of the Constitution which grants only federal ministers, the federal and state governments the power to adopt rules and regulations whose "content, purpose and scope" have already been determined by statute, here, by SGB V, Arts. 92 and 135. The approval of innovative procedures

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268. Karl Jung, *Leitlinien aus der Sicht des Bundesausschusses der Ärzte und Krankenkassen—Rechtspolitische und rechtspraktische Probleme [Clinical Practice Guidelines Viewed by the Joint Federal Committee of Physicians and Sickness Funds—Problems of Law, Application and Policy] in* MEDICAL GUIDELINES, *supra* note 241.

269. *See* PLAGEMANN, *supra* note 213.

270. Thomas Clemens, *"Verfassungsrechtliche Anforderungen an untergesetzliche Rechtsnormen [The Constitutionality of Rulemaking by Non-Legislative Bodies]"*, 9 MEDR 432 (1996), at 436.

271. *See id. See also* BSG 14a Rka, *supra* note 165.

by a corporate entity under public law would, therefore, be unconstitutional.[272]

Two rulings of the Supreme Social Court, however, have confirmed the constitutionality of the delegation of rulemaking power below the regulatory level to the Federal Committee by SGB V, Art. 92.[273] These decisions clarified that innovative procedure guidelines and other coverage guidelines issued by the Joint Federal Committee are not just internal administrative SGB V implementing rules for physicians and sickness funds, which would conflict with the separation of powers since coverage guidelines are binding for the sickness funds and have an external effect[274] on their members but would have been issued by an administrative body without such external rule-making power. They are integral elements of the normative contracts ensuring health care delivery concluded between the physician and sickness fund associations on state and federal levels, and, thus, are legally binding for both physicians and sickness funds while impacting on patients. This was confirmed by the BSG in 1998, specifically rejecting arguments in the literature questioning the democratic legitimacy of the Joint Federal Committee rule-making power.[275] The final arbiter, however, is the Federal Constitutional Court which has not yet had the opportunity to address the issue.[276]

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272. *See* Clemens, *supra* note 270.

273. BSG 1 RK 32/95, Sept. 16, 1997 (clarifying the approval procedure for innovative procedures). Dreher, Clemens, *supra* note 262, at 234. BSG 6 Rka 62/94, March 20, 1996 (adoption of methadone substitution as a covered benefit, "The Methadone Ruling").

274. *Außenwirkung.*

275. BSG Az B6 KA 37/97 (March 18, 1998). *In* Martina Boni, *Verfassungsmäßigkeit der Zulassung zur vertragsärztlichen Versorgung [The Constitutionality of Limiting The Licensing of Sickness Fund Physicians]*, 5 MEDR 232 (1999). Guidelines are norms issued by the Committee as a corporate entity under public law granted rulemaking authority by its charter. (German material law comprises the Constitution, statutes, executive regulations, and, on the lowest level, charters conferring rulemaking power to corporate entities under public law. Municipalities and counties, for example, as components of the political system of self-governance, are corporate entities exercising such power.) Delegation to the Committee is proper under the SGB V and does not conflict with the Constitution, Arts. 20 (establishing the Federal Republic as a democratic system of government based on the rule of law), 80 (executive agencies may promulgate regulations when authorized by law), 2 (protecting the right to self-determination, self-development, physical inviolability) and 12 (the right to freely choose and exercise a profession). HAUCK, *supra* note 241, K§2, at 43.

276. Since the SGB V is subject to social court jurisdiction, the Supreme Social Court is in essence concerned with the "democratic legitimacy" of the legislative delegation of

So far, judicial review is unavailable to patients, providers, sickness funds and their associations.[277] In particular, courts are prevented by precedent to examine coverage guidelines according to medical and scientific criteria.[278] Only once a guideline has led to controversy such as a benefit denial or a fine imposed on a physician having exceeded the prescription drug budget—a violation of a coverage guideline—may an individual sue before the appropriate court. Third parties, however, such as pharmaceutical or medical supplies manufacturers may file actions with the social courts challenging decisions of the Joint Federal Committee to promulgate new coverage guidelines or expand existing ones.

ii. Clinical Practice Guidelines[279]

Currently, more than 600 clinical practice guidelines have been published, defined as "systematically developed statements to serve as the foundation for joint decision making by practitioners and patients about health care to be provided for specific clinical circumstances."[280] They result from systematic institutional determinations of best methods and practices, intended to protect the patient and to ensure the quality of diagnosis and treatment. Whenever considered reflective of the standard of care, they may, however, impinge on independent clinical judgment[281] calling for an individualized approach.[282]

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rulemaking power to the Joint Federal Committee. Whether such delegation is in fact constitutional would have to be decided by the Supreme Constitutional Court.

277. The Social Court Statute (*Sozialgerichtsgesetz, SGG)* does not provide for judicial review as confirmed by rulings of the Supreme Social Court (*Bundessozialgericht, BSG,* E 72, 15, Jan. 13, 1993), and a State Supreme Social Court (*Landessozialgericht, LSG,* Berlin, Dec. 5, 1996; MEDR 381 (1997)).

278. *See* BSGE 81,73 (Sept. 16, 1997).

279. This section also draws on Kemmnitz, *supra* note 241.

280. Ferdinand M. Gerlach, Matthias Berndt, Martin Beyer, *Professionelle Normsetzung durch Implementation medizinischer Leitlinien [Setting Professional Norms by Implementing Clinical Practice Guidelines] in* MEDICAL GUIDELINES, *supra* note 243. The above definition corresponds to the guideline definition of the Institute of Medicine (IOM) and the former Agency for Health Care Policy and Research (AHCPR), now called Agency for Healthcare Research and Quality (AHRQ).

281. This may conflict with physicians' constitutional right to freely exercise their profession.

282. *See* Jung, *supra* note 270.

CPGs are issued by several organizations, foremost among them is the Association of Scientific Medical Societies in Germany (AWMF).[283] Its 121 members represent medical specialties from allergology to cytology ("Zytologie") and have produced over five hundred clinical practice guidelines. Examples are seventy CPGs for pediatric surgery, sixty-six for oto-rhino-laryngology, and fifty-five for diagnostic radiology. Many more are currently under development. CPGs provide a range ("corridor") of diagnostic and treatment options for the attending physician to choose from in individual cases and are often used by courts as the reasonable professional standard. The AWMF also issues "Quality Recommendations,"[284] more detailed as to indication, diagnostic equipment specifications, ranges for diagnostic parameters to be evaluated, treatment protocols, side effects, documentation, and the specialist's required qualifications. Both CPGs and Quality Recommendations are available on-line. The AWMF quality efforts center on the structure, process and outcome of medical procedures, and individual member societies conduct their own research programs with the goal of improving care.

According to the AWMF, economic considerations should not enter into the development of guidelines, exclusively intended to serve medicine and science.[285] Economics do play a part, however, since developing a new product, drug or technology, and collecting adequate evidence for approval require major investments. Furthermore, practitioners do not always receive information on innovations from neutral sources, such as scientific conventions or journals, but also from companies who finance some of this research, such as pharmaceutical manufacturers, for example, and from micro-allocate health care funds when deciding whether the use of available procedures in individual cases is "medically necessary." The sickness funds therefore advocate economic aspects as an appropriate element of guideline development which would also contribute to meeting the cost-effectiveness mandate of the SGB V.[286]

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283. *Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften (AWMF).* AWMF on-line: <www.uni-duesseldorf.de/WWW/AWMF >(Aug. 1999).

284. *Empfehlungen zur Qualitätssicherung; Qualitätsleitlinien.* One author noted the "inflation" in the usage of the term "guidelines" *(Leitlinien, Richtlinien).*

285. Member societies do not accept funding from outside sources.

286. *See* Christoph Straub, *Ziele, Normsetzungsprozesse und Implementation von Leitlinien in der Medizin: Leitlinien aus der Sicht der Krankenkassen [Goals, Normative Procedures and Implementation of Clinical Practice Guidelines: The Sickness Funds' Point of View] in* MEDICAL GUIDELINES, *supra* note 241.

The Joint Federal Committee of Physicians and Sickness Funds has established a Medical Clearinghouse for Quality Control[287] which has issued a "Guideline for Guidelines",[288] and evaluates guidelines under agreement with the federal physician and sickness fund associations and the German Hospital Society.[289] The Clearinghouse has also proposed a multi-stage procedure for guideline development and a "checklist" to determine their methodological quality. Its work is based on the review of international literature, the available results of evidence-based medicine (EBM), and the participation of experts in the respective working groups. All results are published. The AWMF does not cooperate with the Clearinghouse and rejects its efforts to evaluate the quality of all CPGs.[290] Some steps to resolve the conflicts, however, have already been taken. Both organizations consider EBM a major factor when no agreement can be reached on a particular guideline because of a respectable minority opinion ("two schools"). How to weight EBM, however, has not been decided by either organization, and the AWMF leaves this determination to its individual member societies. Both entities advocate consultation with outside experts and patient participation.

iii. Conclusion

Coverage guidelines and CPGs are intended to influence clinical decision-making, eliminate the use of unnecessary and outdated procedures, and contain costs. Coverage guidelines must also reflect current and generally accepted medical practice to meet the social law standard of care for both sickness funds and physicians. Guideline validity is of great relevance because of their norm-setting quality and the delegation issues involved. There is, however, no current uniform methodological approach to their development which should be transparent and public, based on

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287. *Ärztliche Zentralstelle für Qualitätssicherung (ÄZQ).*

288. *Beurteilungskriterien für Leitlinien in der medizinischen Versorgung [Evaluation Criteria for Clinical Practice Guidelines], Beschlüsse der Vorstände von Bundesärztekammer und Kassenärztlicher Bundesvereinigung, [Board Decisions of the Federal Association of Physicians and the Federal Association of Sickness Funds]* (June 1997), 33 DEUTSCHES ÄRZTEBLATT A-2154, 1997.

289. *Deutsche Krankenhausgesellschaft.* This is a voluntary organization of hospitals. German hospitals are owned privately, publicly (municipalities, counties, universities) and by charitable organizations, all subject to the same laws and standards.

290. *Qualitätssicherung [Quality Control].* AWMF, *supra* note 283.

adequate scientific evidence (content), and reflect scientific minority and patient opinions through representation in the issuing entities (process).[291]

For coverage guideline development, the Federal Committee depends on outside expert opinion which could be provided through cooperation between the Clearinghouse and the Association of Medical Societies. If the AWMF CPGs became coverage guidelines, their normative value and influence on the daily practice of medicine would be enhanced. The Federal Committee, in turn, would benefit from increased scientific evidence supporting its decisions. Its mandate under SGB V, Art. 135, also includes updating benefits according to changing standard of care, and such a collaborative approach would improve the quality of care while controlling costs.[292]

3. Civil Law: Contract and Tort Law[293]

For centuries, illness was considered God-given punishment and fate, and complaints about malpractice were unthinkable.[294] In more modern times, physicians were considered "demi-gods in white," whose authority and actions were not questioned. Even in the 1950's, malpractice lawsuits were extremely rare. Medical negligence law, therefore, is a recent development and attorneys have been specializing in it for no more than twenty years. Today, however, as patients are becoming "informed consumers" of health care, as medical technology and the division of labor have impersonalized the practice of medicine, as more Germans have obtained insurance coverage for court and attorneys' fees[295], and as the media—and legal journals—are regularly reporting on malpractice litigation and court rulings, the number of lawsuits is on the rise.

Under German civil law, medical malpractice liability is subject to the same contract and tort norms as other categories of liability. Claims may be

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291. Rainer Pitschas, *Empirie und Recht professioneller Normsetzung: Perspektiven der Transformation medizinischer Normsetzung in rechtliche Verbindlichkeit [Empirical and Legal Aspects of Establishing Professional Norms: Translating Medical Guidelines Into Legal Norms] in* MEDICAL GUIDELINES, *supra* note 241.

292. *See* Jung, *supra* note 270.

293. *Arzthaftungsrecht/Deliktrecht.*

294. This section is based on Alexander P.F. Ehlers, *Einleitung (Introduction) in* PRAXIS DES ARZTHAFTUNGSRECHTS [THE APPLICATION OF MEDICAL MALPRACTICE LAWS] 1, (Alexander P.F. Ehlers, Maximilian G. Broglie, eds., Verlagsgruppe Jehle-Rehm, Munich, 1994) [hereinafter Ehlers, Broglie].

295. *Rechtsschutzversicherungen.*

filed in parallel but injury, standard of care, causation and damages will be adjudicated in almost identical fashion. Damages for pain and suffering are available for tort claims only, and differing statutes of limitation apply. Medical negligence law is mainly case law, and the highest court is the Supreme Court for Civil and Criminal Law.[296]

a. Contract Law

The relationship between patients (privately or publicly insured) and physicians is considered a service contract and regulated by the Civil Code,[297] which requires customary care in the provision of services[298] and allows compensatory damages to be awarded for injuries.[299] Patients are entitled to proper history-taking, diagnosis and treatment by specialists.[300] Physicians are liable in case of positive violations of the contract for the provision of medical services (violation of duty owed and personal injury). Causes of action are identical to those arising under tort law (malpractice).[301] The contract to treat is concluded between the (adult) patient or parent of a child and the physician, and may be inferred from the parties' conduct. Physicians are liable for damages in case of malpractice, but do not owe the duty of a successful outcome. Physicians (and hospitals) only owe reasonable care as even the best practitioners do not control the human body in such a way that

296. *Bundesgerichtshof (BGH)*, Karlsruhe.

297. BGB §§611-620 (service contracts), BÜRGERLICHES GESETZBUCH [CIVIL CODE] (Beck Verlag, München, 44th edition, 1999) [hereinafter BGB]. It was first adopted in 1896 and become law on Jan. 1, 1900.

298. *See id.* §276 (liability in case of negligence).

299. *See id.* §249 (compensatory damages), §823 (liability for damages in case of intentional or negligent personal injury, damage to health, freedom, property, or the violation of any other legally protected right). German law does not recognize punitive damages.

300. Both §223 of the Criminal Code and BGB §823 protect the patient's physical inviolability. Criminal actions can be filed for negligent personal injury and involuntary manslaughter but such lawsuits are rare because the standard of proof is difficult to meet. Absence of informed consent and violations of confidentiality (§203) are also matters of criminal law.

301. WOLFGANG FRAHM, WOLFGANG NIXDORF, ARZTHAFTUNGSRECHT [MEDICAL MALPRACTICE LAW] 3 (Verlag Versicherungswirtschaft e.V., Karlsruhe, 1996). The authors support all of their statements with an extensive listing of the relevant court rulings and citations from the literature.

an unsuccessful outcome would already indicate malpractice.[302] Since the contract concerns the provision of medical care, it is mainly intended to protect the patient's physical integrity, and liability is limited to personal injury, excluding property. Courts, however, have awarded parents damages for the care of an injured child.

Some authors have addressed the inconsistency between the liability arising from the civil law service contract between physicians and patients and the origin of their relationship in social law.[303] According to the SGB V, sickness funds must ensure the adequate provision of medical care so that, it is argued, malpractice liability would rest with the insurers, incurring "official liability"[304] as quasi-governmental bodies, and not their provider-agents.[305] The current prevailing interpretation, however, relies on SGB V, Art. 76(4), requiring the general negligence standard of customary care under the Civil Code as of the moment the physician has agreed to provide services for a patient.[306]

Contracts between patients and hospitals originate at the time of hospitalization after referral by a physician or in an emergency. These contracts are "comprehensive,"[307] requiring the hospital to render all medical and non-medical services as needed for adequate and appropriate care as a function of the patient's syndrome, its severity, and hospital facilities and staffing. The hospital as enterprise is liable for all services including those provided by its agents.[308]

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302. BGH VersR 428 (1980).

303. Reimund Schmidt-De Caluwe, *Das Behandlungsverhältnis zwischen Vertragsarzt und sozialversichertem Patienten [The Legal Relationship Between the Plan Physician and the Socially Insured Patient]*, 4 VIERTELJAHRESSCHRIFT FÜR SOZIALRECHT 207, 224 (1998). *See also* Thomas Clemens, *Abrechnungsstreitigkeiten, Wirtschaftlichkeitsprüfung, Schadensgregreß [Claims Processing Disputes, Cost-Effectiveness Audits, Sanctions] in* HANDBUCH DES SOZIALVERSICHERUNGSRECHTS, BAND 1, KRANKENVERSICHERUNGSRECHT [HANDBOOK OF SOCIAL INSURANCE LAW, VOL. 1, HEALTH INSURANCE LAW] 894, 971 (Bertram Schulin, ed., Verlag C.H. Beck, Munich, 1994).

304. *Amtshaftung.* Individuals or entities under public law can be held liable for civil law damages.

305. *See* BGB § 278 (vicarious liability for agent); § 839 (liability when exercising a public function).

306. *See* Ehlers, Broglie, *supra* note 296, at 174. SGB V, Art. 76(4). This article also guarantees patient choice of provider. *See also* Schmidt-De Caluwe, *supra* note 305, at 207.

307. *"Totaler" Krankenhausvertrag.*

308. *See* Ehlers, Broglie, *supra* note 296, at 18. BGB §278.

b. Tort Law[309]

Because of the rising number of medical malpractice lawsuits, standard of care determinations have gained considerable importance. The tort standard of care for acts and omissions is objectively determined by generally accepted preventive, diagnostic and therapeutic practices, and the state of medical knowledge at the time of treatment. It is national and uniform, without allowances for personal factors such as temporary incapacitation of the provider at the time of treatment or lack of experience (beginner) and up-to-date expertise (physician close to retirement).[310] For diagnosis, physicians must personally examine patients and make home visits when required. They may not rely alone on information provided by either patients or their relatives, and diagnosis by phone is prohibited.[311] Physicians are free to choose a particular course of therapy, and deviations from the standard are permissible whenever needed in a patient's particular circumstances. In case of alternative prevailing treatments, practitioners must opt for the safer approach. "The civil law standard must justify the trust claimed by medicine as an institution."[312]

Standards of care and liability, however, should not invariably correspond to what is technically doable, but must reflect social law cost-effectiveness requirements,[313] and patients cannot expect optimal care and equipment under all circumstances.[314] The Supreme Civil and Criminal Court has ruled that hospitals are entitled to some standard of care variance depending on location and size. "Above an essential minimum level reflecting prevailing standards, a standard below that of a university medical

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309. Standard of care and causation requirements are identical under both contract and tort law. BGH NJW 767 (1989). Tort damages, contrary to contract damages, may be awarded not only to the injured party but to third parties incurring loss of financial support or services due to personal injury or death caused by malpractice. BGB §§ 844, 845.

310. Heinrich Hanika, *Patientencharta [A Charter of Patients' Rights]*, 4 MEDR 159 (1999). Also quoting: BGH, Apr. 24, 1988 (*Bundesgerichtshof*, ruling of the Supreme Civil and Criminal Court), NJW 2298, 2300 (1988).

311. *See* Ehlers, Broglie, *supra* note 296, at 180. *See also* BGH NJW 1248 (1979).

312. *See* Erich Steffen, WOLF-DIETER DRESSLER, ARZTHAFTUNGSRECHT [MEDICAL MALPRACTICE LAW] 50 (RWS Verlag, Kommunikationsforum GmbH, Cologne, 1999) [hereinafter STEFFEN].

313. For further discussion, *see infra* II.B.4.a.

314. *See* STEFFEN, *supra* note 312.

center is acceptable for rural hospitals."[315] Courts differentiate between routine conditions that may be treated without the risk of malpractice liability at less than optimally staffed and equipped hospitals and cases requiring more sophisticated technology and expertise that must be referred to specialized clinics.[316] Patients must accept "rationing" of services if hospital capacity does not allow the use of special diagnostic procedures for all those who apply or necessitates waiting periods.[317] However, clinics equipped with above-average medical technology must employ it whenever indicated.

The Evidentiary Role of Clinical Practice Guidelines. Clinical practice guidelines, when adopted, should represent the current standard based on scientific knowledge, practical experience, and professional acceptance.[318] Deviations from the standard of care constitute malpractice, deviations from a guideline do not automatically imply negligence unless the guideline represents the standard.[319] In cases of outdated and not yet officially updated guidelines, physicians are expected to have acquired current knowledge through continuing education and awareness of official publications recommending the reevaluation of CPGs. Guidelines may serve as the basis for establishing proof in malpractice cases, and judges may apply them to expert testimony. Testifying experts may rely on CPGs for the evaluation of treatment in individual cases but also as indication of the generally applicable standard of care. But standards of care, be they structural (national coverage guidelines) or clinical (practice guidelines), do not absolve practitioners from exercising clinical judgment, even though guidelines may be "legal criteria for what is prohibited and what is permissible." No liability results if the physician has acted as a prudent professional.

Some authors caution that CPGs should not become the gold standard for courts since randomized controlled clinical studies are not and can not be available for every recommended treatment approach. CPGs should also not

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315. *See* BGH VI ZR 201/87 (March 8, 1988) and BGH VI ZR 200/88 (May 30, 1989). *See also* STEFFEN, *supra* note 312, at 51. This corresponds to the American "locality rule."

316. PIA RUMLER-DETZEL, *Budgetierung–Rationalisierung–Rationierung*, 13 VERSICHERUNGSRECHT 564 (1998).

317. *See id.* at 548. BGH VersR 88, 155 (a hospital may limit amniocentesis to women whose age correlates with an increased probability of fetal Down syndrome). OLG Cologne, 27 U 13/91, VersR 93, 52 (the waiting period did not constitute malpractice since surgery was advisable but not urgent). BGH cert. denied (March 10, 1992). Waiting periods in Germany are extremely rare, and patients may choose their hospital.

318. Dieter Hart, *Ärztliche Leitlinien und Haftungsrecht [Clinical Practice Guidelines and Malpractice Liability] in* MEDICAL GUIDELINES, *supra* note 241.

319. *See* Hart, *supra* note 237, at 12.

serve the standardization of diagnosis and therapy, thus becoming instruments of forensic judgment. They are neither laws nor regulations and not legally binding.[320] Furthermore, the standard of care may develop independently of guidelines and their methodological requirements.[321] Guidelines provide quality criteria but appropriate care also depends on patient preferences and clinical judgment as treatment must be responsive to a patient's individual circumstances and cannot be standardized.[322] The law, scientifically accepted practices, individual circumstances, and the informed patient's preferences must be evaluated in combination by the courts or testifying experts. In addition, clinical practice guidelines do not and should not, by their existence, introduce strict liability.[323] They do, however, result in a covert reversal of the burden of proof whenever cited by a plaintiff, forcing the attending physician to justify that a potential deviation did not violate the prevailing standard of care.[324]

Economic considerations, if intertwined with the quality aspects of a CPG, complicate the situation even further. Unless both are kept separate and made transparent, as laid down in the "Guidelines for Guidelines,"[325] a CPG may not be used to determine liability. "Evaluating the connection between quality and politically motivated legislation, between standard of care and costs, between the level of professional prudence required and financial feasibility, is reserved for liability jurisprudence."[326] The social and civil law standards defining patients' claims to coverage should not diverge whenever physicians' choices are limited by the social law cost-effectiveness mandate and its enforcement mechanisms (budgets, cost-effectiveness

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320. *See* Albrecht Wienke, *Leitlinien als Mittel der Qualitätssicherung in der medizinischen Versorgung [The Quality Assurance Role of Guidelines in the Provision of Medical Care]*, 4 MEDR 172 (1998).

321. OLG Cologne, 27 U 169/89, May 5, 1990 (in spite of the absence of a CPG, adequate published evidence indicated that acyclovir therapy of herpetic encephalitis was a generally accepted practice and the delayed administration of the drug violated the standard of care).

322. *See* Gerlach et al., *supra* note 282.

323. Some physicians, however, already perceive the courts moving in this direction. Klaus Schnetzer, *personal communication by e-mail* (Nov. 8, 1999).

324. Robert Francke, *Leitlinien ärztlichen Handelns und Sozialrecht [Clinical Practice Guidelines and Social Law] in* MEDICAL GUIDELINES 173, *supra* note 241.

325. ÄRZTLICHE ZENTRALSTELLE FÜR QUALITATSSICHERUNG [CHECKLIST], (Jan. 1998).

326. *See* Hart, *supra* note 237, at 14.

reviews, and penalties).[327] Political decisions to ration, leading to deviations from the medically determined standard of care and applicable to the entire health care system, should bind liability determinations,[328] and social law should preempt civil law.[329] However, the coverage guidelines of the SGB V do not do so because civil law, granting an individual's right to damages, does not recognize the cost-effectiveness mandate of social law. Hence, malpractice standards should not be applied in a vacuum, and physicians should not be held liable for system deficits.

c. Conclusion

The statutory system of health care must allow for rational coverage decisions in order to maximize the use of available resources. The SGB V coverage guidelines are increasingly amended to serve this purpose. Clinical practice guidelines specify treatment options and protocols, and help to determine the "generally accepted medical standard of care in keeping with the progress of medical science" as stipulated by SGB V, Art. 2. Whether they actually correspond to this standard must be evaluated in each individual case.[330] In the future, CPGs may be linked in some yet undetermined fashion with the SGB V through the coordinating activities of the different public and private bodies involved in their elaboration.[331] Clinical practice guidelines requiring constant updating may eventually serve as guideposts in the face of increasing efforts to contain health care expenditures and to achieve a more cost-effective use of scarce resources in an era of rapidly changing medical technology and patient expectations. "Keeping in mind the first Hippocratic aphorism "ars longa, vita brevis": standards for care may not become immutable ars longa as medicine is always concerned with vita brevis.[332]

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327. *See* STEFFEN, *supra* note 312, at 50.

328. *See id.*

329. *See* Dieter Hart, *Ärztliche Leitlinien und Haftungsrecht (Clinical Practice Guidelines and Malpractice Liability) in* MEDICAL GUIDELINES, *supra* note 241.

330. *See* Francke, *supra* note 324.

331. *See id.* at 173.

332. *See* Eberhard Buchborn, *Ärztlicher Standard: Begriff, Entwicklung, Anwendung [The Medical Standard of Care: Definition, Development, Application]*, 9 MEDR 328, 332 (1993).

4. The Allocation of Health Care Funds Through SGB V Reforms

a. The Cost-Effectiveness Mandate

i. History

The cost-effectiveness mandate of the SGB V, Art. 12, reminds physicians of the traditional micro-allocation function of their clinical decision-making and provides the normative foundation for the retrospective economic utilization review of German providers.[333] Cost containment, however, is not a new concept in the history of the German health care system. In 1887, four years after the prepaid social health insurance system was introduced by law, a contract between one of the sickness funds and four physicians (an early form of a "provider network" since the contract was intended to give patients a choice of physicians so far unavailable due to the requirement that patients see their "district physician") was published containing the clause: "The physician, while striving for a successful treatment outcome, accepts the obligation to prescribe economically, especially limiting the prescription of champagne and other expensive wines to the lowest acceptable minimum."[334]

In 1924, the National Joint Committee of Physician and Sickness Fund Associations issued a "guideline" requiring the refusal of unnecessary treatment, followed by a drug prescription "guideline" in 1925. In case of excessive care, physicians were held financially liable.[335] A clause in the RVO of 1930 already stipulated physicians' obligation towards the sickness fund to provide "adequate and appropriate care." The term "cost-effectiveness," however, was only mentioned in connection with medication and adjunct treatments. Sanctions were triggered by above-average expenditures of individual sickness funds which then could terminate physician contracts. A "cost-effectiveness mandate" for all aspects of care was first adopted in 1955. As of 1968, fee-for-service compensation became increasingly common and was later considered one of the elements

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333. *See* SGB V at Art. 12 (*see* section II.B.2.a. *supra* for the definition of cost-effectiveness). *See also* SGB V at Art. 103 (Cost-effectiveness review for physicians, conducted by both physician and sickness fund associations). *See also* SGB V at Art. 116 (Cost-effectiveness review for hospitals, conducted by the sickness fund associations).

334. ERIK GOETZE, ARZTHAFTUNGSRECHT UND KASSENARZTLICHES WIRTSCHAFTLICHKEITSGEBOT [MALPRACTICE LIABILITY AND THE COST-EFFECTIVENESS MANDATE FOR PHYSICIANS] 94 (Springer Verlag, Berlin, 1989).

335. *See id.* at 96.

contributing to escalating health care expenditures.[336] As a consequence, additional forms of physician compensation, such as fee-capping and capitation for certain procedures, were reintroduced in 1977. Furthermore, the rising number of physicians was rapidly inflating the number of claims filed, requiring regional limitations for new practices by specialty. Physician associations were held to ensure the economical use of medical technology. In 1988, the venerable RVO was replaced by the SGB V mandating "cost-effectiveness" in its current form.

ii. Definition[337]

The cost-effectiveness concept is not limited to social law but is a general principle of budget policy on all levels of government—federal, state and local. It also applies to public education,[338] all social insurance and welfare programs (unemployment, social security, welfare, etc.), and is an expression of the fiduciary function of the State. It is defined as achieving the best possible result with the means available or as producing a predetermined result at the lowest cost possible. Cost-effectiveness has the dual function of protecting the community as well as the individual member's interests. It establishes individual entitlement to care, but imposes certain constraints.[339]

Accordingly, SGB V, Art. 12, requires the "adequate, appropriate and cost-effective" delivery of "necessary" health care benefits. These terms are considered to be general only, requiring interpretation in individual cases. "Appropriate" as the central concept of cost-effectiveness applies a qualitative aspect to Arts. 1 and 27, together stipulating the provision of all care required for the preservation, restoration, or improvement of members' health. Whether treatment is "appropriate" is judged by its conformity with the "generally accepted standard of medical care in accordance with the progress of medical science"[340] and "good medical practice."[341] "Appropriateness" precludes care which is unnecessary, counter-productive, or even detrimental, and establishes a member's claim to the benefits needed

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336. *See id.* at 105.

337. This section is based on GABRIELE NEUGEBAUER, DAS WIRTSCHAFTLICHKEITSGEBOT IN DER GESETZLICHEN KRANKENVERSICHERUNG [THE COST-EFFECTIVENESS MANDATE AND THE STATUTORY SYSTEM OF HEALTH CARE] (Erich Schmidt Verlag, Berlin, 1996).

338. Almost all institutions of learning in Germany are public, including universities.

339. *See* HAUCK, *supra* note 241, K§12, at 4.

340. *See* SGB V at Art. 2(1).

341. *See id.* at Art. 28(1).

under specific circumstances to produce a successful outcome. Whether care is appropriate is to be determined only *ex ante*, to require otherwise would imply the physician's ability to predict the exact course of an illness. "Adequate" care depends on each individual case and denotes the quantitative aspect of appropriate care. It signifies the minimum standard for benefits considered "necessary" whenever required for adequate care. Physicians must decide if the desired treatment outcome could be achieved without a particular procedure. The term "necessary" sets an upper limit by precluding excessive procedures. "Adequate and appropriate care" guarantees the quality of treatment for members, while the term "necessary care" protects the sickness funds and the community of all insured individuals.[342]

"Cost-effectiveness" thus introduces economic considerations into the choice of treatment. The cost of care (to the sickness fund) must be weighed against its diagnostic and therapeutic benefits (for the patient). SGB V, Art. 1, however, stipulates the primary purpose of the statutory health care system: the preservation, restoration, or improvement of health. In case of a single existing procedure, cost is irrelevant (a life-saving transplant, for example).[343] Whenever several treatments are available, the most promising one must be provided. Cost-effectiveness only enters into the equation in case of several equally effective, but more or less costly, customary options. The least costly procedure should then be chosen.

SGB V, Art. 106, for the first time mandated the retrospective economic review of physicians' practices to be conducted by joint sickness fund-physician committees.[344] Taking regional particularities into consideration, the mean expenditures for medical services per patient by individual practice are calculated and compared with other same-specialty practices.[345] It is assumed that all physicians treat in a cost-effective manner and that overruns are indicative of violations. If the deviation from the mean

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342. *See* NEUGEBAUER, *supra* note 337, at 68.

343. *See* HAUCK, *supra* note 241, K§12, at 7.

344. *Wirtschaftlichkeitsprüfung.* Currently 75% of all health care expenditures are occasioned by physicians either through out-patient care, referrals to hospitals, and prescriptions of drugs, adjunct treatments and durable medical equipment. It has been suggested that this should not exceed 70%. Franz Knieps, Herbert Reichelt, *Globalbudget und Arzt-Netzwerk [The Global Budget and Physician Networks]*, 3 SOZIALE SICHERHEIT 96 (1999).

345. Mean values are applied to medical care (*Durchschnittswerte.* SGB V, Art. 106), while the total prescription drug expenditures per practice are capped separately (*Richtgrößen. Id.* at Art. 84).

cannot be justified, a certain percentage is deducted from sickness fund reimbursements. In addition, the law provides for random quarterly audits of approximately 2% of all practices which can take place either as statistical reviews or case-specific evaluations. The actual number of reviews leading to sanctions is quite low and sickness funds provide few statistics.[346] Enforcement of sanctions has been fairly lax, and the government has amnestied groups of providers more than once.

iii. Impact on the Standard of Care

As discussed above, care must be adequate and appropriate (social law) while also subject to customary (criminal, contract and tort) standards. The Supreme Social Court has confirmed the priority of clinical judgment over cost-effectiveness considerations.[347] It has also clarified that sanctions for violations of the cost-effectiveness mandate are inappropriate whenever clinical judgment is in accordance with criminal and civil law standards of care. In actual practice, collisions between the cost-effectiveness mandate and liability standards seldom occur. First, cost-effectiveness (or micro-allocation) decisions have traditionally been part of medical practice. Second, liability determinations or individual case audits permit the case-specific "balancing" of cost-benefit considerations even in cases of injury due to the omission of special diagnostic or treatment procedures or measures of "defensive medicine," performed to lower the risk of malpractice actions, provided they are medically indicated.[348]

However, numerous physicians object to the economic (social law) utilization reviews out of concern that they may increasingly be forced to lower the standard of care, thus raising their risk of committing (civil law) malpractice. Furthermore, physicians are penalized financially if they exceed the mean expenditure coefficients for their specialty, but which do not factor in quality of treatment and outcome sustainability. This could be accomplished only through a case-based analysis, considered too resource-intensive in comparison with the potential gains (reduction of reimbursement to physician).

So far, the social law economic utilization norms are limited to excessive care, neglecting the added expenses incurred in cases of insufficient diagnostic evaluations or treatment leading to injury requiring

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346. Timothy Stoltzfus Jost, *Health Care Rationing in the Courts: A Comparative Study.* 21 HASTINGS INT'L & COMP. L. REV. 639, 674 (1998).

347. *See* Clemens, *supra* note 303. *See also* BSGE 62, 24, 26 (June 2, 1987).

348. *See* Clemens, *supra* note 303, at 916.

more expensive care and, potentially, to sanctions whenever the civil and criminal law standards of care have been violated. "In this respect, the term cost-effectiveness in social law is one-eyed: it is unrelated to general economic cost-effectiveness. It has become a singular concept resistant to abstract definition and can be understood only within the SGB V framework."[349] Current interpretations, however, carefully attempt to transcend the limited construction of the SGB V by including the "type, duration, and sustainability of the successful outcome."[350] This indicates that a cost-benefit analysis is not to be merely economic but should also comprise qualitative medical considerations, touching upon the difficult quantification of quality of care which may require some, yet undefined, standardization.[351]

b. National Budgets and Caps

Budgets have become a "paradigm of health care reform policy."[352] The SGB V, as adopted in 1988, codified the voluntary spending targets already in place at that time, some of them negotiated by physicians and sickness funds. From 1993 to 1995, however, non-negotiable mandatory sector budgets were introduced for physicians, dentists, hospitals, and prescription drugs, intended as a temporary emergency measure to contain the continued rise in health care expenditures since voluntary targets had failed. As of January 1, 1996, the national fee scale for physicians based on relative value units (RVUs)[353] was revised, also to provide structural incentives for a shift towards primary care.[354] The sickness funds capped the global amount of fees to be paid to their providers, but the fee scale continued to allow mostly fee-for-service billing, resulting in increased numbers of procedures performed by physicians and hence a significantly lower RVU value. This in turn induced additional physicians to inflate their services in an attempt to preserve their shrinking income and to accelerate

349. *See id.* at 918.

350. *See* HAUCK, *supra* note 241, K§12, at 8. *See also* BSGE 52, 79, 74 and 134, 138.

351. *See* HAUCK, *supra* note 241, K§12, at 8.

352. Josef Düllings, *Die Budgetierung des Krankenhaussektors [Budgets for Hospitals], in* VON DER BUDGETIERUNG ZUR STRUKTURREFORM IM GESUNDHEITSWESEN [FROM BUDGETS TO STRUCTURAL REFORMS OF THE HEALTH CARE SYSTEM] 191 (Josef Düllings, ed., R. v. Decker's Verlag, Heidelberg, 1996).

353. *Punktwerte.* This scale was first introduced in 1978.

354. Patients can refer themselves to specialists.

the downward spiral of the RVU.[355] In order to prevent it from spinning out of control, the National Evaluation Committee, representing physicians and sickness funds,[356] resorted to "partial budgets" for certain benefit groups such as lab work, outpatient surgery, and preventive measures. Their purpose was to remove these rapidly expanding services from the overall provider compensation budgets to eliminate their deleterious effect on the RVU. In some of these groups, however, the RVU decreased even more rapidly, seriously threatening physicians' incomes.[357]

On July 1, 1997, "practice budgets" were introduced, designed as an incentive for cost-effective care while stabilizing both physician income and the RVU without compromising the quality of care. A maximum number of RVUs per office was calculated by the National Evaluation Committee, based on practice-specific factors such as different operating costs by specialty and number of patients per office in 1994 and 1995. Only 71% of procedures considered standard by specialty were covered by practice budgets so that physicians could still receive compensation by workload while able to micro-allocate their resources according to clinical judgment. Additional allowances were made for claims for procedures performed due to physicians' special qualifications, above-average requirements for seriously ill patients, regional needs and laboratory usage. No caps applied to 13% of all services, including the use of high-tech equipment (such as CT-scanners).[358] Whenever physicians exceeded their individual budgets, additional care was reimbursed at progressively lower rates.[359] The absolute number of RVUs per budget was subject to judicial review, and the Evaluation Committee, in case of a complaint, was required to justify the

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355. *Der Hamsterradeffekt [Treadmill Effect]*. Manfred Partsch, *Neuorientierung in der ärztlichen Vergütung [Physician Compensation - New Directions]*, 13 DIE ORTSKRANKENKASSE 421 (July 1997).

356. *Bewertungsausschuß*. This committee also developed and keeps amending the national fee scale.

357. Rainer Hess, *Angemessenheit der Vergütung und angemessenes Arzthonorar - aus der Sicht der ärztlichen Selbstverwaltung [Appropriate Compensation and Appropriate Physicians' Fees - The Position of the Physician Associations]*, 5 VIERTELJAHRESSCHRIFT FÜR SOZIALRECHT 367 (1995).

358. Birgit Schauenburg, *Die Einführung des Praxisbudgets in den EBM [The Introduction of Practice Budgets as Component of the National Fee Scale]*, ZEITSCHRIFT DER BETRIEBLICHEN KRANKENKASSEN 193 (May 1997).

359. *See* SGB V at Art. 85(4).

correctness of its calculations.[360] Complaints concerning the fees for individual procedures, however, were subject to limited judicial review only.[361]

Hospital compensation was capped as well by substituting budgets based on prospective utilization rates for uniform daily rates per patient independent of diagnosis and calculated retrospectively to cover costs. Individual hospital budgets were (and are) negotiated by hospitals and sickness funds according to the number of cases per diagnostic category. If a hospital exceeds the budget by more than 15 percent, reimbursement is cut in half. Beginning in 1995, payments according to patient management categories, diagnosis-related fees and fees for excepted special procedures[362] were phased in. Rates are jointly determined by the hospital and sickness fund associations for each state.

Since controversy has been the hallmark of German health care reform, a natural side effect of a system evolving through negotiation and consensus-building, the introduction of practice budgets generated considerable disagreement. While the sickness funds welcomed them ("Practice budgets allow the effective limitation of procedures while preserving physicians' independent clinical judgment"[363]), primary care physicians staged protests in Berlin ("Practice budgets in their current form would end quality primary care and reduce it to the level of barefoot medicine"[364]). German physicians, unaccustomed to externally imposed constraints, fear that budgets will fundamentally alter the medical profession and thus destroy the traditional physician-patient relationship, resting on independent clinical decision making by the physician and patient autonomy, both protected by the

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360. *See* Thomas Clemens, *Ärztliche Berufsfreiheit aus juristischer Sicht [Implications of the Constitutional Right to the Independent Practice of Medicine] in* DIE ÄRZTLICHE BERUFSAUSÜBUNG IN DEN GRENZEN DER QUALITÄTSSICHERUNG [THE PRACTICE OF MEDICINE WITHIN THE LIMITS OF QUALITY ASSURANCE] 17, 42 (Wienke, Lippert, Eisenmenger, eds., Springer Verlag, 1998). BSG SozR 3-2500 §87, No. 16, at 66 (Jan. 29, 1997).

361. *See id. See also* BSG 79, 239, 242 (Nov. 13, 1996). *See also* LSG Baden-Württemberg (Sept. 4, 1997).

362. *Sonderentgelte.*

363. Bernd Metzinger, Andreas Woggon, *Praxisbudgets als Ausweg aus dem EBM-Dilemma beschlossen! [Practice Budgets Will Resolve the National Fee Scale Dilemma!],* DIE KRANKENVERSICHERUNG 12, 14 (Jan. 1997).

364. Reinhold Schlitt, *Einführung der Praxisbudgets: Es bleibt spannend [Introducing Practice Budgets: The Suspense Continues],* 20 DER KASSENARZT 16 (1997).

Constitution.[365] Budgets also create conflict between civil and criminal liability standards and social law which increasingly requires micro-level rationing of care while the standard of care patients are entitled to remains unchanged: according to the SGB V itself, it must be in keeping with prevailing practices and the progress of medical science. Physicians, exercising due care and obtaining informed consent, must choose the most promising treatment according to each patient's individual circumstances.[366] In addition, the Supreme Social Court, despite the recognition that cost-effectiveness reviews have become more threatening in an era of macro-level cost containment,[367] continues to give civil and criminal law standards priority over economic considerations, leaving physicians caught between financial restrictions and unchanged (or even rising) standards of care.

"Budgets shift benefit determinations to providers who must now pitch in for politicians by making political coverage decisions."[368] "We physicians are always focused on the individual patient, unable to send anyone home who arrives on the hospital doorstep. But the politicians lack the courage to take responsibility for their reforms and are unwilling to make rationing decisions. Instead, they leave us holding the bag."[369]

These two contributions to a panel discussion reflect the current thinking about cost containment: most physicians understand and accept the necessity for reducing benefits, but, used to near-complete freedom in clinical decision-making, call on politicians to take responsibility for the slippery slope of rationing[370] through more precise legislated ("political")

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365. *See* Laufs, *supra* note 15, at 2718.

366. *See id.* Another chapter, left for another time, could be entitled "The Rise of Patient Autonomy and Informed Consent." Both concepts were close to irrelevant until more stringent cost containment measures were enacted in Germany, creating numerous conflicts for physicians as discussed in this article. The more physicians felt that the responsibility for the consequences of cost containment was passed on to them, the more the patients were expected to share the responsibility. This was supported by court decisions strengthening informed consent requirements, due also, in all fairness, to increasing patient self-confidence and the rising number of malpractice actions.

367. *See* Clemens, *supra* note 303, at 917.

368. Christian Freund, Panel Discussion *in* DIE BUDGETIERUNG DES GESUNDHEITSWESENS-WO BLEIBT DER MEDIZINISCHE STANDARD? [HEALTH CARE BUDGETS-WHAT WILL HAPPEN TO THE MEDICAL STANDARD OF CARE] 81,82 (Thomas Ratajcak, Gabriela Schwarz-Schilling, eds., Springer-Verlag, Berlin, 1997) [hereinafter HEALTH CARE BUDGETS].

369. *See* H.F. Kienzle, *id.* at 83.

370. Dieter Schütz, *Ärzte verschenken Leistung – aber noch sind wir nicht in England [Physicians Give Away Care – But We Are Not in Great Britain Yet]*, 220 ÄRZTEZEITUNG

coverage determinations. Macro-level definitions of "medical necessity" correspond to "overt" rationing, excluding from coverage, for example, dialysis for older patients (as in Great Britain), drugs, adjunct therapies and durable medical equipment of undetermined effectiveness, or over-the-counter medication for minor ailments.[371] Budgets and caps on physician compensation, however, lead to "covert" rationing of services by introducing economic considerations into clinical decision making.[372] Legislators are therefore criticized as "ignoring the impact of budgets on the micro-level"[373] and leaving patients bereft of any means to determine whether the services rendered violate the social law standards of care. But in light of the historical background of the comprehensive German health care system and recent German history, engaging in a national debate on the ethics of rationing is a difficult step to take on the part of any politician. "Politicians currently avoid discussing our value system."[374] Capping health care expenditures through legislation is the easier way out.

On the occasion of the 1994 National Physicians' Convention, it was resolved that:

> "Faced with the conflict between the interest of the patient and that of the community, the physician must protect the patient's interest and act according to good medical practice. In order to provide optimal care, medical necessity decisions must be grounded in medical science, especially when the gap is widening between what is medically reasonable, humanly appropriate and technically doable."[375]

Unfortunately, the question whether the standard of care should include everything "medically doable" or be limited to what is "affordable" under the

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(Dec. 2, 1999).

371. *See* SGB V at Art. 34.

372. *See id.* Ingwer Ebsen, *Ressourcenknappheit im Gesundheitswesen [Scarce Health Care Resources], in* HEALTH CARE BUDGETS, *supra* note 370, at 112.

373. *See id.* at 113.

374. Lothar Weißbach, President of the German Cancer Society, *quoted in* Michael Emmrich *"Rationierte Medikamente für ausgewählte Kranke? [Rationed Drugs for Which Patients?],* FRANKFURTER RUNDSCHAU, Oct. 12, 1999.

375. Resolution adopted by the National Physicians' Convention, 24 DEUTSCHES ÄRZTEBLATT 1 (Supplement, May 1994).

budget remains unresolved.[376] But physicians and their associations, integral elements of the self-governed system of health care, wield considerable influence and will ensure that their voices continue to be heard.

c. Physician Compensation

SGB V, Art. 72, mandates "adequate physician compensation." In 1995, the BSG ruled that the legislative intent was not to guarantee the adequacy of individual physicians' incomes or individual fees but to ensure the delivery of health care to the public through the adequate overall payment of physicians' services.[377] The national and regional collective agreements, negotiated by the federal and regional physician and sickness fund associations—normative under public contract law—detail all services and their corresponding number of RVUs, based on the national fee scale.[378] The regional physician and sickness fund associations then determine the regional global amount available for physician compensation,[379] factoring in physicians' office operating costs, working hours, and the type and volume of services rendered. All agreements are renegotiated annually and the global payment is adjusted upward but limited to the revenue increases of the sickness funds (premiums in step with rising incomes). Statistics are compiled by the Federal Ministry of Health.

The sickness funds make regional global lump-sum payments for all providers combined to the regional physician associations which in turn

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376. The consequences of combining budgets and capitation were addressed in a recent malpractice action. Because of the capitated payment for routine cases, a urologist failed to conduct a PSA screening test for a patient whose prostate cancer had already metastasized by the time of detection. The court acquitted the physician and held that he could have recognized the condition at a much earlier stage but was not negligent by not doing so. Public criticism was leveled at the regional physician associations agreeing to payment arrangements which allow physicians to benefit financially from withholding benefits. *Die heimliche Rationierung bringt Ärzte in die Zwickmühle [Covert Rationing Puts Physicians in a Bind]*, 220 ÄRZTEZEITUNG, Dec. 2, 1999.

377. Eckart Fiedler, *Angemessenheit der Vergütung - angemessenes Arzthonorar aus der Sicht der Krankenkassen [Adequate Compensation - Adequate Physicians' Fees as Seen by the Sickness Funds]*, 5 VIERTELJAHRESSCHRIFT FÜR VERSICHERUNGSRECHT 355 (1995).

378. *Einheitlicher Bewertungsmaßstab (EBM)*. SGB V, Art. 87. The SGB V also provides for a temporary quarterly flat rate which would "pass on the entire actuarial risk to the physician." Needless to say, this approach has never been considered in practice. ROLF LIEBOLD, HANDLEXIKON FÜR DEN VERTRAGSARZT [POCKET ENCYLOPEDIA FOR THE PLAN PHYSICIAN] 103 (Asgard Verlag, Sankt Augustin, 1994).

379. *Gesamtvergütung*. *See* SGB V at Art. 85.

process the claims filed by their physician members. Allowing for regional particularities, the physician associations determine the combination of fee-for-service, capitation and diagnosis-related payments, and the total number of RVUs to be reimbursed for each medical specialty by office.[380] In 1972, the Supreme Constitutional Court confirmed the general constitutionality of this procedure because it "does not limit physicians' contractual right to compensation but is a distribution of the global funds allocated by law within the social insurance system benefitting the physicians."[381] But since the introduction of regional global payments, the distribution and fee setting methodologies have gained considerable importance, and more stringent controls may be advisable, as already envisaged by the Supreme Social Court in its recent rulings.[382]

Since overall budgets are set on a federal level and additional constraints imposed on a regional basis, physicians' incomes were unstable and even unpredictable when the RVU fluctuated according to the total number of claims filed (it has been returned to a fixed value). Since then, "adequate compensation" has become another subject of public debate. The State as organizer of the statutory health care system must ensure physician compensation commensurate to the value of the services rendered.[383] Physicians' statutory social law obligations are accompanied by their entitlement to adequate compensation, and to require the delivery of care at or below cost would also violate their constitutional right to adequate compensation for services rendered by statute.[384] Certainly, efforts to preserve the viability of the health care system legitimately aim to protect the community but physician payments may only be predetermined to serve

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380. *Honorarverteilungsmaßstab (HVM - unterschiedlicher Verteilungspunktwert nach Facharztgruppe).* The mean income by practice should be considered whenever capping compensation for individual specialties. Clemens, *supra* note 360, at 44.

381. BVerfG 33, 171 (May 10, 1972).

382. Thomas Clemens, *Die Regelungen der Honorarverteilung – Der Stand der Rechtsprechung des BSG [Determining Physician Payment – Current Supreme Social Court Authority],* 1 MEDR A 164 (2000). BSG Sept. 9 and Oct. 21, 1998; Jan. 1, and Aug. 25, 1999.

383. Josef Isensee, *Das Recht des Kassenarztes auf angemessene Vergütung [The Right of Sickness Fund Physicians to Adequate Payment],* 5 VIERTELJAHRESSCHRIFT FÜR SOZIALRECHT 352, 355 (1995).

384. Meinhard Heinze, *Die rechtlichen Rahmenbedingungen der ärztlichen Heilbehandlung [The Legal Framework of Physician-Provided Medical Care],* 6 MEDR 252, 255 (1996). GRUNDGESETZ [CONSTITUTION] Arts. 12 (Professional Independence), 14 (Protection of Property).

global principles without violating the constitution.[385] Hence, limiting physician compensation through budgets designed to preserve premium stability may be unconstitutional since office operating expenditures, working hours, and scope of care provided can no longer be adequately factored in as stipulated by the SGB V.[386] For example, physicians' global compensation growth rate in 1999 may not exceed that of sickness funds' revenues in 1998 over the 1997 baseline.[387]

In addition, physicians are considered self-employed, further strengthening their constitutional right to adequate payment without which the participation of self-employed individuals in the statutory system of health care would violate the Constitution.[388] But whether physicians are truly "self-employed" and properly treated as such by tax law is questioned by many since their professional activity is subject to numerous social law provisions. The issue remains hotly debated, yet unresolved. It is not just an academic subject since social law limits or prohibits practices such as balance billing for care covered by the national fee scale, delegation of procedures to qualified staff, delegation to another physician in case of long-term illness, patient selection, and cost accounting according to business management principles.[389]

Physicians object to the current compensation system which permits the sickness funds to meet their cost containment goals, but the system is said to force some groups of physicians to provide medical care below cost or, for some, to eliminate any type of physician "income."[390] But the BSG recently ruled that individual items of the national fee scale as negotiated by both physician and sickness fund associations are not subject to judicial review

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385. Isen*see*, *supra* note 356, at 352.

386. *See* SGB V at Art. 85.

387. Otto Ernst Krasney, *Das neue Gesetz zur Stärkung der Solidarität in der gesetzlichen Krankenversicherung [The New Law on Strengthening Solidarity within the Statutory Health Care System]*, 24 NJW 1745, 1750 (1999). *GKV-Solidaritätsstärkungsgesetz [Law on Strengthening Solidarity within the Statutory Health Care System)*, BGBl. I 1998, 3857, Dec. 19, 1998.

388. *See* Heinze, *supra* note 384, at 256.

389. *See* Clemens, *supra* note 303, at 918, 919.

390. Raimund Wimmer, *Rechtsschutz gegen Honorarbescheide muß in Deutschland verbessert werden [Legal Protection Against Sickness Fund Reimbursement Decisions Must be Strengthened]*, ÄRZTEZEITUNG, article name 124a1401 (July 6, 1999) (quoting Fritz Ossenbühl) (1998). Even though the practice of medicine today is subject to formerly unknown constraints, physicians are still among those in the highest income brackets.

since the schedule is considered a coherent rate system.[391] Furthermore, how the global payment is distributed among physicians by their regional associations is subject to no more than limited judicial review by the social courts, as the associations are entitled by law to a certain degree of rule-making discretion. It is argued, however, that the judiciary must safeguard the constitutional rights of all components of the statutory health care system which, as a whole, does not enjoy the protection of the Constitution. If the BSG agreed, this would mean full judicial review of all fee-setting mechanisms, and the norm-setting entities, in case of violations, would have to "redo their homework, only better this time."[392]

d. Prescription Drug Spending Controls

Prescription drug spending controls have been and continue to be another contentious issue of German health care reform. SGB V, Art. 35, introduced "reference prices"[393] for pharmaceuticals, capping the amount covered per prescription drug ("innovative" and recently patented drugs are excepted). SGB V, Art. 84, mandates annual global budgets[394] for drug expenditures. In case of budget overruns, the amount is deducted from the lump-sum compensation for all physicians by the sickness funds, making physicians collectively liable. In addition, claims filed for prescriptions by individual physicians are subject to retrospective cost-effectiveness (economic prescription utilization) reviews,[395] based on "standard prescribing

391. BSG Az B 6 KA 46/97 (January 20, 1999).

392. *See* Wimmer, *supra* note 390.

393. *Festbeträge.* These became law with the adoption of the SGB V in 1988 despite heavy lobbying by domestic and international pharmaceutical manufacturers.

394. The Federal Minister of Health may raise the budget any time should unusual circumstances unexpectedly increase demand for prescription medication.

395. In 1992 all sectors of health care, including pharmaceuticals, became subject to mandatory, non-negotiable budgets (intended as a three-year emergency measure). Savings through both reference prices and budgets were achieved due to fewer prescriptions for drugs with questionable therapeutic effects and a shift to generics. Current cost control provisions not only limit physicians' former discretion to prescribe any drug on the market, including OTC preparations, but exact contributions from pharmacies (contractual providers under the SGB V) and the pharmaceutical industry as well. Before regulation, pharmaceutical manufacturers supplying the German market had some of the highest profit margins in the world. In 1988, German per capita expenditures for prescription drugs exceeded those in the United States where health care spending per person is almost double that of Germany. GENERAL ACCOUNTING OFFICE, GERMAN HEALTH CARE REFORMS (GAO/HRD-93-103,

amounts"[396] by office and medical specialty, negotiated jointly by the regional sickness fund and physician associations. In the case of a 15 percent overrun, a practice will be reviewed individually. Whenever overruns exceed 25 percent, physicians are financially liable for excess expenditures unless justified due to practice-specific factors or circumstances. Statistical comparisons must be followed by an "intellectual" check before a decision may be rendered. Physicians' efforts to stay within the budget are complicated by the fact that sickness funds are no longer required by law to provide physician-specific prescribing data to the physician associations.[397] Once an individual physician's budget has been exhausted (commercial office software is allegedly available to correlate prescriptions and budgets), physicians' contractual obligations to provide services continue. There have been reports, however, that patients were inappropriately refused treatment or practices closed. More subtle methods to beat the budget are patient wait-listing, for example, or the pretense of practice overload. It has been suggested that medication for seriously ill patients should be excluded from the standard prescribing amounts in order to eliminate any disincentive to treat such patients.[398] Chronic pain specialists have demanded a waiver from budgets because newer, more effective—but costlier—pain medication and opioids had not been considered when the budgets were introduced.[399]

Global drug budgets and standard prescribing amounts have been in force concurrently for several years now, triggering protests by prescribing physicians who feel in double jeopardy. The new Social Democratic government continued this approach under the interim amendment to the SGB V,[400] adopted in December 1998, but limited total physician liability for budget overruns to 5 percent of the budget. Still, physician representatives protest that practitioners remain in double jeopardy for penalties, and that promises to eliminate the budget and to return the morbidity risk to the

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1993)).

396. *See Richtgrößen.* SGB V at Art. 84(3).

397. Sabine Glöser, *Kassenärzte zwischen Budget und Richtgrößen [Sickness Fund Physicians Stuck Between Budget and Standard Prescribing Amounts]*, 5 DEUTSCHES ARZTEBLATT C-191 (Feb. 1999).

398. Wolfgang Spellbrink, *Rechtsfolgen der Budgetüberschreitung nach §84 SGB V [Legal Consequences of Budget Violations under SGB V, Art. 84]*, 2 MEDR 65 (1997).

399. *Mediziner fordern mehr Geld für Schmerztherapie [Physicians Demand More Funds for Pain Control Medication]*, HERSFELDER ZEITUNG, Oct. 20, 1999.

400. *See* Krasney, *supra* note 387.

sickness funds have not been kept.[401] In 1998, some regional physician associations had already calculated a new standard prescribing amounts designed to replace the budgets. The reference price system was also preserved by the Social Democrats who added provisions requiring that an adequate variety of drugs for appropriate treatment be available, and that reference prices "should" not exceed a certain range, thus allowing exceptions in order to ensure sufficient supplies.[402]

As an added cost-saving measure, SGB V, Art. 92, calls for a new prescription drug coverage guideline to be issued by the Federal Committee of Physician and Sickness Fund Associations. Such a guideline was first promulgated in 1993 and last modified in September 1998. It reiterates patients' right to drug treatment according to the prevailing standard of care in keeping with the progress of medical science, but also incorporates cost-effectiveness (utilization) considerations. It lists general groups of (mostly over-the-counter) items not covered for minor ailments, groups to which indication-dependent coverage may apply (appetite suppressants, vitamins), and groups of medication to be prescribed only when alternative approaches alone have failed (diet, exercise) and need to be supplemented. This coverage guideline does not correspond to a drug formulary and preserves discretion for clinical judgment.

A recent, unique case illustrates the quandary resulting from spending controls for physicians, patients, and sickness funds.[403] A general practitioner, prescribing three drugs for a 90-year old women suffering from multiple conditions, was fined by her physician association and warned by the local social court that she would lose her license to practice as a sickness fund physician unless she discontinued the "inappropriate and wasteful" treatment, considering the patient's age and the redundant therapeutic effects of the drugs. According to expert testimony, the treatment was appropriate and corresponded to the standard of care. The expert noted that withholding the medication would increase suffering, and the physician added that she was unwilling to deny care to someone who had raised eight children, numerous grandchildren and great-grandchildren, merely because of age and diminished capacity to produce. The physician, pointing to the apparent lack of pharmacological expertise on the part of the physician association medical review committee, sued the committee for solicitation to commit battery and

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401. Wolfgang Brech (Board Member, Federal Association of Physicians), *Nachgefragt [Interview]*, 5 DEUTSCHES ARZTEBLATT C-191 (Feb. 1999).

402. *See* Krasney, *supra* note 387, at 1747. *See* SGB V at Art. 35(1),(5).

403. Klaus Schnetzer, *personal communication by e-mail* (Sept. 9, 1999). Lawsuit-related documents on file with the author.

murder, to violate the duty of care, and misrepresentation of scientific facts. The case is still pending and is a poignant illustration of the unresolved conflict between the increasing tendency of the social courts to implement social law cost containment measures and the tort standard of care.

e. The Coverage of Innovative Treatments

The recently amended SGB V, Art. 135,[404] authorizes the Federal Committee of Physician and Sickness Fund Associations, upon application by one of the federal or regional physician or sickness fund associations, to evaluate "innovative"[405] diagnostic and treatment procedures for coverage. Approval depends on diagnostic and therapeutic usefulness, medical necessity, and cost-effectiveness compared to traditional methods. "Usefulness" is defined as effectiveness for a particular indication, a positive cost/benefit analysis, and usefulness compared to other methods designed to achieve the same goal. "Medical necessity" denotes the relevance of the procedure for care, the epidemiology of the illness and its spontaneous course, and the availability of diagnostic and therapeutic alternatives. "Cost-effectiveness" covers the estimated expenditures per patient, the cost/benefit analysis per patient and for the community including follow-up costs, and the comparative cost/benefit analysis in relation to other methods. "Art. 135 thus becomes the "eye of the needle" for medical progress and an element of health care rationing."[406] Critics interpret recent BSG rulings[407] in support of this procedure as a "comprehensive denial of coverage of innovative procedures with the proviso of future approval," thus subjecting the progress

404. *Richtlinie über die Einführung neuer Untersuchungs- und Behandlungsmethoden (NUB-Richtlinie) [Coverage Guideline for Innovative Diagnostic and Treatment Procedures]* (amended Jan.1, 1998), *supra* note 250.

405. Procedures so closely related to already prevailing practices that they can not be considered to be innovative are excepted. Wolfgang Spoerr, *Medizinischer Fortschritt unter Verbot mit Erlaubnisvorbehalt? [Medical Progress Excluded from Coverage Unless Approved by Administrative Decision?]*, 24 NJW 1773 (1999). BSG 1 RK 14/96 at 6 (Sept. 16, 1997). Currently in the United States, the emphasis of cost containment efforts is on coverage exclusions and benefit denials. Even though cost containment is also a German goal, the SGBV continues to stipulate patient entitlement to care and protection as an integral element of all reform efforts.

406. *See id.* at 1773.

407. BSG 1 RK 28/95 (Sept. 16, 1997), BSG 1 RK 14/96 (Sept. 16, 1997).

of medicine to administrative decision making by the Federal Committee whose capacity to be the sole arbiter of medical progress is questioned.[408]

Claims for innovative procedures will be reimbursed by the sickness funds only if a corresponding guideline has been issued but a denial can be appealed based on "system failure." If it can be shown that the Federal Committee failed to rule on an innovative procedure, that a ruling was unduly delayed or questionable, the patient (and provider) may legitimately claim coverage. One of two conditions, however, must be met: (1) the procedure must have been proven effective, or (2) must be common practice. The assumption is that successful treatments will become integral elements of physician training and customary care. A customary procedure is covered even if not proven effective according to the empirical criteria of Art. 135. This appears circular since innovative procedures not covered will not become common practice[409]—90% of all patients and physicians participate in the statutory system—and whenever a procedure has been shown to be effective it is irrelevant whether it has also become prevailing practice.

The Art. 135 process, contradicting precedent, and current interpretation in the literature also touches on patients' yet unresolved entitlement to coverage under the SGB V in the light of rapid medical progress. Entitlements are phrased in general terms ("the right to the prevention, early diagnosis and treatment of illness") and given particular meaning by innovative procedure coverage guidelines which are subject to limited judicial review only.[410] The evaluation of innovative diagnostic and treatment procedures for coverage will remain controversial for as long as doubts concerning the legitimacy of the legislative delegation of rule-making powers to the Federal Committee, the constitutionality of its rulings, its decisional criteria and the gap between these criteria and those applied by the courts persist.[411]

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408. *See* Spoerr, *supra* note 405.

409. The same "Catch-22" concern is shared in the United States: "The refusal to reimburse at the outset will greatly slow the dispersion of new technology." Mark A. Hall, Gerard F. Anderson, *Health Insurers' Assessment of Medical Necessity.* 140 U.Pa.L. Rev. 1637, fn. 158 (1992), *quoted in* ROSENBLATT ET AL., *supra* note 17, at 269.

410. *See* Spoerr, *supra* note 405, at 1774.

411. *See id.*

5. The Health Care Debate: Legislative Reforms

The health care reform debate continued when the newly elected German government, a coalition of the Social Democratic Party and the Greens, was sworn in on October 27, 1998. Reform legislation had already been a campaign subject, and a major revision of the SGB V was announced immediately by the new government. Interim provisions became law on January 1, 1999, capping expenditures in all major sectors of the health care system, lowering co-payments for prescription drugs, eliminating some of the recent dental benefit exclusions, and expanding coverage for the chronically ill. The draft "Health Care Reform Bill of 2000"[412] of May 25, 1999, emphasized the current adequate funding of the health care system (operating funds and reserves of 7.5 billion Deutschmark) but considered the premiums of 13.6 percent and higher co-payments a burdensome legacy of the prior Christian Democratic government.[413] In addition to introducing global budgets in order to stabilize or lower the premiums, the bill was intended to further the integration of office-based and hospital care (strictly segregated for decades), strengthen the role of primary care physicians, expand quality management and preventive dental care, promote more economical drug prescribing practices while broadening access to effective medication, ensure adequate investments for hospital maintenance, improve health promotion, rehabilitation, self-help options and the evaluation of therapeutic and diagnostic procedures, expand patients' rights and protections, strengthen the system of self-governance, eliminate cherry-picking by private insurances (covering 10 percent of the population), and limit the number of practicing physicians, for example, through "golden handshakes" for those willing to close their offices in regions with disproportionately high numbers of practitioners.

a. The Global Budgets

One of the most far-reaching components of the reform bill was the proposed global budget for health care expenditures, defined as the sum of all individual "global budgets" made available for the sickness funds under

412. REFERENTENENTWURF EINES GESETZES ZUR REFORM DER GESETZLICHEN KRANKENVERSICHERUNG AB DEM JAHR 2000 (GKV-GESUNDHEITSREFORM 2000) [DRAFT BILL, REVISION OF THE STATUTORY HEALTH CARE LAW FOR 2000] (Bonn, May 25, 1999).

413. Chancellor Kohl's government of Christian Democrats and Free Democrats was reelected three times and held office for four consecutive four-year terms from 1982 until 1998.

SGB V, Art. 142. Each sickness fund thus disposed of an annual budget for all sectors of care combined, permitting the flexible allocation of funds according to need while controlling expenditures and preserving premium stability. Adjustments based on demographics were permissible, and budgets could be balanced through cuts in other areas if providers, for example, faced unforeseen events inflating expenditures. Sickness fund associations were to advise their sickness funds in case of budget overruns which were to be offset within two years. Global budget increases were linked to growth in member family income and thus sickness fund revenues (expected to rise by DM 1.3 billion in 1999 and DM 2 billion in 2000) based on statistics calculated by the Federal Ministry of Health.

As each and every amendment to the German consensus-based health care system is accompanied by a detailed and polemic public debate among all participating players (the federal government practicing more restraint than physicians and sickness funds), the global budgets were extensively dissected and analyzed. Physicians predicted dire consequences since optimizing outcomes with limited means would lower the standard of care, and called for quality assurance measures to prevent medical care from deteriorating into "barefoot medicine." Some observers warned that such measures would become meaningless if budgets were restricted to the point of rendering more complex procedures unaffordable.[414] One federal physician association official concluded that the main purpose of all budgets since the SGB V reform of 1993, instead of furthering the optimization of individualized treatment plans, had been to lower the standard of care, "an automatic occurrence as soon as the budget has been spent."[415]

Physicians also saw the Reform of 2000 intent on shifting the balance of power in favor of the sickness funds,[416] while the German Hospital Association perceived it as a threat to uniform nationwide access to hospital care.[417] The Association further predicted that the global budget, only allowed to rise proportionately to members' income, would bear no relation to the actual cost of needed care and would transfer the morbidity risk to the hospitals, inescapably leading to "rationing" of necessary care and the loss

414. Wilhelm Bulk, *Globalbudgets senken das Qualitätsniveau [Global Budget Lower the Quality of Care]*, 9 ZAHNÄRZTLICHE MITTEILUNGEN 26 (May 1999).

415. Sabine Glöser (quoting Lothar Krimmel (Vice President of the Federal Association of Physician Associations) in *Globalbudget weckt keine Zuversicht [Physicians Weary of Global Budget]*, 18 DEUTSCHES ÄRZTEBLATT C-834 (May 1999)).

416. *See* id.

417. *See* FRANKFURTER RUNDSCHAU, *supra* note 6.

of jobs.[418] Employers (who pay half of their employees' insurance premiums) questioned whether the reform would even attain one of its fundamental purposes—stable premiums. They proposed uprooting the system altogether by reducing universal coverage to a basic package for all and severely restricting employer contributions.

But all federal sickness fund associations welcomed the global budget and called for strict adherence despite concerns that the prohibition of member selection might unfairly skew the actuarial risks for some of the individual funds.[419] Since growing health care costs were seen as mainly "supply-induced"—physicians have more freedom to determine the quantity and quality of their services than any other service providers—, sickness funds supported the budgets as the singularly effective means of cost containment: a well-designed budget concept would ensure financial predictability while generating desirable pressure on all participants to implement indispensable structural reforms and stabilize premiums.[420] "What ails our health care system is not inadequate care but an excess of it."[421]

Eulogy. After the Reform 2000 passed the Lower House dominated by the Social Democratic majority on November 4, 1999, the bill was submitted for ratification to the Upper House on November 26.[422] It was defeated by the Christian Democratic majority, resulting from recent gains in state elections, which objected to the "rationing" of health care, the presumed effect of the global budget. The Minister of Health, assured of a Lower

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418. *See id.*

419. *See* Anton Engels, *Globalbudgets und Vertragsgestaltung [Global Budgets and Contracting with Providers]*, DIE KRANKENVERSICHERUNG 202 (July/Aug. 1999).

420. *See* Raimund Neuß, *Referentenentwurf zur Gesundheitsreform: Wer soll das bezahlen? [Health Care Reform Draft Bill: Who Can Afford It?]*, DIE KRANKENVERSICHERUNG 173 (June 1999).

421. *See* Christian Korbanka, *Weiterentwicklung der sozialen Krankenversicherung – Globalbudget: Chancen und Risiken [The Evolution of the Social Health Insurance – Opportunities and Risks of Global Budgets]*, DIE KRANKENVERSICHERUNG 166 (June 1999) (quoting Rolf Stubbard (Chairman of the Board of one Federal Association of Sickness Funds)).

422. *Bundesrat.* The Upper House members (representing states not constituencies, similar to the U.S. Senate) are not elected but appointed by the state legislature majorities. Only bills impacting on individual states must be ratified by the Bundesrat, including some components of the health care reform legislation.

House[423] majority after re-submission following conference proceedings, immediately amended the bill. She replaced the global budget with sector-specific budgets, and separate budgets for hospitals, physician compensation, and prescription drugs, and eliminated the physician associations' rights to object to sickness fund selective contracting with individual providers and to call for arbitration procedures. Both items would have required Upper House approval and would have led to another stalemate between both chambers.[424]

b. Drug Spending Controls

Physicians protested the prescription drug budgets, feeling forced to shoulder the burden for medical progress, demographic changes, increased morbidity, and coverage decisions on the part of the sickness funds.[425] Efforts to stay within the budgetary limits were compared to "flying without visibility" since the practice-specific prescription statistics compiled earlier by the sickness funds were no longer made available to the physician associations.[426] Physicians also predicted that the budget would be depleted in the five new states by October 1999.[427]

Furthermore, SGB V, Art. 92 was amended to include the establishment of a National Institute for Prescription Medicine, to be run by a commission. Commission members, all of them physicians or pharmacists (three experts on clinical practice, two on pharmacology and clinical pharmacology, one on clinical statistics, and one expert each on phytotherapy, homeopathy, and anthroposophy—three covered alternative specialties) were to draft a "reimbursable drug list"[428] of pharmaceuticals for the "appropriate, adequate and necessary treatment, prevention and diagnosis

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423. *Bundestag.*

424. *See* Marc Hujer, *Fischer schränkt Rechte der Ärzte weiter ein [Minister of Health Fischer Further Limits Physicians' Rights]*, SÜDDEUTSCHE ZEITUNG, Nov. 30, 1999, at 6.

425. *See* Glöser, *supra* note 415.

426. *See* Glöser, *supra* note 397, at C-191.

427. Health care expenditures in the former east Germany have consistently exceeded those in the west since unification in 1989, due to the lower quality of care under the now-defunct communist regime.

428. *Positivliste.* Before the passage of the SGB V in 1988, more than 60,000 preparations were available, many of them combining several active ingredients ("combination drugs"), often not all of them needed for a particular indication. Today, many of these drugs have been taken off the market. Medication excluded from coverage under SGB V, Art. 34, such as OTC preparations for minor ailments or of uncertain therapeutic value, would still be reimbursed if included on the Art. 92 list.

of illnesses." Inclusion criteria reflecting the state of scientific knowledge were to be adopted by the Federal Ministry of Health, and the list was to be continuously updated according to new scientific developments while excluding outdated drugs. Medical and pharmaceutical experts were to be consulted—that is, representatives of physician, pharmacist and sickness fund associations, of the pharmaceutical industry, and representatives of the different medical specialty societies (welcoming the appreciation of their independent scientific expertise and knowledge of the current state of medical practice[429]). The reimbursable drug list was hailed as a road map through the drug market thicket, identifying drugs with questionable effectiveness, and improving the quality of care when combined with the standard prescribing amounts and broader access by physicians to official sources of pharmaceutical information.[430] By specifying covered prescription medication, the list would also shift some of the responsibility for decision-making from physicians to legislators.[431] Whether it would actually contain expenditures was questioned by some as physicians might replace questionable drugs with more expensive effective medication.[432]

But until the SGB V amendments would become law, an interim solution was required. For 1999, a drug budget of DM 39 billion was appropriated, but considered insufficient by physicians who viewed the standard prescribing amounts as adequate for cost containment. The ensuing public debate typified the struggle over the proposed Health Care Reform of 2000. Physicians threatened to implement an "emergency program": patients would be "wait-listed" for prescriptions, receive generics or "out-of-pocket" prescriptions only. They also emphasized that the social law global budget, subjecting expenditures to "medical necessity" criteria, created a liability dilemma since patients would continue to be entitled to the tort standard of

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429. Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften, *Stellungnahme der außerordentlichen Delegiertenkonferenz der AWMF zur GKV-Gesundheitsreform 2000 [Communique of the Extraordinary Assembly of the Scientific Medical Societies Concerning the Health Care Reform Of 2000]* (AWMF online, Frankfurt, June 26, 1999). *Supra* note 283.

430. Rolf Rosenbrock, *Das Globalbudget – Chancen und Risiken für die Versorgungsqualität [The Global Budget – Opportunities and Risks for the Delivery of Health Care Quality]*, DIE KRANKENVERSICHERUNG 174 (June 1999).

431. *See* Glöser, *supra* note 397, at C-191 (quoting Wolfgang Brech, Member of the Board of the Federal Association of Physician Associations).

432. *See* Neuß, *supra* note 420.

care.[433] One day before the health care debate in the Federal Parliament, six thousand East German dentists and their assistants took to the streets in Berlin while one thousand physicians, pharmacists and physical therapists (all contractual providers under the SGB V) demonstrated in Wiesbaden.[434] Fundamental questions were at issue: how to avoid the inflation of services in a fee-for-service system while ensuring adequate provider compensation under a global budget, how to preserve the health care system built on solidarity in the face of government plans to strengthen competition among sickness funds,[435] and how to define "medical necessity" on a macro-level at times of budgetary constraints.

In order at least to resolve the drug budget problems, the Federal Association of Physicians entered into negotiations with the Federal Minister of Health and the Federal Sickness Fund Associations. After "tedious semantic fine-tuning," a joint action program was adopted outlining "recommendations" how to support physicians in their efforts to "prescribe economically" to prevent budget overruns and penalties. Major elements of the program were the shift to lower-priced generics,[436] the prohibition of OTC prescriptions for minor ailments (which had already been in effect but was widely ignored by physicians), and recommendations not to prescribe drugs with questionable effectiveness nor "new" products marginally different from already available pharmaceuticals.[437] Second opinions were

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433. Many physicians therefore chose to grant what their patients asked for. Heidrun Graupner, *Geteiltes Leid in der Gesundheitspolitik [Sharing the Suffering Inflicted by the Health Care Policy]*, SÜDDEUTSCHE ZEITUNG Aug. 18, 1999, at 4.

434. *Protest formiert sich [Protesting Health Care Reforms]*, HERSFELDER ZEITUNG, Sept. 9, 1999, at 2. American physicians, increasingly closing ranks, have also begun to resort to collective action. The Federation of Physicians and Dentists called for a boycott of Merck products which was followed by hundreds of physicians across the country and caused quite some corporate anxiety. Merck had opposed the bill pending in Congress granting physicians a waiver from antitrust provisions prohibiting them from collectively negotiating with managed care organizations. Robert Pear, *Doctors in Antitrust Fight Boycott Merck Products.* N.Y. TIMES, May 23, 2000, at A21.

435. *See* SGB V at Art. 1 (solidarity and individual responsibility). "Solidarity means the protection of those at high risk of illness. Any government wanting to preserve this principle must prohibit cherry-picking." Graupner, *supra* note 433.

436. Generics often are still called "imitation products" *(Nachahmerprodukte)*, a term harking back to the polemics by both physicians and pharmaceutical manufacturers in Germany fighting the approval of such products.

437. Numerous "me too" products are on the market whose active ingredients differ only slightly from already available drugs with almost identical therapeutic effects but command

recommended in case of unusually expensive treatments. The Federal Physician Association president praised the negotiations since the sickness funds had conceded publicly for the first time that coverage in a particular sector had to be limited. "We succeeded in getting our political opponents who have been threatening us with penalties into the same boat with us: everyone, including the Minister of Health, was forced to admit that benefits must be cut."[438] But it almost cost him his job since his colleagues from the regional physician associations condemned his willingness to "compromise" with the government and the sickness funds.[439] At one point, the Minister of Health refused to continue negotiations after the regional associations had threatened to reduce patient services in protest of the agreement concluded on the national level.[440] Their demands included exceptions to the drug budget for regions with a known increased demand for prescription drugs (such as in east Germany) and cross-subsidization among regions.[441] Even though the action plan eventually was approved, the reimbursable drug list, just as the global budget, did not survive the vote in the Upper House. Currently, work on a "negative list" is being completed, listing all preparations of questionable effectiveness. [442]

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much higher prices.

438. Marc Hujer, *Die Gesundheitsgesetze dürfen nicht exekutiert werden [Do Not Execute Our Health Care System]*. Interview with Winfried Schorre, Chairman of the National Physician Association, SÜDDEUTSCHE ZEITUNG, Sept. 16, 1999, at 27.

439. His deputy was fired from the Board because there was disagreement even within the Federal Association itself. Marc Hujer, *Konfuse Ärzte [Physicians Confused]*, SÜDDEUTSCHE ZEITUNG, Sept. 11/12, 1999, at 25. Since then, Mr. Schorre himself, the Federal Physician Association president, has resigned.

440. *Andrea Fischer bricht Dialog mit den Ärzten ab [Minister of Health Ends Dialogue with Physicians]*, SÜDDEUTSCHE ZEITUNG, Sept. 23, 1999, at 1.

441. *Medikamente notfalls auf Privatrezept [Nothing but Out-of-Pocket Prescriptions if Budget Inadequate]*, SÜDDEUTSCHE ZEITUNG, Sept. 22, 1999, at 23.

442. In spite of the success in controlling expenditures for office-based medical treatment and hospitals in 1999, costs for medication rose by 8 percent. *See* Andreas Hoffmann, *supra* note 9.

c. Quality Assessment

The revised SGB V[443] now holds all contractual providers responsible for the scientifically up-to-date quality of services, relying on yet-to-be-developed valid quality assessment criteria for "appropriate and cost-effective" diagnosis and treatment, including a macro-level definition of "medical necessity." Internal quality control measures are to be introduced, increasingly based on clinical practice guidelines, subject to guideline development approval procedures to be adopted by the federal associations of physicians, sickness funds and hospitals, and followed by normative Art. 92 guidelines for quality assessment.[444] The Federal Committee of Physician and Sickness Fund Associations, in consultation with independent experts, must prioritize guideline promulgation by focusing on "those groups of patients whose morbidity and mortality is expected to change through higher quality care." Quality management is extended to hospitals, covering the assessment of diagnostic and treatment methods, inpatient and outpatient preventive care, and rehabilitation.[445] A new "Working Group for the Promotion of Quality Control" will create a uniform approach to all sectors and professions of the health care system.[446]

Since such comprehensive assessment and quality control measures constitute uncharted territory, all parties concerned are called upon to cooperate and contribute their expertise to guideline development, a process expected to become increasingly evidence-based.[447] One example of such cooperation was the recent attempt at establishing a clearinghouse for cancer treatments to be staffed with experts from the German Cancer Society, the Cancer Foundation,[448] the medical societies, the Federal Ministry of Health, the sickness funds and their medical services divisions.[449] But the

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443. *See* SGB V at Art. 136.

444. *See* SGB V at Art. 136(a).

445. *See* SGB V at Art. 137(c), (d).

446. *See* SGB V at Art. 137(b).

447. *See* Jung, *supra* note 270.

448. *Die Deutsche Krebsgesellschaft. Die Krebshilfe.*

449. "Innovative" treatments for cancer, commonly excluded from coverage by U.S. managed care companies, continue to be reimbursed in Germany—but not in any consistent nor official fashion. Sickness funds, in the absence of national coverage guidelines, often deny autologous bone marrow transplants (ABMT) because of the low statistical probability of successful outcomes. On the other hand, high dose chemotherapy and immune therapies (such as interleukin) are reimbursed at hundreds of millions of Deutschmark every year while their effectiveness is considered equally inconclusive. Since the SGB V expressly permits

clearinghouse failed at the very last minute because one of the sickness funds balked and argued that such a body would only duplicate the efforts of the Federal Committee under Art. 92. The president of the German Cancer Society observed, however, that evaluating cancer treatments, a complex procedure, would overtax the limited capabilities of the Federal Committee. Attempts at resuming the negotiations are currently under way. Until a national quality assessment program is implemented, truly necessary treatments continue to be funded through the reallocation of funds within the global budgets. The difficult debate of how to define medical necessity on a macro-level and how to ration health care resources according to outcome probabilities has begun, but quietly.[450]

d. Sickness Funds: Selective Contracting and Provider Networks

"Whenever politicians are clueless how to resolve their self-made problems, they call on the system of self-governance."[451] Selective contracting with providers known to deliver cost-effective services ("economic credentialing") would shift the responsibility for cost containment to sickness funds and physicians. Sickness funds may also contract with integrated provider networks of primary care physicians and specialists,[452] considered to be more cost-effective than a system of individual practitioners only. While benefits would remain uniform according to law, selection by the sickness funds would most likely follow economic ("cost-effectiveness") criteria, inducing providers in turn to engage in patient "cherry-picking." Since only physicians with comparatively favorable practice morbidity structures might then form networks, cost savings would flow from the reduced actuarial risks, but not from any improvement in health care delivery.[453] One of the leading Social Democratic members of parliament has proposed that all providers should be

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experimental treatments in individual cases, the sickness fund medical services divisions, known for their generous decisions, often preauthorize such treatments on a case-by-case basis and have required sickness funds to reimburse "experimental" treatments in life-threatening situations. Numerous American courts have ordered insurers to pay for such treatments as well. *See* ROSENBLATT ET AL., *supra* note 17, at 275.

450. *See* Michael Emmrich, *Rationierte Medikamente für ausgewählte Kranke? [Rationed Drugs For Which Patients?]*, FRANKFURTER RUNDSCHAU, Oct. 12, 1999.

451. *See* Neuß, *supra* note 420.

452. *See* SGB V at Art. 140.

453. *See* Knieps, Reichelt, *supra* note 344, at 99.

permitted to form integrated delivery systems which could manage their own budgets and redistribute surpluses to both providers and patients.[454]

Once again, physicians and sickness funds are of a different mind. Physicians perceive a threat to the social law guarantee of a universal health care system and the solidarity it is based on. Selective contracting would also bypass their associations, strengthening the sickness fund influence and weakening the system of self-governance. The sickness funds, however, welcome the "competition for more innovative delivery systems."[455] To what extent there will be experimentation with new delivery systems and how they may impact on patients, physicians, and health care expenditures remains to be seen.

e. Discovering the Patients

"What about the patient?"[456] As the "myth of the white coat" has receded and passive patients have metamorphosed into informed consumers, challenging physicians' clinical judgment and requesting particular procedures or prescription drugs, this question is voiced more frequently. But as abundantly clear from the above health care reform debates, patients do not participate. They remain administered, cared for and paternalistically protected objects of the health care system while almost 50% have grown uncomfortable with the practice of "school medicine," resorting to alternative approaches.[457] Patients pay the piper without picking the tune.

But patient autonomy or "self-determination" is protected under the Constitution.[458] On May 8, 1998, the Social Democratic members of the German parliament submitted the issue of "patient autonomy and patient protection in case of malpractice" for debate.[459] Calling for a "patients' rights charter," the Social Democrats emphasized the heavily skewed relationship between physicians and patients, the lack of enforcement of

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454. Gudrun Schaich-Walch, spokesperson for health care of the Social Democratic Party, *quoted in* Korbanka, *supra* note 421.

455. *See* FRANKFURTER RUNDSCHAU, *supra* note 6.

456. Alexander Hoffmann, *Wo bleibt der Patient? [What about the Patient?]*, FRANKFURTER ALLGEMEINE ZEITUNG, Nov. 13, 1999, at B1.

457. *See id.*

458. *See* Constitution, *supra* note 179 Art. 2. "Each person is entitled to life and physical inviolability. Each person's freedom is inviolable."

459. *Große Anfrage der Fraktion der SPD vom 8.5. 1998 zum Thema Patientenselbstbestimmung und Patientenschutz bei fehlerhafter medizinischer Behandlung, BT-Drs. 13/10701, S. 1-16.* 8 MEDR 359 (1998).

informed consent, and the difficulty of the injured party to overcome the standards of proof and causation in medical negligence cases. In October 1999, one of the federal physician associations submitted such a charter to be publicly debated and ratified in 2000. In keeping with tradition, immediate protests arose: the Federal Minister of Health objected because her ministry had just met with the states and consumer protection associations to discuss strengthening patients' rights. In June of 1999, the state ministers of health had published a lengthy paper on patients' rights in Germany, declaring their intent to establish "independent patient counseling offices" on the state level, a proposal derided by physicians as devoid of any "medical credibility."[460]

The courts, mindful of the unequal patient-provider relationship, have already strengthened patients' rights, in particular, ruling on informed consent intended to off-set physician authority, and defined the permission to treat as valid only after the patient has been adequately informed. Informed consent, however, does not relieve physicians of the need to exercise responsible clinical judgment as they retain their "therapeutic privilege." The information imparted need not enable patients to make a medical decision, but is considered adequate when they are advised of the kind and degree of risk involved and can assess the impact on their individual circumstances.[461] Patients must be made aware of alternative procedures offering an equal likelihood of success but entailing different types of risks. They may also not be persuaded nor may the physician assume that the patient is aware of the risks.[462] Informed consent may not be obtained shortly before surgery after administration of a sedative.[463] Consent and medical indication combined form the basis for treatment of the patient as an individual who is the subject, not the object, of care.

To date, the Supreme Civil and Criminal Court has not ruled on informed consent in cases of coverage exclusions for socially insured patients when the procedure is available if paid for out-of-pocket.[464] This is currently

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460. *Ärzte legen "Charta der Patientenrechte vor" [Physicians Submit "Patients' Rights Charter"]*, HERSFELDER ZEITUNG, Oct. 10, 1999.

461. BGH VI ZR 178/93 (June 14, 1994). Since informed consent is subject to civil and criminal law, the jurisdiction lies with the Supreme Civil and Criminal Court.

462. BGH VI ZR 260/93 (June 14, 1994).

463. BGH VI ZR 42/97 (Jan. 17, 1998).

464. In the United States, it has been suggested that plan beneficiaries might want to have the choice to buy coverage for "experimental" treatments by paying a higher premium. *See* ROSENBLATT ET AL., *supra* note 17, at 276. In numerous managed care malpractice cases, courts have emphasized that the injured plaintiffs were never given the option of paying for

interpreted as implying the physicians' right, but not their obligation, to inform the patient.[465] One of the Court's Justices, however, recently urged physicians to disclose to patients all available alternatives.[466] Informed consent will assume even more relevance as physicians, subject to new cost containment requirements, feel ever more cornered between the need to micro-allocate services and the tort standard of care.

German courts have also been keenly aware of the steep hurdles faced by plaintiffs in malpractice suits (such as the "code of silence" and the difficulty of finding expert witnesses willing to testify), and have lowered the standards of proof for medical negligence and proximate cause to redress the patient-physician imbalance. Physicians must document all treatment details and keep files for ten years, which often makes medical records the most important source of evidence. Gross negligence by a physician reverses the burden of proof.[467] In case of reasonable certainty that an omitted diagnostic procedure would have indicated a condition requiring treatment, the standard of proof is lowered to restore the injured party to the position in which she would have been with proper diagnosis.[468] Causation standards are also reduced in cases of negligent omission of diagnostic procedures, especially if the mis-diagnosed condition was so serious that non-treatment would have been grossly negligent.[469]

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procedures or hospitalization denied by their MCO. *See* Bauman v. U.S. Healthcare, Kennedy Memorial Hospital, 1 F.Supp.2d 420, 1998 U.S. Dist. LEXIS 4110 (D. N.J. March 1998), *supra* note 99.

465. *See* STEFFEN, *supra* note 312, at 133-172, listing all relevant Supreme Civil and Criminal Court Rulings (BGH).

466. Hagedorn, *Behandlungsstandards und Behandlungsleitlinien zwischen Individualität und Wirtschaftlichkeit aus haftungsrechtlicher Sicht [Liability Implications of Treatment Standards and Guidelines – Clinical Judgment vs. Economic Considerations]*. 3 BONNER ÄRZTLICHE NACHRICHTEN 28 (1999) (quoting Justice Dressler).

467. Andrea Nasemann, *Grenzenloses Mißtrauen [Unlimited Distrust]*. SÜDDEUTSCHE ZEITUNG, May 5, 1998, at 706.

468. BGH VI ZR 253/97 (Nov. 11, 1998), 12 NJW 863 (1999).

469. BGH VI ZR 239/97 (Oct. 6, 1998), MEDIZINRECHT 36 (1999) (Goodpasture syndrome resulting in kidney failure was misdiagnosed in an accident victim with some renal injury.) BGH VI ZR 253/97 (aneurism undiagnosed because of omission of CT-scan).

III. Conclusion

Numerous issues are shared by the two very different systems of health care delivery, and many of the solutions proposed or implemented indicate a slow trend towards conversion.

Regulation vs. the Market. After almost 120 years, the German statutory system is highly complex, and efforts to innovate and deregulate to achieve the needed gains in efficiency are under way. German legislators, revising the SGB V, have already introduced a number of market elements such as the new period of open enrollment and selective provider contracting intended to stimulate competition among plans.[470] However, as a consequence, sickness funds might begin to offer "low cost" and "luxury" coverage plans and, just as every manufacturer of consumer products, would then be able to squeeze the market for more profit, raising health care expenditures. Since this would destroy the foundation of the current health care system whose premiums are already considered barely acceptable,[471] observers warn that only universal coverage based on solidarity can guarantee the survival of the German system. The trend towards loosening the strictures of social law, however, is expected to continue.

Health care for most Americans is still subject to the dictates of the market, but legislators increasingly recognize their responsibility. All states by now have adopted more or less stringent managed care acts mandating minimum benefits, prohibiting certain practices,[472] and defining "medical necessity" on a macro-level[473] while Congress has passed several contradictory "patients' rights" bills.[474] State regulation, however, may be nothing but a "subterfuge designed to deter the needed movement toward coverage for all Americans."[475] There are also indications that state managed

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470. Coverage by law is universal, however, and plans were able to compete only by offering a limited number of additional optional benefits. Furthermore, cross-subsidization among funds with differing demographics achieved the government goal of roughly equalizing the so far diverging premiums, reducing their importance as an element of competition.

471. Marc Hujer, *Kein Allheilmittel zur Kostendämpfung [No Cost-Containment Panacea]*. SÜDDEUTSCHE ZEITUNG, Jan. 28, 2000, at 27.

472. *See* STATE GUIDE 2000, *supra* note 141, appendix C.

473. Twenty-one states have defined "medical necessity" on a macro-level. *Id.* at 5-4.

474. As one commentator observed, "You can't litigate your way to quality health care." Stephanie Kanwit, *quoted by* Michael Higgins, *supra* note 147.

475. *See* N.Y. TIMES, *supra* note 81.

care bills of rights have not had much of an effect on managed care abuses because of ineffectual state enforcement agencies.[476]

Is the Practice of Medicine an Independent Profession? So far, American physicians have not been able to convince the National Labor Relations Board, the Federal Trade Commission, and the Senate that MCOs exercise a degree of control over their professional practices which turns them into part-time employees and, thus, should have the right to unionize and collectively defend the standard of care and their working conditions. Whether German physicians truly are "independent practitioners" is not only questioned by physicians, but by scholarly authors as well. Social law regulates the practice of medicine in numerous ways, and social law cost control measures impact on clinical judgment. So far, however, sickness funds do not directly interfere with clinical decision making, contrary to managed care organizations in the United States, and physicians, represented through their associations, negotiate with them the framework for the delivery of health care. But physicians in both countries struggle with external interference with the "independent" exercise of their profession, pressuring them to provide medical services below the standards they consider appropriate.

Physicians' Roles in Negotiating Contracts with Insurers. James S. Todd, then Executive Vice President of the AMA, observed: "One of the main strengths of the German system is the presence of formalized medical input.... Such formal roles for medicine in the decision making process in this country are badly needed, particularly in areas such as reimbursement, appropriateness of fees, and the review of the quality and the appropriateness of services."[477] The German system of "self-governance" relies on physicians' quasi-regulatory input into budget implementation and the development of treatment standards in cooperation with the sickness funds. Nevertheless, German physicians complain of losing their traditional, almost unlimited freedom in clinical decision-making since the increased emphasis on cost-effectiveness and the introduction of budgets force them to make

476. Randy Kennedy, *Long Delays by H.M.O.s Cited in New York Report,* N.Y. TIMES, June 6, 1999, at A18. State agencies have "allowed themselves to become so ineffectual as to become anticonsumer." Many aspects of the New York law, such as mandatory response times for preapproval of end stage cancer patients' pain management treatments and colonoscopies for cancer diagnosis are routinely ignored while fines are minimal. Physicians have reported that patients were forced to wait for hours on operating tables for preapproval. In addition, MCOs create "such a confusing and frustrating gauntlet for obtaining permission that medical providers are often discouraged from trying."

477. *Quoted in* John K. Iglehart, *Health Policy Report: Germany's Health Care System, Part II.* 324 NEW ENG. J. MED. 1750 (June 1991).

micro-allocation decisions they are unaccustomed to. In the United States, physician unionization has recently gained momentum as physicians feel the need to combine their resources to better confront the giant corporations currently undermining the standard of care and their clinical autonomy. Collective bargaining would publicize doctors' concerns and capture the media's attention similar to the often colorful, very public and detailed German health care debate.

Physician Compensation. As payment would be one subject of collective negotiations, American physicians expressed the desire that their future leadership will first and foremost be committed to patient care, not the "protection of [physicians'] presumed Lexus entitlement."[478] Bargaining for income should not be seen as the profession's main focus,[479] and physicians will have to face the test whether they can be public advocates without primarily promoting their self-interest. German sickness funds have already questioned physicians' motives behind their seemingly increasing willingness to take to the streets. "When arguing over health care reforms, we must be quite clear whether the issue is optimizing our health care delivery system or preserving the income of a rather well-off segment of our population."[480]

Payment is, however, an important element of any quality health care system. In both Germany and the United States, incomes of physicians have dropped considerably over the past few years as either legislated or private industry cost control measures have taken effect. "Adequate compensation" is a subject of scholarly debate in Germany because physicians' entitlement to it is protected by both the Constitution and social law, and little or no odium is attached to physicians' participation in this discussion. But what represents an "adequate" level of payment may remain unanswered until brought before the Supreme Social Court with jurisdiction over the subject matter.

The optimal method of compensation is another yet unresolved issue. German physicians today receive a combination of fee-for-service, case-based, and capitated payments, and the recent practice budgets were calculated to preserve incentives for productivity. But urologists have submitted their own model fee scale, and the McKinsey consulting firm has proposed a health care delivery system of multi-disciplinary practice associations, receiving lump sum payments, indication and diagnosis-related

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478. *See* Mullan, *supra* note 158.

479. Darlene Lawrence, *The Pros and Cons, in Physicians' Own Words,* WASH. POST, July 18, 1999, at B3.

480. *See* Korbanka, *supra* note 421, at 166.

fees, and some fee-for-service compensation.[481] There is agreement in both countries that financial incentives undermine the trust between patient and physician.[482] Financial conflicts have always been part of medical decision-making, but physicians generally have succeeded in preserving patient welfare. "However, incentives to limit care are more problematic than incentives to provide care."[483] In the United States, a quality-oriented approach is advocated to reward excellence, but, considering that financial incentives do impact on quality of care, "whether and how this force can be harnessed in the service of quality improvement is unanswered."[484] Over time, German experimentation with different methods of compensation may yield at least a partial answer.[485]

The Impact of Cost-Containment on the Quality of Care. Physicians in both countries are troubled by the impact of resource limitations on the standard of care, whether through national budgets, managed care cost containment techniques or changes in physician compensation. "The micro-allocation of health care funds by physicians imposed by the financial crisis of the health care system would change the medical profession and destroy the freedom and privacy of the physician-patient relationship."[486] German physicians, even though increasingly dissatisfied with their micro-allocation role, retain most of their autonomy to exercise clinical judgment since utilization ("cost-effectiveness") reviews are merely economic and retrospective. American physicians, by nature averse to collective action and a universal health care statute in a nation built on individualism and the

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481. Birgit Schauenburg, *Die Einführung von Praxisbudgets in den EBM [Integrating Practice Budgets into the National Fee Scale],* 5 ZEITSCHRIFT DER BETRIEBLICHEN KRANKENKASSEN 193 (1997).

482. *See* Rumler-Detzel, *supra* note 316. In the United States, numerous actions against managed care organizations allege malpractice resulting from financial incentives for physicians. Courts, including the Supreme Court (Pegram v. Herdrich, *supra* note 107, at 2154, fn.8), currently struggle to determine whether such arrangements must be disclosed and whether they violate fiduciary duty.

483. Council on Ethical and Judicial Affairs (AMA), *Ethical Issues in Managed Care.* 273(4) JAMA 330, 335 (Jan. 1995) [hereinafter Council Report].

484. Mark R. Chassin, *Assessing Strategies for Quality Improvement.* 16 HEALTH AFFAIRS 151, 154 (1998).

485. Comprehensive statistics documenting changes in the health care system are maintained by German sickness funds and the Ministry of Health.

486. *See* Laufs, *supra* note 15.

defense of individual rights,[487] are rallying to defend their right to independent clinical judgment against managed care organizations usurping medical decisions. "The duty of patient advocacy is a fundamental element of the physician-patient relationship that should not be altered by the system of health care delivery."[488] The recently announced United Healthcare move to eliminate preauthorization procedures and "return medical decision making to physicians" seems to amount to little more than a subterfuge aimed at shifting malpractice liability back to physicians while still retaining considerable control over the standard of care through other means.[489]

Physicians in both countries are prepared to accept some form of health care cost containment but feel unfairly held liable for the inevitably lower standard of care. "Managed care organizations must take full responsibility for the decisions they render—just like the rest of us."[490] German physicians are calling for macro-level, regulatory definitions of "medical necessity." However, such legislative interventions could curtail clinical autonomy to a greater degree than German physicians currently may be able to foresee. Practitioners in both countries agree that statistical averages or standardized clinical guidelines, ignoring patient differences, have no place in the practice of medicine. "The standard patient with a standard illness curable by standard treatment administered by the standard physician does not exist."[491] But MCOs, often applying "average case" utilization and corporate practice guidelines, opt out of the common law reasonableness or professional standard.[492] "Physicians should ... advocate for guidelines that are sensitive

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487. For a more detailed discussion of the differing philosophical approaches to access to and distribution of health care in the United States and Germany, *see* Ursula Weide, *supra* note 12.

488. *See* Council Report, *supra* note 483, at 334.

489. Financial incentives, publishing "provider profiles" rating physicians according to their adherence to corporate practice guidelines and utilization rates, at-will contracts, and "deselection" in case of non-compliance, exert pressure on physicians to acquiesce to managed care norms. David Hitzenrad, *H.M.O. to Leave Care Decisions Up to Doctors,* WASH. POST, Nov. 9, 1999, at A1. Milt Freudenheim, *Big H.M.O. to Give Decision on Care Back to Doctors,* WASH. POST, Nov. 9, 1999, at A1.

490. Mohammad Saeed, *Meeting Needs of Providers: A Request to Managed Care.* 17(1) PSYCHIATRIC TIMES 78, 79 (Jan. 2000).

491. Adolf Laufs, *Zur Freiheit des Arztberufs [The Independent Practice of Medicine], in* FESTSCHRIFT FUR ERWIN DEUTSCH [HONORING ERWIN DEUTSCH] 625, 626 (Heymanns Verlag, Cologne, 1999).

492. *See* Dukes, *supra* note 72. The court, ruling on the ERISA preemption of state laws regulating the quality of care, observed that "we leave for another time the issue whether an

to differences between patients."[493] Many American physicians, however, faced with managed care control over the exercise of their profession,[494] have been forced to "internalize" managed care clinical practices and norms, often unrelated to a patient's individual circumstances and based on actuarial calculations. German physicians confront similar conflicts arising from more stringent social law restrictions and evolving civil law standards. Scholars have warned that social law cost-effectiveness requirements may result in "clinical self-restraint," negatively affect the standard of care, and preordain the quality of future research by introducing economic considerations into the development of quality criteria for diagnosis and treatment.[495] But some standardization through practice guidelines based on scientific evidence and medical expertise may be unavoidable in order to achieve the needed efficiency gains in the provision of health care. German physicians, equal partners of the sickness funds, will continue to influence the standard of care in accordance with the SGB V process while their American colleagues are still lacking any mechanisms of formalized input.

Health care delivery will continue to undergo major transformations in both countries, searching for a middle-of-the-road solution acceptable within their respective philosophical frameworks. Both will most likely come to rely on some form of contractual (macro-level) standard of care, deviating from the professional standard and reducing physician autonomy. But to determine what is medically doable and economically feasible while protecting patient welfare will be fraught with difficult choices, and who eventually will make these determinations remains unanswered.[496] In the absence of national legislation, American efforts to free medicine from market domination, to limit the deregulation of the health care "industry," and to restore some of the autonomy in clinical decision making to

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H.M.O. should be permitted to opt out by contract of the common law standard of care."

493. *See* Council Report, *supra* note 483, at 334.

494. *See* Hitzenrad, *supra* note 489.

495. *See* Laufs, *supra* note 466, at 493.

496. In the United States, few seem to question the validity of both MCO-internal and external appeals procedures in the case of treatment denial. An internal appeals process would leave treatment decisions with the insurers while an external review process would rely on outside "experts." In both instances, to determine what is "medically necessary" in an individual patient's case is no longer left to the attending physician's hands-on clinical judgment. "Only by restoring the intimate bond between doctor and patient can Congress return free-market principles to an industry that in many ways resembles an arbitrary and inefficient Soviet-style economy." Rep. Tom A. Coburn (Oklahoma), *Patients' Rights, Done Wrong*, N.Y. TIMES, July 30, 1999, at A23.

physicians and patients, may succeed only through the "commodification" of medicine: by turning it into a "product" or "service" subject to state regulation.[497] Germany, with its recent statutory revisions adding market-oriented elements and more stringent cost-benefit evaluations, is embarked on a similar path, in contradiction with traditional ideals. "Every law regulating the practice of medicine should recognize that its foundations are love and charity."[498] American authors emphasize patient trust and physician trustworthiness as anchors of the patient-physician relationship so that the sick can "take comfort and draw strength from their doctors during their most anxious and fearful moments."[499] They also point to the growing number of uninsured Americans for whom charity care provided by physicians and hospitals is dwindling following the "managed care revolution."[500]

Confronted with the painful necessity of health care cost containment, it is tempting to succumb to economic dictates. However, the preservation of human dignity in times of need, whether we help safeguard it for others or claim it for ourselves, is prime among the duties owed by any modern industrialized society.

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497. Alternatively, and in the absence of congressional action, citizens, physicians and some state politicians may increasingly resort to "self-help" such as holding referendums on universal health care. In both Washington and Massachusetts, such popular initiatives are under way, and Maryland is beginning a similar "push." Carey Goldberg, *State Referendums Seeking to Overhaul Health Care System.* N.Y. TIMES, June 11, 2000, at A1.

498. *See* Laufs, *supra* note 15 (quoting Küchenhoff, regretting that this philosophy seems to have receded into the past. But we should at a minimum try to remember that "such laws embody the promise that individuals will wholly serve others in their being and their suffering.").

499. Jay Katz, *The Silent World of Doctor and Patient* (1984), *quoted in* Brief of Health Law, Policy, and Ethics Scholars as Amici Curiae in Support of Respondent, at 15, Pegram v. Herdrich, *cert. granted* (U.S. Sept. 28, 1999) (No. 98-1949).

500. "Until we have some form of universal [health insurance] coverage, the expectation that organizations can provide free care to 40 or 50 percent of the people who walk in their door is unrealistic." *See* David Brown, Medical Safety Net Seen in Peril, WASH. POST, March 31, 2000, at A2 (quoting John Billings, New York University, member of the Institute of Medicine committee, reporting on the consequences of health care cost control efforts in the 1990s). "But [charity care] is a real safety net that allows our country to have humane qualities even at the same time we have 45 million people with no health insurance." *See id.* (quoting Stuart Altman, Brandeis University, IOM committee chairman). John Kenneth Galbraith, in support of the Massachusetts drive for universal health care, has expressed "grave doubts whether health care can be a business enterprise, where one saves money by cutting back care." *Quoted in* Goldberg, *supra* note 497.