

COVERAGE AND MEDICAL NECESSITY DETERMINATIONS: U.S. MANAGED CARE TREATMENT DECISIONS VERSUS GERMAN ADMINISTRATIVE RULEMAKING

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I. INTRODUCTION

Efforts at health care cost containment are common to all industrialized nations. In most countries, governments set the framework for such measures, and exert a certain degree of control over both the delivery and the standard of health care. Macro-level decisions define coverage and allocate health care funds, micro-level allocation is mostly left to the clinical judgment of the attending providers. Since at least some restraints on the provision of care to individual patients are exercised in all our nations, either through specific state rationing decisions (such as limiting the access to dialysis in Great Britain) or through budgets for health care (as in Germany), clinical and financial considerations have become inextricably intertwined. Physicians are increasingly moving from “advocacy to allocation.”¹ The United States Supreme Court, in its recent ruling in *Pegram v. Herdrich*,² created the term “mixed eligibility and treatment decisions,” and declared rationing to be an integral element of the managed care approach to health care cost containment. A high-level official of the German Ministry of Health chided physicians for chafing against cost-based considerations imposed on them through budgets by claiming that rationing has always been a component of clinical decision making as resources have never been unlimited.³

1. John K. Iglehart, *Health Policy Report: The American Health Care System*, 327(10) *NEW ENG. J. MED.* 742 (1992) (quoting DAVID MECHANIC, *FROM ADVOCACY TO ALLOCATION: THE EVOLVING AMERICAN HEALTH CARE SYSTEM* (1986)).

2. *Pegram v. Herdrich*, 120 S.Ct. 2143 (2000).

3. Dr. Schulte-Sasse, *Was soll das “Geschrei der Ärzte”?* [Why are Physicians “Whining”?], 26 *MED. TRIBUNE* 18, June 30, 2000.

Macro-level allocation of health care funds is based on coverage and medical necessity definitions, micro-level allocation involves the; performance or denial of treatment and diagnostic procedures. Coverage is set by contract (managed care) or by statute (Germany), specifying either specific benefits (managed care) or general categories of services (Germany) members⁴ are entitled to receive. Macro-level medical necessity definitions in managed care plan documents can be quite generous and reflective of the prevailing standard of care, but on the micro-level are operationalized through the application of restrictive criteria for access to care. Benefits may be included in the macro-level coverage contract and certainly covered by the promise to "provide all medically necessary care according to good medical practice" but may still be denied at the bedside for lack of "medical necessity." The SGB V (Title Five of the Social Code), the foundation of the German statutory health care system, defines both coverage and medical necessity as concepts but does not use those terms. Only lately, influenced by information on managed care techniques in the United States, has "medical necessity" found its way into the most recent German code revisions. But in spite of apparent similarities, the cost containment approaches pursued in these two countries is diametrically opposed. In Germany, the law provides a general framework for the guaranteed delivery of health care and relies on the therapeutic autonomy of the clinical decision maker. In the United States, managed care organizations (MCOs) have implemented an elaborate utilization management bureaucracy to control care at the bedside.

II. UNITED STATES: MANAGED CARE TREATMENT DECISIONS

A. *The Managed Care Approach to Health Care Delivery*

Almost fifty percent of all health care expenditures in the United States are financed by the government through programs such as Medicaid and Medicare, while sixty percent of the population are covered by private insurers, accounting for only thirty percent of total spending.⁵ Seventy five percent of working Americans obtain private health insurance through employer-sponsored plans which rely on contracts with large managed care

4. The common German term is "patient," not "subscriber" or "member," since 90% of all Germans are covered under the statutory health care system, the remainder by private insurance. All therefore are patients as of the first day of their lives.

5. Sheila Smith et al., *The Next Decade of Health Spending: A New Outlook*, 18 HEALTH AFFAIRS, No. 4, July/August 1999 at 86.

corporations, providing health care on a prepaid basis for a total of over 170 million individuals.⁶

Managed care was initially conceived as a cost-effective alternative to the traditional fee-for-service indemnity plans. It consisted of vertically integrated, brick-and-mortar health care delivery systems (called HMOs) and employed salaried providers. Today, having metamorphosed into giant corporations, MCOs offer employers a multitude of contractual arrangements—"products"—for the provision or arrangement of medical care which may include an insurance and claims processing function.⁷

6. Currently, 16% of Medicare beneficiaries—6.2 million among 39 million individuals covered by the program—also receive their medical care through MCOs because the Health Care Financing Administration temporarily assumed that managed care would help to lower costs. But since Medicare, a system of social insurance similar to the German statutory health care system, has attempted to curb spending, MCOs are increasingly terminating services to Medicare beneficiaries. By January 2001, almost 1.7 million elderly patients will have their medical care disrupted. Even though government studies have shown that Medicare is already paying MCOs more for individual patients than it would pay for them in its fee-for-service program (all those dropped by a MCO will revert back to the traditional Medicare coverage), Republican members of Congress have agreed on adopting a Medicare spending package which "would pump large sums of money into HMOs." As a representative of a managed care trade association noted, "Medicare managed care is a program in crisis . . . it needs to be rescued"; while the president of the Greater New York Hospital Association observed, "Congress is channeling money from hospitals on Main Street to investor-owned HMOs on Wall Street, enhancing the profits of managed care companies without improving the delivery of services." Robert Pear, *Congress Near Deal to Raise Fee Payments to H.M.O.s*, N.Y. TIMES, Oct. 12, 2000, at 16. So far, Congress has been unable to pass a "Patients' Rights Bill," regulating managed care abuses on a national level.

7. Most employers today, however, are "self-insured," bearing all actuarial risks while minimizing them through reinsurance. "Self-insurance" creates a legal vacuum because §502(a), the civil enforcement section of ERISA (the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001 *et seq.*) preempts state law causes of action for malpractice and denials of benefits against providers and MCOs, and limits actions to benefit recovery and the clarification of current and future rights under the plan. §514(a) preempts all state tort law claims against employee benefit plans "relating to" ERISA plans; §514(b) "saves" from preemption any state law regulating insurance, but §514(c) "deems" all self-insured employee benefit plans not to be insurers, thus exempting them from state insurance regulation. The Supreme Court, however, has reined in the preemptive reach of §514(a) by limiting the expansive interpretation of the term "relate to" in three cases: *New York State Conference of Blue Cross & Blue Shield v. Travelers Ins. Co.*, 115 S.Ct. 1671 (1995); *DeBuono v. NYSA-ILA Med. And Clinic Services Fund*, 117 S.Ct. 1747 (1997); *California Division of Labor Standards Enforcement Division v. Dillingham Construction*, 117 S.Ct. 832 (1997).

In Unum Life Ins. Co. of Am. v. Ward, 119 S.Ct. 1380 (1999), the Supreme Court weakened the scope of §514(b) by ruling that California's "notice prejudice rule" regulates insurance and thus falls outside of this section. The Court specified that all three factors enumerated in the McCarran-Ferguson Act defining when a business is to be considered an insurance company are merely "checking points or guideposts."

Furthermore, after the Third Circuit ruling in *Dukes v. U.S. Healthcare*, 57 F.3d 350 (3d Cir. 1995), distinguishing between the "quality" and "quantity" of medical care, many malpractice cases which formerly would have been preempted by §502 as actions for

Common to all these plans is patient access to a limited network of providers such as physicians and hospitals which receive discounted, often capitated, fees in exchange for a higher volume of cases. Increasingly, plans include a POS option (point of service) which permits members to receive treatment by non-network providers but requires a higher copayment to be paid out-of-pocket.

MCOs rely on a number of cost-containment mechanisms: primary-care gate keeping to restrict referrals to more expensive specialists; telephone hotlines staffed by nurses to be called in emergencies to reduce emergency room utilization; financial incentives for providers⁸ and administrative staff; capitated payments shifting the morbidity risk to providers, and utilization management, a corporation-wide complex system designed to reduce the use of health care resources. Based on corporate averages and/or treatment guidelines both corporate and commercial, health care funds are micro-allocated through case-by-case preauthorization for medical procedures and hospital admissions. Treatment plans submitted by providers are reviewed prospectively, followed by the concurrent review of the course of treatment. Administrative case managers may deny procedures and shorten hospital stays, often contrary to the attending physicians' recommendations. Regional and national norms are computed and compared with the utilization data collected for individual providers. Such "provider profiling" allows the MCO to detect patterns of "overutilization" and the frequency with which a provider has appealed case managers' decisions. Providers falling outside of the norms are "deselected." Furthermore, accounting firms are called in to audit utilization management procedures, analyze treatment and hospitalization denial rates, and suggest areas for additional cost-savings. Increasingly, medical decisions and guidelines are thus determined by cost-based criteria, ignoring the clinical circumstances of individual patients, and lowering the quality of care across the board.

administrative benefit denial, were remanded to state court. In *Pegram, supra* note 2, the Supreme Court created the term "mixed eligibility and treatment decisions," defined as all benefit decisions involving medical judgment. Health care, however, has traditionally been reserved to state regulation. The door is now open for courts to limit ERISA preemption to the few purely administrative coverage decisions, making available the full range of state law remedies for patients or their survivors victimized by managed care abuse.

8. Financial incentives include year-end bonuses or withholds from compensation to limit the referral to specialists, and the utilization of diagnostic and therapeutic procedures, as compared with corporate benchmarks. Financial incentives for achieving such performance targets are often laid out in the provider contracts. In regions served by no more than one or two MCOs where most of the insureds are members, providers have no or very limited choice but to sign such contracts.

While utilization management serves the micro-allocation of health care funds on a case-by-case basis, macro-allocation occurs when employers contract with MCOs for the provision or management of medical services. These contracts determine eligible individuals such as employees, spouses and children up to a certain age, and cover benefits such as ambulatory care, hospitalization and prescription drugs. Frequently excluded from coverage under such “plans” are preexisting conditions, cosmetic and other “elective” surgery, mental health benefits, “experimental” treatments such as high dosage chemotherapy and autologous bone marrow transplants, alternative therapies, “convenience items” such as some types of durable medical equipment, childhood immunization, obesity treatment, in vitro fertilization, and surgery to correct nearsightedness. These could be termed “categorical exclusions” while “selective coverage” limits certain services under certain conditions. Rehabilitative therapy may be covered only “when the personal physician determines that significant improvement of a member’s condition can be expected within a period of two months.” Physical, occupational, and speech therapy may not be authorized “when there is no reasonable expectation that the member’s condition will *improve* over a predictable period of time as determined by the plan.”⁹ Plan subscribers often receive only summary plan descriptions promising “all medically necessary care.”¹⁰

9. CLARK C. HAVIGHURST ET AL., *HEALTH CARE LAW AND POLICY* (1998). See also *Bedrick v. Travelers*, 93 F.3d 149, 153-155 (4th Cir. 1996). Travelers had argued that physical therapy for a small child with cerebral palsy was no longer a covered benefit “based upon a finding that the specified treatments did not reach a level of potential for significant progress which would allow the therapies to be provided on a medically necessary level.” The boy’s pediatrician had given the child a fifty/fifty chance of walking by age five. The court ruled, first, that the “significant progress” requirement was not laid down in the plan nor in any internal corporate guidelines, and second, that “the implication that walking by age five would not be ‘significant progress’ for this unfortunate child is simply revolting.” Furthermore, the application of the *Firestone Tire and Rubber Co. v. Bruch Standard*, 489 U.S. 101 (1989) led to a finding of abuse of discretion by the MCO as the policy had promised as medically necessary and covered durable medical equipment “which replaces a lost body organ or part or helps an impaired one to work.” (An upright stander is important for bone and hip joint development in a child with cerebral palsy, and facilitates sustained neck and trunk extension.) But the court upheld the lower court’s denial of speech therapy since the policy specified that “these services must be given to restore speech.” As the child had never been able to speak, “medically necessary or not, there is just no coverage here.”

10. Micro-allocation issues have been litigated more frequently than coverage issues on a macro level. Managed care companies micro-manage treatment on a case-by-case basis. Macro coverage issues concern, for example, the ERISA preemption of state laws mandating standards of care and prohibiting discrimination, and the fiduciary duties of ERISA fiduciaries such as disclosure and avoidance of dual loyalties. See RAND E. ROSENBLATT, SYLVIA A. LAW, SARA ROSENBAUM, *LAW AND THE AMERICAN HEALTH CARE SYSTEM* 140-41 (1997) [hereinafter ROSENBLATT ET AL.].

B. Medical Necessity

Even though plan documents may promise all medically necessary care, medical necessity determinations by the managed care company, functioning either as the payor or the arranger of medical services, often result in the denial of procedures recommended by the attending physician.¹¹ This raises two questions: is there a valid definition of medical necessity, and how do managed care companies operationalize medical necessity?

So far, no federal agency has received the mandate and resources to propose a valid definition. For many years, however, state courts have struggled with the issue since managed care policies are private insurance contracts, and federal courts have ruled in employee benefit cases under ERISA. At least one state court found that "medical necessity" was ambiguous as a matter of law and hence, under the rules of construction for insurance contracts, a question of fact for the jury.¹² But no consensus has emerged among the courts. State legislatures, however, have responded to the need to prevent MCOs from denying needed care. Today, almost half of all states have adopted statutory definitions of "medical necessity," most of them for managed care plans, some for Medicaid.¹³ A typical example is the definition adopted by the state of Virginia:

"Medical necessity" or "medically necessary" means appropriate and necessary health care services that are rendered for any condition that, according to generally accepted principles of good medical practice, requires the diagnosis or direct care and treatment of an illness, injury, or pregnancy-related condition, and that are not provided only as a convenience.¹⁴

Some states define the standard of care more or less restrictively: "Treatment or care in accordance with *nationally* accepted current medical criteria" (Louisiana); "Within generally accepted standards of medical care

11. The German term for medical necessity is "*medizinische Notwendigkeit*." *Notwendigkeit* is a composite noun of *Not* (distress, misery, imminent danger) and the verb *wenden* (to change, to turn around). As a German physician commented, "The question is how to define distress, who should turn it around, and who should decide on both." Klaus Schnetzer, *personal communication*, on file with the author.

12. ROSENBLATT ET AL., *supra* note 10, at 211, 212. *Dallis v. Aetna Life Ins. Co.*, 574 F.Supp. 547, *aff'd* 768 F.2d 1303 (11th Cir. 1985).

13. PANEL PUBLISHERS, 2001 STATE GUIDE TO MANAGED CARE LAW §5.1 (2001) [hereinafter 2001 STATE GUIDE TO MANAGED CARE LAW].

14. 1998 Va. Acts ch. 891.

in the *community*" (North Carolina); "In accordance with the *prevailing* practices and standards of the *medical profession* and community" (Texas). Several states mandate that medical necessity must be determined by a physician (Louisiana, Texas, Wisconsin).¹⁵

C. *Managed Care and The Operationalization of Medical Necessity*

1. The Use of Corporate Criteria

Even though many plans contain a seemingly appropriate contractual definition of medical necessity (often in accordance with state law), the procedures by which coverage is operationalized through a panoply of (unregulated) corporate criteria determine the actual provision of medical care. Such restrictive criteria, sometimes spelled out in policies provided to members but often supplemented by additional internal undisclosed guidelines, often fly in the face of the prevailing standard of care, sometimes even in the face of logic. They have spawned a spate of novel lawsuits, most of them still pending, which incorporate, for example, causes of action for breach of contract and fiduciary duty based on internal undisclosed cost-based criteria and procedures. These result in coverage determinations according to factors other than medical necessity, and designed to reduce the level of medically necessary services.

The complaint in *Pennsylvania Psychiatric Society v. Green Spring, Magellan*,¹⁶ stated that the Provider Agreement concluded with psychiatrists required Green Spring to "provide medically necessary health services to patient-subscribers in a prompt and efficient manner consistent with the standard of practice of the community in which the Provider renders Health Services." According to the Agreement, "Green Spring's utilization management procedures shall not diminish Provider's obligation to render Health Services consistent with the applicable standard of care."¹⁷ Plan documents assured patient-subscribers that, whenever medically necessary, they would receive up to twenty outpatient treatment sessions per calendar year, thirty inpatient days per consecutive twelve-month period, seven days of detoxification, and thirty days of rehabilitation for substance abuse care. The complaint alleged, however, that Green Spring applied more restrictive internal guidelines, not disclosed to patient

15. LA. REV. STAT. ANN. §§ 22:657(D)(3)(e) (West, 2001), 40:2232(B)(5) (West, 2001); N.C. GEN. STAT. ANN. §§ 58-3-200(b), 58-3-200 (2001); TEX. ADMIN. CODE tit. 4, ch. 88, § 88:001 (no longer in effect); WIS. ADMIN. CODE § 3.54(3)(d) (2001).

16. Amended Complaint (Aug. 1999), in *Pennsylvania Psychiatric Soc'y v. Green Spring Health Services*, 2000 U.S. Dist. LEXIS 7953 (W.D. Pa. 2000) (Civil Action No. 99-937), *vacated and remanded*, 280 F.3d 378, 2002 U.S. App. LEXIS 1816 (3d Cir. 2002).

17. *Id.* at 10.

subscribers, to reduce benefits. These internal guidelines and standards, “developed to increase profits by denying care,” allegedly violated Green Spring’s obligations under the Provider Agreements, contradicted representations made to both employer-purchasers and patient-subscribers¹⁸, and routinely and systematically undermined the quality of behavioral health care and substance abuse treatment.¹⁹ Green Spring care managers, for example, were said to have refused to authorize treatment plans for another round of therapy sessions when the proposed treatment plan was identical to the one for the sessions which had already taken place. This rendered the provision of medically necessary and appropriate treatment impossible for those patients who had not responded “to therapy within the arbitrary time frame allotted to patient-subscribers by Green Spring.”²⁰ The management of mental illness, including substance abuse, however, often requires longer-term treatment planning because of therapy-resistant syndromes, comorbidity and repeat episodes—no different from many somatic illnesses.

In spite of a number of poignant cases presented in the complaint as examples, the magistrate judge found for lack of association. He recommended dismissal of the action for breach of contract, good faith and fair dealing, interference with present and prospective economic advantage, tortious interference with the physician-patient relationship, and fraudulent misrepresentation. Even though acknowledging that “this case is pregnant with issues constituent to the ongoing public debate concerning managed health care,” the magistrate judge stated that individual patients could instead sue in their own behalf, alleging specific injuries.²¹

The Green Spring medical necessity and utilization review criteria for residential treatment for substance abuse have recently been the subject of

18. *Id.* at 25.

19. From 1988 to 1998, the employer-provided value of health benefits generally declined by 11.5% while both in- and outpatient substance abuse benefits were reduced by 74.5%. 80% of the participants of an American Society of Addiction Medicine annual meeting felt that managed care had a negative impact on “the quality of care of my addicted patients.” 81% indicated that managed care also had a negative impact on their “ethical practice of addiction medicine.” Marc Gallanter, *The Impact of Managed Care on Addiction Treatment: Evaluating Physician’s Views and the Value of Health Plan Benefits*, 18(4) J. ADDICTIVE DISEASES 1 (1999).

20. Amended Complaint (Aug. 1999) at 24, in *Pennsylvania Psychiatric Soc’y v. Green Spring Health Services*, (Civil Action No. 99-937) 2000 U.S. Dist. LEXIS 7953 (W.D. Pa. 2000, vacated and remanded, 280 F.3d 378, 2002 U.S. App. LEXIS 1816 (3d Cir. 2002).

21. *Pennsylvania Psychiatric Soc’y v. Green Spring Health Services*, 2000 U.S. Dist. LEXIS 8017 (2000). Defendant’s motion to dismiss was granted. *Pennsylvania Psychiatric Soc’y v. Green Spring Health Services*, 2000 U.S. Dist. LEXIS 7953 (W.D. Pa. 2000) (Civil Action No. 99-937), vacated and remanded, 280 F.3d 378, 2002 U.S. App. LEXIS 1816 (3d Cir. 2002).

two lawsuits.²² Both complaints alleged that the Green Spring medical necessity definition and medical necessity interpretive criteria were more restrictive than the medical necessity definition in the plaintiffs' policy with Blue Cross Blue Shield of Maryland (BCBSM), contracting with Green Spring for mental health utilization management (prior authorization, concurrent review and retrospective review). The following BCBSM medical necessity definition was applicable at the time when plaintiffs' causes of action arose:

Services and supplies by a provider to identify or treat an illness that has been diagnosed or is suspected. They are:

- a. consistent with:
 - (1) the diagnosis and treatment of a condition, and
 - (2) the standards of good medical practice;
- b. required for other than convenience; and
- c. the most appropriate supply or level of service.

When applied to inpatient care, the term means: the needed care cannot be safely given on other than an inpatient basis.²³

Green Spring supplemented this medical necessity definition with criteria for mental health treatment, including admission and continued stay criteria for substance abuse residential treatment. The most controversial elements were, first, a "fail first" admission requirement: "Structured professional outpatient treatment is the treatment of first choice. Residential treatment . . . should follow recent outpatient treatment in a structured professional program of significant duration and intensity during the course of which the patient has not been able to maintain abstinence for

22. Amended Class Action Complaint, *Jane Doe et al. v. Blue Cross Blue Shield of Maryland, Inc.* (Civil Action No. 183811) (Circuit Court for Montgomery County, Md., March 2000). This lawsuit for breach of contract was settled. Second Amended Complaint, *John Doe et al. v. Blue Cross Blue Shield of Maryland, Inc.*, (Civil No. L-98-121) 173 F. Supp. 2d 398 (D. Md. Sept. 2001). The complaint alleged several causes of action under ERISA such as failure to disclose, breach of fiduciary duty, and denial of benefits.

23. Second Amended Complaint at 5, *John Doe et al. v. Blue Cross Blue Shield of Maryland, Inc.*, (Civil No. L-98-121) 173 F. Supp. 2d 398 (D. Md. Sept. 2001).

a significant period of time.”²⁴ In other words, unless potentially irreparable harm to the patient’s personal and professional life had already occurred, the possibly most appropriate treatment according to “good medical practice “would not be approved and the patient would be placed at risk for further harm.”²⁵

Second, if this requirement for residential treatment was not met, the following conditions applied: “1) patient must be residing in a *severely* dysfunctional living environment (emphasis added); or 2) there must be actual evidence for, or clear and reasonable inference of serious, imminent physical harm to self or others directly attributable to the continued abuse of substances which would prohibit treatment in an outpatient setting.”²⁶ Since all family environments of alcoholics are marked by a certain degree of impairment, the Green Spring criteria imposed further deterioration and potential irreparable harm before treatment according to good medical practice might be approved. Serious, imminent harm to self or others is an indication for involuntary commitment and as such, an excessively stringent and inappropriate standard for residential substance abuse treatment.

Third, the Green Spring Medical Necessity Criteria required the “documentation of restorative potential for the proposed admission” in cases of repeated relapses.²⁷ In other words, unless patients with a history of failed treatment compliance could prove their current ability to benefit from residential treatment, they would be assigned to a lower level of care. But “a more appropriate clinical approach would be careful assessment and identification of the barriers to recovery . . . Failure to address specific recovery barriers and match the client to appropriate services and settings only increase the human and financial cost to the client and society.”²⁸ And lastly, the criteria for continued stay required that “all of the

24. GREEN SPRING HEALTH SERVICES, INC., GSHS MEDICAL NECESSITY CRITERIA: SUBSTANCE ABUSE RESIDENTIAL TREATMENT 16 (1992, 1995) [hereinafter GSHS MEDICAL NECESSITY CRITERIA].

25. Denial of “having a problem” is common among alcoholics but whenever a patient accepts responsibility for the condition, appropriate treatment is essential for a successful outcome. Complete “remission” from alcoholism often occurs only after several failed attempts at recovery. Denying residential care may expose patients to failure at a time when they are most amenable to treatment.

26. GSHS MEDICAL NECESSITY CRITERIA, *supra* note 24, at 17.

27. *Id.*

28. LEE GARTNER & DAVID MEE-LEE, U.S. DEP’T OF HEALTH AND HUMAN SERVICES, THE ROLE AND CURRENT STATUS OF PATIENT PLACEMENT CRITERIA IN THE TREATMENT OF SUBSTANCE ABUSE DISORDERS. 13 TREATMENT IMPROVEMENT PROTOCOL (TIP) SERIES 15, at 17 (1995).

admission criteria must be met “on a daily, continuing basis.”²⁹ This requirement defies all logic of treatment—patients may not improve in order to qualify for continued residential therapy. If they responded to such a structured treatment approach which, by definition, spans a certain period of time, they were no longer eligible for continued approval of the appropriate level of care.

In 1995, the Green Spring alcohol and drug detoxification and rehabilitation criteria for utilization review were compared by Green Spring authors with the Patient Placement Criteria (PPC) of the American Society of Addiction Medicine.³⁰ While both sets of criteria dealt with level-of-care determinations for substance-abusing patients and included admission, continued stay and discharge criteria, the authors emphasized that the Green Spring medical necessity criteria were intended for utilization management while the ASAM criteria served “a broader treatment rationale and purpose.”³¹ The article concluded that the ASAM criteria “are helpful in treatment planning” but in their current form “are not adequate in medical-necessity review for utilization management purposes.”³² The Center for Substance Abuse Treatment (CSAT) of the U.S. Department of Health and Human Services, however, striving to lay the groundwork for the development of national uniform patient placement criteria, found that the ASAM criteria represented the “best effort to date” and provided “a solid base upon which to build.”³³ The CSAT team had reviewed all available sets of public and private placement criteria for its Treatment Improvement Protocol (TIP) as both public and private treatment systems were seen as increasingly relying on PPCs. A more standardized approach was also considered advisable since most managed care organizations employed their own criteria attempting “to place patients in the least restrictive and least expensive treatment setting that is most likely to produce positive treatment outcomes.”³⁴ The TIP emphasized that managed care criteria were “substantially more restrictive in regarding intensive levels of care” than the ASAM criteria. Noted advantages of the ASAM criteria were their development by consensus

29. GSHS MEDICAL NECESSITY CRITERIA, *supra* note 24, at 17.

30. Jonathan Book et al., *The ASAM and Green Spring Alcohol and Drug Detoxification and Rehabilitation Criteria for Utilization Review*, 4(3) AM. J. ON ADDICTIONS 187 (1995). Dr. Book is the current Magellan (formerly Green Spring) Medical Director in the Magellan corporate office in Columbia, Maryland.

31. *Id.* at 189.

32. *Id.*

33. GARTNER & MEE-LEE, *supra* note 28.

34. *Id.* at 11.

among a range of clinicians (even though not as broad as might ideally be desirable), their publication after extensive field review, and their high visibility in the clinical arena in general.

2. The Use of Clinical Practice Guidelines

According to the Institute of Medicine, chartered by the National Academy of Science, clinical practice guidelines (CPGs) are “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”³⁵ Currently, more than 2,200 scientifically derived guidelines have been developed by recognized scientific institutions (including the former Agency for Health Care Policy and Research AHCPR, now called Agency for Healthcare Research and Quality AHRQ³⁶) and medical specialty organizations. Their use, however, is not required by law, and MCOs are free to develop and apply their own customized guidelines.³⁷ As a MCO representative observed in response to an informal survey of the use of official practice guidelines: the AHCPR guidelines “did not seem to fit his circumstances.”³⁸ 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.”³⁹ “Among these managed care guidelines, a staggering diversity reigns. Indeed, the full extent of the variety can not be known since many of them are proprietary, kept confidential partly to

35. INSTITUTE OF MEDICINE, COMM. ON CLINICAL PRACTICE GUIDELINES, CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM (M.J. Field & Kathleen N. Lohr, eds., 1990). The IOM definition has also been adopted by German institutions and medical specialty societies developing clinical practice guidelines.

36. AGENCY FOR HEALTH CARE POLICY AND RESEARCH, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, USING CLINICAL PRACTICE GUIDELINES TO EVALUATE QUALITY OF CARE (1995). Volume 1 contains a “List of attributes of good practice guidelines” and a twelve-point checklist for guideline development, similar to the approach developed by the German workgroup *ÄZQ*.

37. U.S. GOVERNMENT ACCOUNTING OFFICE, PRACTICE GUIDELINES: MANAGED CARE PLANS CUSTOMIZE GUIDELINES TO MEET LOCAL INTERESTS 3 (1996). More than 75% of all MCOs use at least some formally implemented guidelines. Frances H. Miller, *Medical Malpractice: External Influences and Controls—Medical Discipline in the Twenty-First Century: Are Purchasers the Answer?*, 60 LAW & CONTEMP. PROB. 31, 46 (1997).

38. Jane Sisk, *How are Health Care Organizations Using Clinical Guidelines?*, 17 HEALTH AFFAIRS, No. 5, Sept./Oct. 1999, at 91.

39. U.S. GOVERNMENT ACCOUNTING OFFICE, *supra* note 37, at 12 (quoting an anonymous expert source on guidelines).

ensure commercial salability and partly to limit physicians' ability to 'game' the system for extra benefits."⁴⁰

3. Commercial Guidelines

Managed care organizations increasingly resort to guidelines developed by actuarial firms (Milliman & Robertson, InterQual⁴¹, Value Health Services) for commercial purposes.⁴² The Milliman & Robertson (M&R) guidelines, for example, are sold to a large number of MCOs including companies such as Cigna, Prudential, United Healthcare Corp., and U.S. Healthcare.⁴³ By 1995, the firm's "Optimal Recovery Guidelines" (ORGs) were applied to the treatment of more than 50 million patients—but not without serious resistance by practitioners and the American Medical Association, dubbing the guidelines "cookbook medicine," sacrificing autonomous clinical judgment and the consideration of each patient's unique circumstances.⁴⁴ In order to avoid costly referrals to specialists or hospital stays, the extensive list of conditions to be treated by general practitioners in Volume 5, "Ambulatory, Primary and Pharmaceutical Care" (developed in focus groups of managed care primary care physicians) includes heart failure, pneumonia, and epileptic seizures. Still, the "purpose of the Guidelines is not to ration or reduce care, but rather to help minimize waste and inefficiency in the healthcare system."⁴⁵

As the company itself consistently emphasizes in its literature, its Healthcare Management Guidelines are "a set of optimal clinical practice benchmarks for treating common conditions for patients who have no complications. If you have an uncomplicated patient with a particular

40. E. Haavi Morreim, *Medicine Meets Resource Limits: Restructuring the Legal Standard of Care*, 59 U. PITT. L. REV. 1, 12 (Fall 1997) (quoting Lucian L. Leape, *Translating Medical Science Into Medical Practice: Do We Need a National Medical Standards Board?* 273 JAMA 1534, 1536 (1995)).

41. Miller, *supra* note 37, at 31, n.104.

42. An extensive search of the National Library of Medicine database revealed only a slim 1992 edition of the Milliman & Robertson Guidelines, an entry of InterQual as a publisher, and no entry of Value Health Services. (The NLM is the largest repository of scientific medical publications in the world.) All three corporations sell clinical practice guidelines for "medical review services" (the precertification and concurrent review of individual patients' medical care) to large managed care corporations.

43. Morreim, *supra* note 40, at 11, n.28. Since then, some of these corporations have merged with other MCOs.

44. Allen R. Myerson, *Helping Health Insurers Say No*, N.Y. TIMES, March 20, 1995, at D1. Most M&R documents emphasize, however, that the guidelines should be adapted to local standards and are not intended to supplant clinical expertise.

45. MILLIMAN & ROBERTSON, INC., HEALTHCARE MANAGEMENT GUIDELINES, QUESTIONS AND ANSWERS 3 (Apr. 1998).

illness, here is the most-efficient, demonstrated-quality course of treatment.”⁴⁶ “Eighty percent of under-age 65 cases and 40% to 50% of over-age 65 cases are generally considered uncomplicated.”⁴⁷ This approach completely ignores the considerable incidence of comorbidity, especially among the elderly.⁴⁸ As one physician commented, “The standards take an absurdly optimistic approach. If all the stars are aligned in the heavens and everything turns out just right, what is the least we can do?”⁴⁹

In some cases, it appears that health plan guidelines are based not even on average needs but on the needs of patients in the best of circumstances. For example, in developing benchmarks to which managed care plans should strive, the consulting company Milliman & Robertson based its benchmarks on the experiences of the 10% of patients in each type of treatment who needed the least amount of care. Thus, if experience showed that 10% of patients could be discharged within one day of an appendectomy, the benchmarks set a goal for discharging appendectomy patients within one day of their surgery.⁵⁰

Empirical studies have supported the contention that only 10% of all hospital treatments provided meet the M&R guideline goals.⁵¹

With hospitalization the most expensive component of health care, guidelines focus on the projected length-of-stay for “the entire spectrum of medical and surgical patients—regardless of the severity of the condition so

46. *Id.* at 1.

47. *Id.* at 2.

48. No guidelines adjusted for comorbidity are provided. Indeed, when developing scientifically valid guidelines for treatments of specific conditions, comorbidity should be excluded to prevent the results from being confounded by the effects of coexistent illnesses and the interaction of multiple treatments. But the Milliman & Robertson estimates of “uncomplicated” cases, especially among those over age 65, are excessive, making the guidelines next to useless and potentially damaging for patients. See generally MILLIMAN & ROBERTSON, INC., *supra* note 45.

49. Myerson, *supra* note 44, at C1 (quoting Gary S. Dorfman, medical society officer and in charge of quality and cost control at Rhode Island Hospital).

50. David Orentlicher, *Paying Physicians More to Do Less: Financial Incentives to Limit Care*, 30 U. RICH. L. REV. 155, n.71 (1996). (quoting Greg Borzo, *R.I. Doctors Face “Absurd” Inpatient Limits*, AM. MED. NEWS, Mar. 21, 1994, at 1, 9).

51. Hirshfeld et al., *Structuring Provider-Sponsored Organizations: The Legal and Regulatory Hurdles*, 20 J. LEGAL MED. 11 (1999).

long as the patient does not develop complications.”⁵² In 1997, the company, supporting its conclusion with six pages of tables, reported that new mothers should be able to be released from the hospital twenty-four hours after an uncomplicated vaginal delivery, and forty-eight hours after a Cesarean.⁵³ The report added that no health status information on mother and newborn nor on post-discharge medical care provided had been considered, but that “such post-discharge care is likely included as medically appropriate for short-stay patients.”⁵⁴ In 1999, the Third Circuit Court of Appeals, in *In re U.S. Healthcare*,⁵⁵ upheld the lower court’s ruling that the twenty-four hour contractual coverage limitation of hospitalization after delivery was a quality of care issue, and thus outside of the scope of the ERISA preemption. Furthermore, the refusal of a requested home visit by a nurse, a covered benefit, was also considered—a *novum* for any court!—a violation of the standard of care. Since the MCO had acted as a “medical provider”, it was not immune to state law medical malpractice claims. Today, forty-two states prohibit “drive-through” deliveries,⁵⁶ and President Clinton’s Newborns’ and Mothers’ Health Protection Act of 1996 has been in effect since January 1, 1998.⁵⁷

4. Guideline Development

How are the Milliman & Robertson guidelines developed? Precise information on the data entering into the guidelines have been difficult to obtain since M&R has limited itself to general statements only. In spite of its claims that “guidelines are developed in accordance with the principles

52. HEALTHCARE MANAGEMENT GUIDELINES, QUESTIONS AND ANSWERS, *supra* note 45, at 6.

53. Frederick W. Spong and Dennis J. Hulet, MILLIMAN & ROBERTSON, INC., RESEARCH REPORT: HEALTH STATUS IMPROVEMENT AND MANAGEMENT HSIM EXTRACT #1 – INPATIENT CARE FOR MOTHERS AND NEWBORNS (1997). The American College of Obstetricians and Gynecologists recommends two days for uncomplicated births and four days for Cesarean sections. German women currently spend an average of four days in the hospital for uncomplicated deliveries.

54. *Id.* at 4.

55. *In re United States Healthcare*, 1999 U.S. App. LEXIS 22464. *U.S. Healthcare Inc. v. Steven Bauman*, 193 F.3d 151 (3d Cir. 1999), *cert. denied*, 68 U.S.L.W. 3552 (U.S. June 19, 2000) (Civil Action No. 99-1383). The newborn Michelina had died of an undiagnosed meningitis the day after she and her mother had been discharged from the hospital 24 hours after delivery.

56. See 2001 STATE GUIDE TO MANAGED CARE LAW, *supra* note 13, at §3.2.

57. *Id.* The Act mandates a minimum stay of 48 hours after a normal vaginal delivery, and a minimum of 96 hours after a Cesarean. Furthermore, no health plan approval is required.

of evidence-based medicine, employing the current best evidence,”⁵⁸ none of the details customarily provided for scientifically derived clinical practice guidelines are made available. Medical literature, especially randomized controlled trials and observational studies in peer-reviewed literature are cited as sources.⁵⁹ But how such data are then aggregated to arrive at the guidelines remains a mystery.⁶⁰ Another source of data for guideline development are utilization review organizations, MCOs and chart reviews of managed care providers.⁶¹ This method relies on insurers’ own decisions instead of scientifically obtained material.⁶² Since all MCOs strive to prevent health care costs from rising by applying increasingly stringent standardized criteria, and their data are returned into the feedback loop for guidelines updates, the standard of care follows the downward spiral.

As M&R admits, the guidelines are targeted at the “financial viability” of the health care system. Actuaries

help measure the financial risks associated with the delivery of health care (e.g. utilization rates, costs, trends, identification of opportunity, volatility, and risk). Actuaries and clinicians together identify the clinical and financial opportunities available, translate these opportunities into specific clinical practices, and measure the financial impact of changes.⁶³

58. James M. Schibanoff, MILLIMAN & ROBERTSON, INC., HEALTHCARE STATUS IMPROVEMENT & MANAGEMENT, PEDIATRIC HSM, (1998).

59. *Id.*

60. For further discussion, *see id.* at 33.

61. HEALTHCARE MANAGEMENT GUIDELINES, QUESTIONS AND ANSWERS, *supra* note 45, at 6.

62. E. Haavi Morreim, *Playing Doctor: Corporate Medical Practice and Medical Malpractice*, 32 U. MICH. J.L. REFORM 939, 983 (1999).

63. HEALTHCARE MANAGEMENT GUIDELINES, QUESTIONS AND ANSWERS, *supra* note 45, at 6. The 2001 edition of *The Managed Health Care Handbook*, edited by a partner in the accounting firm of Ernst & Young “with one of the largest health care consulting practices in the United States”, contains three chapters contributed by authors from Milliman & Robertson. The author of “Actuarial Services in an Integrated Delivery System” discusses how to aid HMOs to select providers to include or exclude from contracting, how to design incentive structures to make regular, budgeted payments or periodic bonus payments to providers from integrated delivery system gains, the design and determination of the value of various provider capitation arrangements, the establishment of financial benchmarks for future measurement, and the quantification of “medical management policy.” Stephen M. Cigich, *Actuarial Services in an Integrated Delivery System*, in *THE MANAGED HEALTH CARE HANDBOOK* 971 (Peter R. Kongstvedt, ed.) (2001).

In 1995, eighteen in-house consultants, nine physicians and nine nurses, “having plenty of clinical and administrative experience especially at health maintenance organizations,” were writing new standards and revising existing ones.⁶⁴ Proposed standards were submitted for review to physicians working for health plans relying on the M&R guidelines but not to medical societies “whose recommendations are invariably more generous than Milliman’s.”⁶⁵ On June 13, 2000, the American Medical Association House of Delegates adopted Resolution 822, introduced by the New York Delegation, and formally rejected “the Milliman & Robertson Guidelines as the clinical standard of care.”⁶⁶

5. The Application of Commercial Guidelines

“Some health plans are apparently using the Milliman & Robertson recommendations as guidelines that should be followed for all patients, unless an extension is justified, rather than as an aspirational benchmark.”⁶⁷ In *Batas v. Prudential*, the plaintiffs alleged the formal guideline application to virtually all subscribers to deny coverage, and without consideration of the treating physicians’ clinical judgment, despite M&R’s caveat that the guidelines are not intended as exclusive criteria.⁶⁸ Humana documents obtained through discovery in cases against Humana Health Insurance and Humana Inc. confirm the trend towards rigid guideline use.⁶⁹

64. Myerson, *supra* note 44, at C1.

65. *Id.*

66. American Medical Association House of Delegates (A-00), Report of Reference Committee H, HOD Action: Original Resolution 822 (Rejection of Milliman & Robertson as Standard of Care).

67. Orentlicher, *supra* note 50, at n.71 (quoting PRIVATE SECTOR ADVOCACY AND SUPPORT TEAM, AM. MED. ASS’N., MANAGED CARE AND THE MARKET: A SUMMARY OF NATIONAL TRENDS AFFECTING PHYSICIANS 2 (2d ed. 1995)).

68. Plaintiff’s Surreply in Opposition to Defendant’s Motion to Discuss the Class Action Complaint at 17 (August 1997), in *Batas v. The Prudential Ins. Co. of Am.*, (N.Y. App. Div., Dept. 1, Index No. 97-107881, IAS Part 49) (filed 1997), *aff’d in part, rev’d in part by Batas v. The Prudential Ins. Co. of Am.*, 281 A.D.2d 260 (N.Y. App. Div. 2001), *motion granted by Batas v. The Prudential Ins. Co. of Am.*, 721 N.Y.S.2d 856 (N.Y. App. Div. 2001).

69. *Chipps v. Humana Health Ins. Co. of Fla.*, (15th Jud. Cir., Palm Beach County, Fla.) (Case No. CL 96-00423 AE) (unreported, filed 1996). The jury awarded the plaintiff \$80 million, and the case was appealed to the Fourth District Florida Court of Appeals. *Humana Health Ins. Co. of Fla. v. Chipps*, 748 So.2d 280 (Fla. 4th DCA 1999)(No. 00-866), *reh’g den.* Oct. 12, 1999, *aff’d in part, rev’d, and remanded by Humana Health Ins. Co. of Fla. v. Chipps*, 802 So.2d 492 (Fla. 4th DCA 2001). *Price et al. v. Humana Inc.*, (S.D. Fla.) (Case No. 9:99-8763 CIV-Moreno) (unreported, filed 1999), *transferred and consolidated In re Humana Inc. Managed Care Litig.*, 2000 U.S. Dist. LEXIS 5099 (2000), *aff’d* 2002 U.S. App. LEXIS (11th Cir. 2002).

After the quarterly earnings of Humana had dropped sharply in early 1995, the company called in the auditing firm Coopers & Lybrand for a utilization management program audit. The Humana utilization management program is centrally administered out of Louisville, Kentucky. Its main components are pre-admission review, telephone pre-certification, concurrent review, case management and written prior authorization. Pre-admission review is conducted by admission coordinators, registered nurses (RNs), licensed practical nurses (LPNs), and supervisors. The Coopers & Lybrand report on the effectiveness of the utilization management program recommended, among other procedures, the more stringent use of commercial guidelines. In order to seize the "tremendous opportunity" of generating additional savings, the patient care coordinators (PCCs), performing concurrent review, should be trained to be more "proactive and aggressive when discussing 'questionable' cases with physicians, and use more aggressive utilization criteria, such as M&R for LOS [length-of-stay] and InterQual for continued stay review *across all markets*."⁷⁰ Furthermore, the nurses' role should be expanded by assigning M&R LOS guidelines for internal management purposes, and by more aggressively addressing "all questionable treatment issues" during the initial contact.⁷¹ "Policies for discharge planning and case management should be reviewed, revised if necessary and reinforced with nurses during training. The revised program should be supported by performance criteria and incentives for the nurses."⁷²

For on-site concurrent review (OSCR), Coopers & Lybrand found that medical necessity criteria were not applied consistently across all markets: Chicago used InterQual SI/IS (severity of illness/intensity of symptoms) criteria while Louisville employed the M&R guidelines. The report recommended more "aggressive" utilization of such criteria for LOS goals, for admission reviews and for continued stay review across all markets was therefore recommended; training OSCR nurses in a "more aggressive review approach"; and developing an "aggressive discharge planning policy that supports the treatment of patients in alternative settings even when in-patient criteria are met."⁷³ The Executive Summary

70. COOPERS & LYBRAND L.L.P., UTILIZATION MANAGEMENT FINAL REPORT 3 (Oct. 17, 1995) (emphasis added) [hereinafter COOPERS & LYBRAND FINAL REPORT].

71. *Id.*

72. *Id.* at 5.

73. *Id.* at 24. The report went on to outline several "corporate issues" needing to be addressed in order to improve the financial performance of the organization. "Many managed care organizations have contractual language which stipulates they will not pay for the admission

concluded that Humana had available a number of opportunities to improve its competitive position through enhanced utilization performance.

Some of these recommendations require a cost benefit analysis before implementation to document the potential financial savings. The process could benefit from a true Business Process Reengineering redesign. The efficiencies gained would then free up existing resources which could be dedicated to the implementation of some of the recommendations in this report which will require additional staffing.⁷⁴

By 1997, the Utilization Management Plan Description for San Antonio and Other Markets listed both M&R Guidelines and InterQual Criteria as inpatient and ambulatory care review decision protocols and criteria for the appropriateness of medical services.⁷⁵ These standards were to be used during review for admission criteria, concurrent review, discharge planning, and the authorization of referrals to specialists and of special procedures. For prior authorization and pre-certification of elective admissions, medical necessity and admission appropriateness were to be determined by the use of "objective criteria" such as M&R and InterQual. Under the concurrent review process, admission and continued stay review relied on M&R Guidelines and InterQual SI/IS criteria for the determination of medical necessity. Concurrent reviews were conducted at specified intervals throughout the in-patient stay, assessing the member's need for hospitalization by "using pre-established objective criteria (InterQual, M&R, and Coverage and Referral Standards)."⁷⁶ "High quality care" is to be assured through "generic outcome screens."⁷⁷

According to the Humana Medical Plan Utilization Management Policy & Procedure Manual for the Northeast Florida market in effect until January 1, 1997, the utilization management of mental health services, delegated to Merit Behavioral Care, was to be monitored by Humana using

even if it was medically necessary when the hospital fails to fulfill its notice obligations. Humana should consider adding such language to its new 'boiler plate' contracts and investigate the feasibility of administering the new policy under its existing agreements. COOPERS & LYBRAND FINAL REPORT, *supra* note 70, at 6.

74. *Id.* at 7.

75. HUMANA HEALTH CARE, HUMANA HEALTH CARE PLAN—SAN ANTONIO AND OTHER DESIGNATED MARKETS—UTILIZATION MANAGEMENT PLAN DESCRIPTION (as approved Mar. 28, 1997) (see Chapter entitled "Screening Criteria" at page 12).

76. *Id.* (see Chapter entitled "Targeted Utilization Management Strategic Plan" at page 13-16).

77. *Id.*

InterQual and M&R Guidelines for the review of 100% of mental health and substance abuse admissions.⁷⁸ The inpatient UM process (for concurrent, prospective, and retrospective medical necessity review) required PCCs to be “thoroughly familiar with InterQual and M&R criteria and their applications.”⁷⁹ PCCs were to review patients’ conditions by applying appropriate InterQual criteria and M&R Guidelines “to determine medical necessity of the admission and appropriateness of the acute setting for concurrent stay review (see InterQual Criteria & M&R Guidelines Manual). [PCC] enters M&R Optimal Recovery Guidelines and assigns LOS. Enters AHDs (Avoidable Hospital Days).”⁸⁰ Among the PCC review activities, the Policies & Procedures Manual lists “onsite admission/subsequent review of the medical record applying appropriate InterQual criteria and M&R Guidelines to determine medical necessity of the admission and appropriateness of the acute care setting.”⁸¹ Cases not meeting the “IS/SI (sic) discharge screens” were to be referred to Medical Directors or PAs (physician advisors). Continued stay reviews were to be conducted Monday through Friday, and results obtained by applying the above guidelines were to be documented.⁸² The Utilization Medical Director’s tasks included the determination of hospital discharges, and “at least bi-weekly ‘grand rounds’ for the review of all inpatients in greater than ten days, all catastrophic cases, and all cases where Market Medical Director intervention may result in more effective utilization, utilizing UM/MD (utilization management/medical director) and Daily Utilization Management Report (DUMR).”⁸³ If the Medical Director determined that “discharge screens are not met,” concurrent reviews were to be continued daily while all information and actions regarding the case were to be documented in Medical Services Review (MSR) “using SI/IS criteria including admission criteria/discharge plan, M&R Criteria and ORGs (optimal recovery guidelines) and LOS.”⁸⁴

78. HUMANA HEALTHCARE, INC., HUMANA MEDICAL PLAN UTILIZATION MANAGEMENT POLICY & PROCEDURE MANUAL FOR THE NORTHEAST FLORIDA MARKET 2/2 (in effect until Jan. 1997) [hereinafter POLICY & PROCEDURE MANUAL FOR THE NORTHEAST FLORIDA MARKET].

79. *Id.* at 1/7.

80. *Id.* at 2/7.

81. *Id.* at 3/7.

82. *Id.* at 4/7.

83. POLICY & PROCEDURE MANUAL FOR THE NORTHEAST FLORIDA MARKET, *supra* note 78, at 4/7.

84. *Id.* at 6/7.

In its Utilization Management Report for the Kansas City and Louisville “markets,” Coopers & Lybrand related that “the case managers are not referring to the M&R guidelines during their inpatient rounds. The case managers use their own judgment in making decision.”⁸⁵ In order to remedy the situation, it was recommended to “reemphasize the use of M&R and InterQual guidelines during concurrent review to ensure process is objective as opposed to subjective”, and to “document when criteria is not met and state rationale when LOS exceeds M&R.”⁸⁶ Another finding was that “PCCs report that network physicians are not supportive and in some cases are openly hostile to utilization management initiatives.”⁸⁷ It was recommended to “conduct focused educational programs with network physicians that stress the importance of their cooperation with utilization management initiatives.”⁸⁸ The Executive Summary emphasized that “PCCs attach M&R guidelines to patient charts. PCCs report that physicians remove the guidelines and/or write inappropriate comments in response. The Medical Director should establish an intervention with uncooperative physicians to resolve this situation. Uncooperative physicians should be identified and the Medical Director should communicate Plan expectations.”⁸⁹

In her trial testimony,⁹⁰ Linda Peeno, M.D., a former medical reviewer/physician advisor with Humana who also worked as case management reviewer for Blue Cross in a hospital setting,⁹¹ commented on the above Coopers & Lybrand audits and recommendations during cross examination:

Q. Is there something inherently wrong with a health care provider, like a hospital or a health insurer, employing accountants to help them be efficient?

85. COOPERS & LYBRAND L.L.P., HUMANA UTILIZATION MANAGEMENT DRAFT REPORT, REGION II, KANSAS CITY AND LOUISVILLE MARKETS 24 [hereinafter HUMANA UTILIZATION MANAGEMENT DRAFT REPORT, KANSAS CITY AND LOUISVILLE].

86. *Id.*

87. *Id.* at 28.

88. *Id.*

89. *Id.* at 12.

90. *Chipps v. Humana Health Ins. Co. of Fla.*, (15th Jud. Cir., Palm Beach County, Fla.) (Case No. CL 96-00423 AE) (unreported, filed 1996). *See also supra* note 69.

91. Dr. Peeno resigned because “I was concerned about the entire way the whole health system was evolving, and I wanted to do something about the consequences to patients.” Record at 1901, in *Chipps v. Humana Health Ins. Co. of Fla.*, (15th Jud. Cir., Palm Beach County, Fla.) (Case No. CL 96-00423 AE) (unreported, filed 1996). *See also supra* note 69.

A. Yes. The way Humana did it with the Coopers & Lybrand audit, there was something inherently wrong with it.

Q. And you know more than Coopers & Lybrand does, right, in terms of their recommendations as to efficiency?

A. Yes. I know that they're an accounting firm that comes in and does an audit of how these utilization management procedures function, and the audit constitutes what is the denial rate and how much money are you saving, and what you do to save more money. And I read through the voluminous report, and there wasn't a single sentence in this entire report that addressed how patients were being cared for, it was all cost driven. So yes, there is something inherently wrong with having an accounting firm come in and tell Humana how to take care of its patients, when it's all cost driven.

Q. Do you know how many doctors were employed by Coopers & Lybrand for their aid and assistance in the audit that was performed on behalf of Humana?

A. No, not exactly. I'm sure several though.

Q. So there were obviously medical people involved, not just accountants. You understand that, do you not?

A. Well, that's kind of a bizarre notion to have medical doctors working for an accounting firm anyway, so I mean, I think that's an inherent conflict.

Q. Well, you have accountants working for the hospital with which you're affiliated. That's no less bizarre, is it?

A. The accountants aren't at the bedside of patients and telling doctors what to do and making judgments about how doctors are practicing medicine.

What I think happened was they came in, they went to the utilization management department, they said okay, how many denials, what's your percent of denials? Well, that's not high enough, that's not industry standard, so let's decrease or increase the rate of denials, let's decrease how many people you admit to the hospital, let's decrease how many days they stay.

And then they went through and calculated and produced a mechanism to do that. They might as well have been standing by the bedside telling the patients they couldn't come into the hospital, they had to leave.⁹²

On re-direct examination:

Q. Dr. Peeno, if Humana was truly, truly concerned with the quality of care of its members, how would a cost benefit analysis apply?

A. It wouldn't. I mean, they would be doing something different, they would be looking at the care of patients, not just the cost.

Q. Would one associate cost benefit analysis with a 'machinery of denial' and treating people like nothing more than widgets moving down an assembly line?

A. That's exactly—I mean, it's just like a factory. You do a cost benefit analysis, we're going to hire these new people, and what they're going to do is this is going to justify the money we make or the money we lose. I mean, it's all cost based.

Q. And let's look at some of the issues that corporate was reviewing, corporate issues [refers to notice provision in new boiler-plate contracts that Humana will not pay for a hospital admission if the hospital failed to fulfill its notice obligation, regardless of medical necessity].

92. Record at 1904-1907, in *Chippis v. Humana Health Ins. Co. of Fla.*, (15th Jud. Cir., Palm Beach County, Fla.) (Case No. CL 96-00423 AE) (unreported, filed 1996). See also *supra* note 69.

A. This is clearly they're not acting in the best interests of the patient. That's a little financial technicality that they can create in order to avoid some of the hospital costs.⁹³

6. Commercial Guidelines in the Court Room

Because of the ways commercially sold guidelines are developed and used, they are now cited in numerous lawsuits as violating the medical necessity standard promised to subscribers in managed care plan documents. In *Weiss v. CIGNA*, general allegations were made that the "highly controversial" actuarial M&R guidelines had been improperly used for medical determinations instead of generally accepted standards, as required by the plaintiff's plan.⁹⁴ The judge, however, dismissed the breach of contract claim since Weiss had not alleged that "CIGNA relies on such guidelines to the exclusion of other factors," nor had she alleged an "injury in fact" arising from the company's medical necessity determinations departing from "generally accepted medical standards." Therefore, the case or controversy requirement for an ERISA §502(a) claim had also not been met. Since then, claims detailing the exclusive use of the guidelines and the scientific inadequacy of their development resulting in standard of care violations have become increasingly specific.

The complaint filed in *Price v. Humana Inc.*, one of several class action suits against managed care corporations consolidated for multidistrict pretrial proceedings in the Southern District of Florida,⁹⁵ referred to "undisclosed cost-based criteria" used by the MCOs in place of or in addition to the medical necessity criteria set forth in the health plan documents. It alleged actionable material omissions and misrepresentation to the class in that the M&R guidelines, InterQual and Value Health Services (VHS) guidelines and criteria were used for the approval or denial of benefit claims. The complaint further alleged that such guidelines were developed by third parties for the purpose of reducing the utilization rates of care, and were used by Humana without regard to actual medical

93. *Id.* at 1935, 1936.

94. *Weiss v. CIGNA Healthcare Inc.*, 972 F. Supp. 748, 755 (S.D.N.Y. 1997).

95. The defendants are Humana Inc., Aetna Inc., Aetna U.S Healthcare Inc., CIGNA Corp., Prudential Ins. Co., PacifiCare, and United HealthGroup, Inc. On Oct. 23, 2000, the Judicial Panel on Multidistrict Litigation ordered the consolidation of all actions into MDL-1334—*In re Humana Inc. Managed Care Litigation*. *In re Humana Inc. Managed Care Litigation*, 2000 U.S. Dist. LEXIS 5099 (2000).

necessity.⁹⁶ Disclosure documents were found devoid of information concerning subcontracts with third parties such as VHS, using more restrictive criteria for payment eligibility determinations for certain medical conditions and procedures than the Humana medical necessity criteria.⁹⁷

The Reply Memorandum in Support of Plaintiff's Motion for Class Certification⁹⁸ listed exhibits indicating the following: "Milliman & Robertson guidelines are used in the review process across all markets,"⁹⁹ "It is the policy of the Utilization Management Department to assure that concurrent review data entry is relevant, concise, and based on criteria developed by Milliman & Robertson or Interqual Criteria,"¹⁰⁰ "Humana's registered nurses use Interqual criteria for medical necessity review,"¹⁰¹ Value Health makes coverage determinations based on "*clinical standards of care* (emphasis added) developed by VHS and its medical advisors,"¹⁰² "VHS estimates that the Medical Review System saved its clients \$67.5 million in 1995. The MRS consistently resulted in a direct savings of approximately 9% after physician review,"¹⁰³ "A preadmission review nurse . . . compares the indications for hospital admission or surgery with nationally-established medical/surgical screening criteria to determine medical necessity."¹⁰⁴ The Humana Job Description of a Patient Care Coordinator in Medical Services includes: "Perform daily admission and concurrent review for hospitalized patients using standard review criteria to

96. Complaint at 40-41, 46, in *Price et al. v. Humana Inc.*, (S.D. Fla.) (Case No. 9:99-8763 CIV-Moreno) (unreported, filed 1999), *transferred and consolidated In re Humana Inc. Managed Care Litig.*, 2000 U.S. Dist. LEXIS 5099 (2000), *aff'd* 2002 U.S. App. LEXIS (11th Cir. 2002).

97. *Id.* at 42.

98. Documents include Reply Memorandum of Law in Support of Plaintiff's Motion for Class Certification, Attachment 1 to Reply Memorandum, Exhibits to First Amended Complaint and Plaintiff's Memorandum in Support of Class Certification in *Price et al. v. Humana Inc.*, (S.D. Fla.) (Case No. 9:99-8763 CIV-Moreno) (unreported, filed 1999), *transferred and consolidated In re Humana Inc. Managed Care Litig.*, 2000 U.S. Dist. LEXIS 5099 (2000), *aff'd* 2002 U.S. App. LEXIS (11th Cir. 2002).

99. *Id.* at Appendix Exhibit 5 (Coopers & Lybrand Utilization Management, Aug. 14, 1996, at 9).

100. *Id.* at Appendix Exhibit 28 (Humana Health Care Plans Policies/Procedures. Documents Concerning Humana's Use of Undisclosed Cost-Based Criteria).

101. *Id.* at Appendix Exhibit 5 (Coopers & Lybrand Humana Medical Affairs Department Review, Nov. 21, 1996, at 14).

102. Reply Memorandum of Law in Support of Plaintiff's Motion for Class Certification, *supra* note 98, at Appendix Exhibit 5 (Humana Inc. and Value Health Services Medical Review System Agreement, Nov. 15, 1990, at 2).

103. *Id.* (Value Health Sciences Corporate Overview, 1997).

104. *Id.* (Humana Physician's Administration Manual, GL-2, May 1996).

determine the medical necessity and appropriateness of care. A PCC must have an active LPN/RN [licensed practical nurse/registered nurse] license, BSN preferred,"¹⁰⁵ "Primary care physicians receive regular reports outlining the utilization of health care services for their patient panel . . . Profiles are developed to identify aberrant practice patterns and who may require orientation, counseling, education, corrective actions or sanctions,"¹⁰⁶ and

The *physician targeting program* [emphasis added] selects HMO primary care physicians or staff model centers where the inpatient utilization exceeds preestablished norm . . . The performance of the targeted physicians is reviewed every four to six weeks by Dr. Langford [*sic*] . . . The Executive Director and Medical Director of each market are then notified about which physicians are on the target lists.¹⁰⁷

In *Batas, Vogel v. Prudential*,¹⁰⁸ a class action suit currently before the Appellate Division, New York Supreme Court, the complaint on behalf of all subscribers of health care plans offered by Prudential alleged that the MCO breached its contract with subscribers by using medical necessity determination procedures, based on the M&R length-of-stay criteria,¹⁰⁹ and in violation of the prevailing standard of care, expressly or impliedly promised in the subscriber agreements. In the agreement entered into by Musette Batas, representative of the standard contracts for Prudential

105. *Id.*

106. *Id.* (Utilization Management Plan Description, 1997, at 26).

107. Reply Memorandum of Law in Support of Plaintiff's Motion for Class Certification, *supra* note 98, at Appendix Exhibit 5 (Coopers & Lybrand Humana Utilization Management Program, at 15).

108. *Batas v. The Prudential Ins. Co. of Am.*, (N.Y. App. Div., Dept. 1, Index No. 97-107881, IAS Part 49) (filed 1997), *aff'd in part, rev'd in part by Batas v. The Prudential Ins. Co. of Am.*, 281 A.D.2d 260 (N.Y. App. Div. 2001), *motion granted by Batas v. The Prudential Ins. Co. of Am.*, 721 N.Y.S.2d 856 (N.Y. App. Div. 2001).

109. Prudential entered into licensing agreements with M&R in 1992 and 1995, eventually comprising all guideline volumes and their electronic versions. See Letter from M&R to Steven Udvarhelyi, M.D., Vice President, Medical Services, The Prudential Insurance Company of America (Feb. 26, 1992), Letter from M&R to Kay Volkert, Manager, Medical Services, Utilization Management, The Prudential Insurance Company of America (Oct. 13, 1995), Memorandum of Law in Support of Motion for Class Certification, at 5, n.6 (Sept. 21, 1999), all available in *Batas v. The Prudential Ins. Co. of Am.*, (N.Y. App. Div., Dept. 1, Index No. 97-107881, IAS Part 49) (filed 1997), *aff'd in part, rev'd in part by Batas v. The Prudential Ins. Co. of Am.*, 281 A.D.2d 260 (N.Y. App. Div. 2001), *motion granted by Batas v. The Prudential Ins. Co. of Am.*, 721 N.Y.S.2d 856 (N.Y. App. Div. 2001).

plans, services and supplies not needed nor appropriately provided were excluded from coverage. The contract specified:

For the purposes of this exclusion, a service will be considered both “needed and appropriately provided” if PruCare determines that it meets each of the following requirements:

It is *furnished or authorized by a Participating Physician* for the diagnosis or the treatment of a sickness or injury or for the maintenance of a person’s good health [emphasis added].

The *prevailing medical opinion within the appropriate specialty of the United States medical profession* that it is safe and effective for its intended use, and that its omission would adversely affect the person’s medical condition [emphasis added].

It is furnished by a provider with *appropriate training, experience*, staff and facilities to furnish that particular service or supply [emphasis added].¹¹⁰

The contract also listed the sources to be relied on when determining whether the above requirements have been met: published authoritative medical literature; regulations and reports issued by government agencies such as the Agency for Health Care Policy and Research (AHCPR),¹¹¹ the National Institutes of Health (NIH), the Food and Drug Administration (FDA); and listings in the American Medical Association Drug Evaluations, and The United States Pharmacopeia Dispensing Information.¹¹²

The lower court upheld the fraud and breach of contract claims against Prudential. The complaint, distinguishing the case from *Weiss v. CIGNA*,¹¹³ detailed the alleged exclusive use of the M&R guidelines for medical necessity determinations in spite of the actuarial firm’s statement that they are not intended to replace the treating physician’s clinical

110. *Id.* at 3.

111. Now the Agency for Healthcare Research and Quality (AHRQ).

112. Reply Memorandum of Law in Support of Plaintiff’s Motion for Class Certification, *supra* note 98, at Appendix Exhibit 28 (Humana Health Care Plans Policies/Procedures. Documents Concerning Humana’s Use of Undisclosed Cost-Based Criteria, at 3).

113. *Weiss*, 972 F. Supp. 748.

judgment.¹¹⁴ Furthermore, it alleged that the guidelines were rigidly applied by a Prudential concurrent review nurse to limit the plaintiffs' hospital length-of-stay without consideration of her individual circumstances, and against the vehement opposition of the attending physicians, "participating physicians" under the plan. The Memorandum of Law in Support of the Motion for Class Certification also alleged that Prudential adopted a company-wide policy for its utilization review staff for all plans to rely on the M&R guidelines,¹¹⁵ and conducted uniform training for guideline use.¹¹⁶ Preauthorization personnel was held to evaluate the medical necessity of hospital admission "by using the M&R guidelines and the Prudential Medical/Surgical guidelines," then to use "M&R guidelines to determine appropriateness of setting and length of stay (LOS)."¹¹⁷ Once a patient was hospitalized, concurrent review nurses were to decide whether the preauthorized length of stay may be exceeded. When making such medical necessity determinations, the nurses could consult with Prudential Medical Directors who orally confirmed "denials of care without examining any medical records, examining the patients or consulting with the patient's treating physician."¹¹⁸ Medical Directors were authorized to deny care based on the M&R guidelines for cases outside of their own specialty: a psychiatrist refused to extend Ms. Vogel's hospitalization after she had undergone a complicated hysterectomy for the removal of uterine tumors, weighing over three-and-a-half pounds.

The decision to discharge Ms. Vogel only two days after her hysterectomy (in agreement with the M&R recommendation) was opposed by Dr. Vetere, Ms. Vogel's attending surgeon, a gynecologist with 20 years of surgical experience and Assistant Professor of Clinical Obstetrics and Gynecology at the State University of New York at Stony Brook.

114. *Batas v. The Prudential Ins. Co. of Am.*, (N.Y. App. Div., Dept. 1, Index No. 97-107881, IAS Part 49) (filed 1997), *aff'd in part, rev'd in part by Batas v. The Prudential Ins. Co. of Am.*, 281 A.D.2d 260 (N.Y. App. Div. 2001), *motion granted by Batas v. The Prudential Ins. Co. of Am.*, 721 N.Y.S.2d 856 (N.Y. App. Div. 2001).

115. *supra* note 94, at 5.

116. *Id.* at 6.

117. "Operating Procedures, Preauthorization of Schedule Inpatient Services" for PruCare of New York, New Jersey and Connecticut (Apr. 17, 1996). Memorandum of Law in Support of Motion for Class Certification at 6 (Sept. 21, 1999). Both available in *Batas v. The Prudential Ins. Co. of Am.*, (N.Y. App. Div., Dept. 1, Index No. 97-107881, IAS Part 49) (filed 1997), *aff'd in part, rev'd in part by Batas v. The Prudential Ins. Co. of Am.*, 281 A.D.2d 260 (N.Y. App. Div. 2001), *motion granted by Batas v. The Prudential Ins. Co. of Am.*, 721 N.Y.S.2d 856 (N.Y. App. Div. 2001).

118. Reply Memorandum of Law in Support of Plaintiff's Motion for Class Certification, *supra* note 98, at Appendix Exhibit 5 (Coopers & Lybrand Humana Utilization Management Program, at 15).

A surgical case with Ms. Vogel's specific circumstances is at increased risk for significant postoperative complications Although one or two of these complications might be evident with 48 hours of surgery, the vast majority will not produce signs of symptoms for at least four to five days postoperatively."¹¹⁹

Generally accepted medical practice following Ms. Vogel's complicated surgery required "around the clock monitoring and evaluation by experienced gynecological nurses and resident gynecological physicians in addition to the one or two daily postoperative visits made by the attending surgeon" for at least five days. According to Dr. Vetere, such care is essential because the patient may develop complications not amenable to self-diagnosis, leading to costly delays of the needed medical attention.¹²⁰

In the course of the appeals procedure initiated by Ms. Vogel, Dr. Vetere was informed by the Chief Medical Officer of Prudential that the company, based exclusively on the M&R guidelines, had preauthorized a two-day hospitalization for a total abdominal hysterectomy.¹²¹ Prudential's refusal to continue coverage after two days complied with the Concurrent Review Nurse's decision. "Remarkably, no effort was made to either examine the patient or discuss her condition with me."¹²²

Aside from the fact that I disagreed with the medical conclusions reached by Prudential's Concurrent Review Nurse concerning the medical needs of my patient, I also object to the process used by Prudential for reaching and implementing this decision. In particular, it is a gross violation of acceptable medical protocols for a medical necessity determination such as this to be made by

119. "These complications include, but are not limited to, postoperative hemorrhage, including retroperitoneal and/or wound hematoma (with or without infection), seroma, bowel and bladder dysfunction, wound infection, wound separation, pelvic cellulitis, tubo-ovarian abscess, and pelvic thrombophlebitis with or without pulmonary embolism. Although most of these complications are uncommon, some are life-threatening if not discovered and treated early." Affidavit of Patrick F. Vetere in Support of Plaintiff's Opposition to Defendant's Motion to Dismiss, at 4 (July 30, 1997), in *Batas v. The Prudential Ins. Co. of Am.*, (N.Y. App. Div., Dept. 1, Index No. 97-107881, IAS Part 49) (filed 1997), *aff'd in part, rev'd in part by Batas v. The Prudential Ins. Co. of Am.*, 281 A.D.2d 260 (N.Y. App. Div. 2001), *motion granted by Batas v. The Prudential Ins. Co. of Am.*, 721 N.Y.S.2d 856 (N.Y. App. Div. 2001) [hereinafter Affidavit of Patrick F. Vetere].

120. Affidavit of Patrick F. Vetere, *supra* note 119, at 4-5.

121. *Id.* at Exhibit 4 (dated June 28, 1996).

122. Affidavit of Patrick F. Vetere, *supra* note 119, at 8.

someone who is not even a physician, let alone one who is trained and experienced in the medical condition at issue Moreover, . . . Prudential did not even consult with a trained gynecologist with experience in these types of operations prior to deciding that further hospitalization was not medically necessary.¹²³

Musette Batas, another example among Dr. Vetere's patients for improper Prudential "interference with the practice of medicine" and whose "health was threatened as a result of Prudential's improper conduct,"¹²⁴ suffered from Crohn's disease, a painful, potentially life-threatening bowel disease. When six months pregnant, her baby at risk as well, she was hospitalized for severe pain, but in spite of persistent severe pain, had to be discharged after two days because Prudential refused additional coverage. Barely one week later, she was readmitted through the emergency room. One of Dr. Vetere's colleagues immediately applied for permission to perform an exploratory laparotomy. Two days and several phone calls later, the hospital having been told that the request was "pending" and "waiting for Prudential's bureaucratic machinery to move," the patient's intestine burst, requiring immediate emergency surgery. Because of the considerable risk of infection, her life was at stake. In addition, the attending surgeon did not expect the baby to survive, and if it would, felt that brain damage might occur.¹²⁵ Four days after the initial request for exploratory surgery authorization and two days after the emergency procedure, Prudential approved the exploratory surgery. Four days after the emergency surgery, the Concurrent Review Nurse called the attending surgeon's office to "demand" the patient's discharge. Only after the physician "expressed outrage at this decision, explaining to Ms. . . .

123. *Id.* at 7, 8. In addition, Dr. Vetere received a letter from Prudential, indicating that a company physician wanted to discuss his apparent dissatisfaction with his "contracted status as a participating physician in the Prudential network", and the desire to speak with the head of Dr. Vetere's department at S.U.N.Y. to confirm whether Dr. Vetere was speaking on behalf of the department when complaining to the Prudential Executive Director about the handling of Ms. Vogel's case. *Id.* at Exhibit 2 (dated May 31, 1996). "I took this request as a veiled threat that she could retaliate against me for objecting to Prudential's mistreatment of my patient." *Id.* at 6.

124. *Id.* at 8.

125. Affidavit of Musette Batas in Support of Plaintiffs' Opposition to Defendant's Motion to Dismiss, at 6, 10 (Aug. 4, 1997), in *Batas v. The Prudential Ins. Co. of Am.*, (N.Y. App. Div., Dept. 1, Index No. 97-107881, IAS Part 49) (filed 1997), *aff'd in part, rev'd in part by Batas v. The Prudential Ins. Co. of Am.*, 281 A.D.2d 260 (N.Y. App. Div. 2001), *motion granted by Batas v. The Prudential Ins. Co. of Am.*, 721 N.Y.S.2d 856 (N.Y. App. Div. 2001) [hereinafter Affidavit of Musette Batas].

[the Concurrent Review Nurse] that I was barely out of surgery, was pregnant and was seriously ill, Prudential backed down."¹²⁶

One week later, the same nurse decided, based on a review of the medical chart and "internal guidelines" never disclosed to the patient, that she had to leave the hospital. The patient acquiesced, fearing the financial burden of out-of-pocket payments for continued hospitalization. In his affidavit, Dr. Vetere disputed Prudential's

right to make such critical medical determinations based on third party guidelines that are not even interpreted by properly trained physicians . . . [h]ad I acted with regard to my patient as it [Prudential] had, I would have committed an act of malpractice. In my opinion, Prudential has done just that.¹²⁷

Dr. Vetere's office manager eventually reported to Prucare the physicians' dissatisfaction with the way the company's medical management division had handled five patients, both plaintiffs included. "We have been told on more than one occasion that 'it doesn't matter how the patient feels or what the doctor feels is medically necessary, it is what Prucare feels is medically necessary.'"¹²⁸

*Johnson v. Humana*¹²⁹ also concerned a hysterectomy. Karen Johnson was diagnosed with cervical cancer *in situ* with endocervical gland extension. Even though her attending physicians considered a hysterectomy medically necessary, Humana only approved a cervical conization. Ms. Johnson paid for the recommended procedure out-of-pocket.¹³⁰ Prior to the denial, she was called by Humana nurses who, in a recorded conversation, asked questions prompted by the VHS software to derive a "profile" which was faxed to VHS reviewers in California, all of them non-practicing physicians. The reviewers generally made treatment decisions without evaluating patients' medical records, followed instructions not to speak with them, and denied or approved claims after a—taped—interview with the treating physician, and a brief review of the

126. Affidavit of Musette Batas, *supra* note 125, at 7.

127. Affidavit of Patrick F. Vetere, *supra* note 119, at 10.

128. *Id.* at Exhibit 5 (dated April 18, 1996).

129. *Johnson v. Humana Health Plan*, (Jefferson Circuit Ct., Ky.) (Case No. 96-CI-00462 (Jan. 23, 1997) (unreported)).

130. For the approved conization, an out-patient procedure, Humana would have had to spend \$787, a discounted \$7,000 for the in-patient hysterectomy. Ms. Johnson, who did not receive a discount, was charged more than \$14,000. Brief for Appellee Johnson, at 4, in *Humana Health Plan v. Johnson* (Ky. Ct. App.) (Case No. 99-CA-166) (unreported) [hereinafter Brief for Appellee Johnson].

“profile.” Also, Humana instructed Ms. Johnson not to obtain a second opinion even though more than ninety gynecologists would have been available for second opinions, based on an actual examination of the patient and of her record for less than what Humana paid VHS.¹³¹ Humana thus relied on the VHS denial even though the VHS contract advised that the medical review system is “not intended as a replacement for the exercise of medical judgment by the treating health care professional.” VHS furthermore pointed out that “there is no assurance that every variable that may bear on appropriateness or effectiveness is known or has been considered by VHS, that the course of treatment is ideal or appropriate for any particular covered person, or that any treatment will be successful.”¹³²

The Brief for Appellee stated that Humana had identified hysterectomies as “high-cost” and contracted with Value Health Services (VHS) to review treatment requests for such procedures.¹³³ The denial rate was a consistent 25%, compared with a national average of 1.2% for patients with Ms. Johnson’s condition. One of the VHS physician reviewers admitted that, based on the VHS computer program and company policy, no patient with Ms. Johnson’s condition would be approved for a hysterectomy without having undergone a conization first.¹³⁴ National Cancer Institute guidelines, however, consider a hysterectomy the appropriate treatment for patients with the plaintiff’s condition. Furthermore, an expert testified at trial that a hysterectomy was the standard of care and the cure for Ms. Johnson’s stage zero carcinoma, compared with a recurrence rate of over 30% for conization.¹³⁵

In addition, none of the VHS reviewers were aware of Humana’s medical necessity definition, and, as a consequence, “used their own definitions of the standard of care rather than what language was contained

131. *Id.* at 3, n.5, 11.

132. *Id.* Leslie D. Michelson, however, then Chairman and CEO of VHS and one of its founders, underlined the following virtues of the Medical Review System: “It uses very specific, very scientific criteria that would distinguish between candidates who would benefit from a medical procedure, and those who would be adversely affected by it.” Ronald Shinkman, *Enterprise: Computers Get Into Disease Management*, 17 L.A. BUS. J. 1, No. 34, Aug. 21, 1995. In 1996, Mr. Michelson added, “A system such as the MRS is valuable because the medical community doesn’t always have enough current information to know precisely what interventions are optimal for which patients and when. Healthcare technology is evolving with unprecedented speed. The MRS helps physicians stay on top of all of those developments.” PR Newswire, *One Millionth Case Goes Through Value Health Sciences’ Medical Review System*, FIN. NEWS (May 20, 1996).

133. Brief for Appellee Johnson, *supra* note 130, at 3.

134. *Id.* at 5. This means in practice that a patient must have a recurrence of her cancer before a hysterectomy will be approved.

135. *Id.* at 6, 8.

in her [Ms. Johnson's] own contract with Humana."¹³⁶ Dr. Lankford, Humana Senior Vice President for Medical Affairs at the time, testified:¹³⁷

Q. Does it disturb you at all if I told you that the doctors at VHS did not understand the definition of medical necessity in Karen Johnson's contract of insurance?

No, we didn't ask vendors to understand our contracts. That was part of keeping the administrative process back here, both the overview of the material and any negative decision making had to be here because that all had to be done internally. We just asked the outside vendors for *clinical expertise* – (emphasis added)

So it did not matter to you whether they were applying a different definition of medical necessity than was in her contract?

No. I don't care what they thought about that issue. My physician director would have clarified it and made the right final decision, that's what their job was here.

Would it matter to you at all if Doctor Maroc testified that in this case that he does not – he did not know at the time he reviewed Karen Johnson's case what the definition of medical necessity was in her contract?

A. Each of—the management process was to look at the contracts before denying it. So if there was anything unusual from what he had been taught, it would have been flagged to him. Whether or not he reviewed the actual document is—is not the issue. There was a process for him to do it. I didn't have the physicians look at individual contracts, the staff did that in the department.

Dr. Maroc, the Humana physician responsible for the final treatment “review” decision who relied on the VHS denial, defined medical necessity during deposition as “a situation where care needs to be provided to

136. *Id.* at 3.

137. Deposition of Ronald D. Lankford at 156, 157 (Dec. 15, 1997), in *Johnson v. Humana Health Plan*, (Jefferson Circuit Ct., Ky.) (Case No. 96-CI-00462 (Jan. 23, 1997) (unreported) [hereinafter Deposition of Ronald D. Lankford]).

prevent loss of life or limb or to prevent excessive morbidity from occurring.”¹³⁸ He admitted that he was unaware of the definition laid down in the patient’s insurance policy (“I didn’t pay any attention to the insurance agreement”¹³⁹):

To be medically necessary a service or supply must be:

A. consistent with the symptoms or diagnosis and treatment of the member’s sickness and injury; and

B. appropriate with regards to the standards of good medical practice.

Dr. Lankford later testified:

A. . . . Medical necessity as he [Dr. Maroc] mentioned is an issue to do with the cost of doing the therapies. So there is always a certain rate of mortality and morbidity associated with treatments and that has to be balanced in some fashion with the outcomes. . . . And then as we formalize things in the practice guidelines, or in this case using the VHS system which was a formalized practice guideline system, you rely on that system to consistently make that decision.

Q. Does Dr. Maroc’s definition of medical necessity have anything to do with whether or not the procedure is consistent with good medical practice?

A. Dr. Maroc’s decision was not critical in this case. The clinical decisionmaking was by a screening process in the VHS system, followed by the clinical review by the physicians that were board-certified and . . . were familiar with the VHS system. Dr. Maroc’s part of the job was to ensure that the processes in that department were going well relative to how the reviews were done He was not making clinical decisionmaking.¹⁴⁰

138. *Id.*

139. Deposition of James A. Maroc, at 101 (Jan. 23, 1997), in *Johnson v. Humana Health Plan*, (Jefferson Circuit Ct., Ky.) (Case No. 96-CI-00462 (Jan. 23, 1997) (unreported).

140. Deposition of Ronald D. Lankford, *supra* note 137, at 159-60.

None of the Humana physicians participating in the decision making process were gynecologists, nor were they in practice.¹⁴¹ They received a salary of \$100,00 plus \$5,000 bonuses for limiting hospital admissions and lowering the numbers of hospital days of Humana patients. For denying Ms. Johnson's four-day hospitalization for a hysterectomy, Dr. Maroc was compensated with two such bonus payments.¹⁴² The Circuit Court jury found the Humana denial of the hysterectomy to be an act of bad faith, and awarded the plaintiff \$14,000, the cost of the procedure, \$100,000 for mental suffering, and \$13 million in punitive damages. The case reportedly was settled for more than \$2 million.¹⁴³

For the first time, a lawsuit has now been filed directly against one of the vendors of commercial guidelines, the actuarial firm Milliman & Robertson. The plaintiffs in *Cleary, Riley v. Milliman & Robertson*,¹⁴⁴ two pediatricians, are suing the company for defamation, appropriation of name, tortious interference with contract of employment, civil conspiracy, and fraud and deceit. According to the complaint, M&R listed both Drs. Cleary and Riley¹⁴⁵ without their consent as contributing authors of the pediatric guidelines, published in 1998.¹⁴⁶ In their affidavits, both physicians stated that at no time were they made aware of nor did they give their approval for the use of their names and professional reputations (the volume lists both plaintiffs as the only experts in their respective fields) in support of the M& R pediatric guidelines.¹⁴⁷ On November 13, 1999, a

141. When Humana hired Dr. Maroc, the corporation was aware that his license was on probation in Iowa, and that he was not licensed to practice medicine in Kentucky. Nineteen months later, at the time of the court proceedings, his status had not changed. *Johnson v. Humana Health Plan*, (Jefferson Circuit Ct., Ky.) (Case No. 96-CI-00462 (Jan. 23, 1997) (unreported).

142. *Id.*

143. 4(18) Mealy's Managed Care Liability Report 15 Sept. 29, 2000.

144. Plaintiff's First Amended Petition, in *Cleary v. Milliman & Robertson*, (Dist. Ct., Harris County, Tex.) (Case No. 99-56719) (unreported, decided 2000) [hereinafter Plaintiff's First Amended Petition].

145. Thomas G. Cleary, M.D., is Board Certified in Pediatrics and Pediatric Infectious Diseases with the American Academy of Pediatrics. He is tenured Professor of Pediatrics, Division of Infectious Diseases, at the University of Texas Medical School, Houston. William J. Riley, M.D., is Board Certified in Pediatrics and Pediatric Endocrinology with the American Academy of Pediatrics. He was tenured Professor of Pediatrics at the University of Texas - Medical School, and currently serves as Vice President of Medical Education at Driscoll Children's Hospital in Corpus Christi, Texas.

146. Schibanoff, *supra* note 58.

147. Affidavit of Thomas C. Cleary (Nov. 11, 2000) in *Cleary v. Milliman & Robertson*, (Dist. Ct., Harris County, Tex.) (Case No. 99-56719) (unreported, decided 2000) [hereinafter Affidavit of Thomas C. Cleary]; Affidavit of William J. Riley (Nov. 10, 2000) in *Cleary v.*

temporary injunction ordered M&R to cease publication of the *Health Care Status Improvement & Management (HSIM)* showing both plaintiffs as contributing authors. The amended complaint¹⁴⁸ asks for exemplary damages under the Texas Civil Practice & Remedies Code, for punitive damages, and a full injunction against M&R to cease use and publication of plaintiffs' names as well as a recall from the stream of commerce all *Pediatric HSIM* volumes listing them as contributing authors.

Both plaintiffs have denounced the guidelines as seriously flawed and dangerous to pediatric patients. Dr. Cleary, after examining the proposed guidelines pertaining to infectious diseases sent to him by Dr. Yetman, one of the defendants, had provided the feedback that "the proposed guidelines were dangerous and would harm kids. I recall that my words to him were that 'children may die because of these guidelines.'"¹⁴⁹ He added in his affidavit,

The published *Pediatric HSIM* are seriously flawed in their approach to in-patient pediatric care. In my professional opinion, the guidelines, overall, have a tendency to mislead the user by understating the actual length of stays that are required and are appropriate for seriously ill children. In regard to my particular area of medical specialty, there are in-patient guidelines and goal lengths of stay for multiple serious pediatric infectious diseases that are severely out-of-line with the standard of pediatric care. As written, these guidelines pose significant risks of harm, death and/or serious injury to children. Dangerous guidelines include those for: endocarditis, brain abscess, septic arthritis, osteomyelitis, neonatal sepsis, neonatal meningitis, and meningitis in the older child.¹⁵⁰

For some illnesses, Dr. Cleary would recommend six weeks of hospitalization while the guidelines suggest three days.¹⁵¹ The pediatrician

Milliman & Robertson, (Dist. Ct., Harris County, Tex.) (Case No. 99-56719) (unreported, decided 2000) [hereinafter Affidavit of William J. Riley].

148. Plaintiff's First Amended Petition, *supra* note 144.

149. Affidavit of Thomas C. Cleary, *supra* note 147, at 2; Plaintiff's First Amended Petition, *supra* note 144.

150. Affidavit of Thomas C. Cleary, *supra* note 147, at 2.

151. Mary Flood, *Doctors Say Book Misused Their Names*, THE WALL STREET J., Nov. 17, 1999, at T1.

also found “at least one risky recommendation on each page of the 400-page document.”¹⁵²

Dr. Riley, who had been asked to write and review two pediatric endocrinology sections, assumed that the project had been abandoned since he received no response to his first draft. In his affidavit, Dr. Riley “vehemently” disagreed with and disavowed in particular the guideline concerning the in-patient care of diabetic ketoacidosis:

This section, as published, poses a significant risk of harm to pediatric patients who might suffer from diabetic ketoacidosis. In fact, the *Guidelines* suggest that for admission to ICU for coma from this condition that the goal length of stay is (1) day. This is so clearly outside of any reasonable approach to the standard of care as to be wholly reckless, without regard to the safety of any child with severe DKA. I am professionally and personally shocked and distraught that my name would be listed as the only endocrine pediatric specialist on a volume that contains such an outrageously irresponsible and dangerous recommendation.¹⁵³

Both physicians expressed mental anguish, embarrassment and humiliation arising from the association of their names and reputations with guidelines posing potential harm to children.

An additional possibly revealing aspect of the legal action is the question whether M&R “tried to buy scientific legitimacy by giving \$100,000 to the pediatrics department at University of Texas Houston in exchange for the schools stamp of approval.”¹⁵⁴ The department is listed as the co-presenter of the *Pediatric HSIM* in the first sentence of the preface¹⁵⁵ but what precise role it actually played in the issuance of the guidelines and whether some of the faculty were manipulated into becoming contributing authors remains to be seen. Dr. Cleary suspected that M&R might have wanted the cachet of medical school research to stave off “a firestorm of anger” at the proposition that pediatric care might be withheld for cost-

152. Ron Nissimov, *Cost-Cutting Guide Used by HMOs Called “Dangerous,”* HOUSTON CHRON., March 5, 2000, at A1 [hereinafter *Cost-Cutting Guide Used by HMOs Called “Dangerous”*].

153. Affidavit of William J. Riley, *supra* note 147, at 2.

154. *Cost-Cutting Guide Used by HMOs Called “Dangerous,” supra* note 152.

155. Ron Nissimov, *Judge Tells Firm to Explain How Pediatric Rules Derived*, HOUS. CHRON., Nov. 3, 2000, at A35 [hereinafter *Judge Tells Firm to Explain How Pediatric Rules Derived*]. Upon request by the UT-Houston Medical School, M&R has refrained from naming it in subsequent *HSIM* editions.

containment purposes.¹⁵⁶ Even though the *Pediatric HSIM* is intended to “communicate best practices in pediatrics, ... developed in accordance with the principles of evidence-based medicine, employing the current best evidence”¹⁵⁷, the methodology by which the guidelines were derived remains unknown and, according to the Texas Pediatric Society, fails to meet the standards set by the American Academy of Pediatrics and the Agency for Health Care Policy.¹⁵⁸ Dr. Cleary has denied the existence of data or clinical studies showing the safety of the recommendations which were “pulled out of thin air.”¹⁵⁹ The Texas Pediatric Society expressed hope that potential methodological flaws of guideline development would be revealed in the course of discovery to public and professional scrutiny.¹⁶⁰

In response to plaintiffs’ request for production of documents, M&R considered the following material “confidential, proprietary and trade secret information”: correspondence with any pediatric association; corrections, recommendations, and/or suggested changes made by any pediatric association; and agreements and contracts with such associations.¹⁶¹ On the same grounds, the company objected to the production of information relating to the medical cost savings to be attained by customers or users of M&R’s new generation of *HSIM*, including the *Pediatric HSIM*. It further rejected as “overbroad, unduly burdensome, and not likely to lead to the discovery of admissible evidence” requests for the production of copies of “any and all epidemiology studies, analysis, or statistical analysis or study done that supports, references, discusses or refers to any factual, medical and/or scientific explanation underlying M&R’s representation that its *Pediatric HSIM* December 1998 volume comprises ‘evidence-based medicine.’” M&R pointed to the references “made to hundreds of published studies and analyses in various areas of pediatrics.”¹⁶² The same objection and references to cited publications were made to requests for copies of epidemiological studies, statistical analysis, studies or other analytical,

156. *Cost-Cutting Guide Used by HMOs Called “Dangerous,” supra* note 152.

157. Schibanoff, *supra* note 58.

158. Texas Pediatric Society, Memo from the Texas Chapter of the American Academy of Pediatrics (AAP), to Joe Sanders, M.D., Executive Director, AAP (June 14, 2000).

159. *Cost-Cutting Guide Used by HMOs Called “Dangerous,” supra* note 152.

160. Texas Pediatric Society, *supra* note 158.

161. Defendant Milliman & Robertson, Inc.’s Response to Plaintiff’s First Request for Production at 3, (Feb. 2, 2000), in *Cleary v. Milliman & Robertson*, (Dist. Ct., Harris County, Tex.) (Case No. 99-56719) (unreported, decided 2000) [hereinafter *Milliman & Robertson’s Response to Plaintiff’s First Request for Production*].

162. Defendant Milliman & Robertson, Inc.’s Response to Plaintiff’s Second Request for Production, (Feb. 2, 2000) Plaintiff’s First Amended Petition, *supra* note 144.

scientific and/or statistical work to support or arrive at the *HSIM's* goal length of stay (GLOS) recommendations, and for studies in support of the representation that the guidelines concern the healthiest 85% of the pediatric population and not the remaining sickest 15%.¹⁶³

The Preface to the *Pediatric HSIM* correctly points out that published empirical studies are not available to validate all medical procedures. Meta-analyses, however, detect trends represented by a large number of studies employing somewhat different methodologies but dedicated to the same subject matter. At least some of the "hundreds of studies and analyses" cited by M&R could have been examined by meta-analysis for guideline development and validation. For the GLOS, much less complex statistical tests could have yielded results revealing prevailing practices.¹⁶⁴ Furthermore, a model could be developed to adjust for "inefficiencies" in the delivery of health care to arrive at the "best practices" ("not the median, not the average"¹⁶⁵), which M&R claims to represent. Since this would equal original research and could stimulate additional research, there would be no reason to conceal it from the public and the scientific community.

On November 1, 2000, the district judge presiding over the *Cleary v. Milliman & Robertson* proceedings, ordered the company to respond to questions concerning the methodology for the development of certain pediatric care recommendations. Company officials had refused to reveal this information during depositions upon the advice of counsel. The judge did not preclude the possibility that questions relating to the origin of other M&R guidelines might be appropriate in the future.¹⁶⁶

Information concerning M&R guideline development would then support or invalidate the company's claim of scientific validity. Several recent publications shed some light on their clinical usefulness. The

163. Milliman & Robertson's Response to Plaintiff's First Request for Production, *supra* note 161.

164. *Cost-Cutting Guide Used by HMOs Called "Dangerous," supra* note 152. (showing a simple calculation by the American College of Surgeons (ACS) of actual average stays for five surgical procedures as suggested by 1,000 of its members, compared with the actual average stays throughout North Carolina (N.C.) in 1996, and the M&R recommendations, yielded the following results: mastectomy: ACS 2.5, N.C. 2.7, M&R 0; appendectomy: 5, 3.5, 1; radical hysterectomy; 9, 5.9, 2; coronary artery bypass: 5, 8.3, 3; esophagectomy; 13, 12.9, 5, *ANNALS OF SURGERY*, vol.228 No.4, Oct. 1998).

165. Jim Schibanoff, *Presentation on Development and Implementation of Managed Care Guidelines* at 9, University of Texas, Houston Medical School (May 13,1997) (transcript available at Houston Medical School, Department of Pediatrics).

166. *Judge Tells Firm to Explain How Pediatric Rules Derived, supra* note 155.

private HCIA-Sachs Institute¹⁶⁷ released the results of two studies, comparing the M&R pediatric length of stay (LOS) guidelines with 1998 data for 3.5 million pediatric discharges at 2,400 general, non-federal hospitals for forty-five pediatric conditions; and the LOS for the same pediatric conditions at the Institute's *100 Top Hospitals*.¹⁶⁸ While M&R considers 85% of all cases as "uncomplicated," the HCIA-Sachs studies adjusted for four severity levels using the All Patient Refined Diagnosis Related Groups (APR-DRGs).¹⁶⁹ Contrary to the M&R guidelines, this system of classification accommodates the severity of the underlying illness, of the comorbidity and complicating conditions. Across syndromes, 74% of cases were found to correspond to the baseline severity level. Among conditions, however, the percentage of low-severity patients ranged from 18% (drug withdrawal syndrome) to 99% (slipped femoral epiphysis).¹⁷⁰ 75% of all complicated and 64% of all uncomplicated cases had LOS exceeding the M&R GLOS. For uncomplicated cases, the LOS varied by condition, exceeding the M&R GLOS by 9% for epiglottitis to 88% for bacterial meningitis. For twenty-seven of forty-five pediatric conditions examined, more than 50% of the LOS for uncomplicated cases exceeded the M&R GLOS. For diabetic ketoacidosis (n=4,955), the HCIA-Sachs Institute found an average LOS of 2.9 (median 2, mode 2) while M&R recommends one day. All LOS at the hospitals included in the study exceeded the M&R GLOS (complicated cases 92%, uncomplicated 80%, all 81%), thus supporting Dr. Riley who had called the one-day hospital stay for DKA "wholly reckless, without regard to the safety of any child." The authors of the study concluded that

the consequences of encouraging clinicians to reduce LOS to the Milliman & Robertson GLOS are of particular concern. . . . In all conditions, clinicians need the latitude to extend the LOS for patients with certain comorbid or

167. HCIA-SACHS INSTITUTE, COMPARISON OF MILLIMAN AND ROBERTSON PEDIATRIC LENGTH OF STAY GUIDELINES (2000) (consulting firm in Evanston, IL, rates hospitals to produce a list of the 100 Top Hospitals in the country, based on efficiency and quality of care. Through its Clinical Research Program, the Institute conducts clinical studies to improve the quality and delivery of care).

168. *Id.* (stating top hospitals are considered the most efficient and well managed facilities in the country).

169. HCIA-SACHS INSTITUTE, *supra* note 167, at 4 (citing RICHARD F. AVERILL, 3M HEALTH INFORMATION SYSTEMS, ALL PATIENT REFINED DIAGNOSIS RELATED GROUPS DEFINITIONS MANUAL, VERSION 15.0. (1998)).

170. *Id.* at 5 (stating less than half of all cases fell in the baseline severity level for the following conditions: drug withdrawal syndrome, endocarditis, bacterial meningitis, burn (major), neonatal sepsis, gastrointestinal bleed, sepsis (strep pneumonia)).

complicated conditions that require further care. Because M&R assumes that sophisticated home health care is available, it is also important that clinicians be able to provide inpatient care when such services are unavailable.¹⁷¹

As Dr. Cleary observed, “These guidelines are merely a mechanism for insurance companies to avoid their responsibilities and to shift the cost of care from themselves to kids’ families. The guidelines quite literally appear to have been made up.”¹⁷²

Results of the *100 Top Hospital* study showed that lengths of stay for 60% of uncomplicated cases exceeded the M&R GLOS. For twenty-three of the thirty-six conditions in this study, more than 50% of the uncomplicated cases had LOS exceeding M&R recommendations. Interestingly, the top hospitals applied LOS shorter or equivalent to non-winner hospitals for almost all of the conditions included in the study.¹⁷³ A M&R spokesman questioned the studies’ credibility by emphasizing that they were conducted by a competing consulting medical firm.¹⁷⁴ But another recent investigation found that the LOS in New York State in 1995 for sixteen pediatric conditions also exceeded those of M&R. (No adjustments, however, were made for severity of condition.) The authors warn of the “potential effects of such guidelines on both patients and the hospitals caring for them. While endorsing the need for cost-effective practice, we call attention to the methods used to develop and validate guidelines.”¹⁷⁵

D. Conclusion

Courts have increasingly recognized that managed care companies make medical decisions.¹⁷⁶ By subjecting the attending physicians’

171. *Id.* at 7.

172. Linda O. Prager, *Pediatric Hospital Stay Goals Questioned*, AM. MED. NEWS, Oct. 9, 2000, at http://www.ama-assn.org/sci-pubs/amnews/pick_00/pr121016.htm.

173. HCIA-SACHS INSTITUTE, *100 TOP HOSPITALS PEDIATRIC LOS COMPARISON WITH NON-WINNERS AND MILLIMAN & ROBERTSON GUIDELINES* 7, 8 (2000).

174. Ron Nissimov, *Studies: Children Shortchanged by Hospital Guidelines*, HOUS. CHRON., Sept. 15, 2000.

175. MARION S. SILLS ET AL., *Pediatric Milliman and Robertson Length-of-Stay Criteria: Are They Realistic?* 105(4) PEDIATRICS 733 (Apr. 2000).

176. *Snow v. Burden*, M.D., 1999 U.S. Dist. LEXIS 6932 (E.D. Pa. May 1999) (delaying authorization by MCO for diagnostic procedures was substandard medical care); *Plocica v. Nylcare of Texas, Inc.*, 43 F. Supp. 2d 658 (N.D. Tex. 1999); *Moscovitch v. Danbury Hosp.*, 25 F. Supp. 2d 74 (U.S. Dist. Conn. Oct. 1998) (in both cases, the appropriateness of the medical and psychiatric care decisions of the MCOs were successfully challenged); *Blaine v. Community*

treatment recommendations to medical necessity determinations according to corporate criteria, often based on commercial guidelines deviating from the prevailing standard of care, MCOs substitute their medical judgment for that of the attending physicians. Frequently, such medical necessity evaluations, judging the appropriateness of the treating physician's diagnosis and proposed treatment plan, are made by individuals without the required experience, medical training and knowledge of patient's individual circumstances.¹⁷⁷ This practice has been rejected by the American Medical Association, which insists that clinical judgment be left to properly qualified licensed physicians with adequate patient contact, and be in agreement with the applicable standard of care and the prevailing medical opinion.¹⁷⁸ The organization further considered utilization review programs that "involve the gathering of symptoms from a patient and communication of a diagnosis to the patient" (such as on-site concurrent review by nurses) as having many of the characteristics of the practice of medicine. Physicians themselves have protested the "undue interference in their practice of medicine" by MCO medical management staff without proper

Health Plan, 687 N.Y.S.2d 854 (N.Y. 1998) (stating that decision by MCO to have patient seen by a nurse instead of a physician for diagnosis and treatment represented a unilateral determination of medical treatment); *Nascimento v. Harvard Community Health Care Plan, Inc. et al.*, 1997 Mass. Super. LEXIS 166 (Mass. 1997) (stating MCO denial of autologous bone marrow transplant in spite of contractual promise to provide all medically necessary care was medical malpractice); *Roessert v. Health Net et al.*, 929 F. Supp. 343 (N.D. Cal. 1996) (stating the MCO's decision to commit plaintiff to a mental institution was a medical decision).

177. Affidavit of Patrick F. Vetere, *supra* note 119, at 3. See also *Batas v. The Prudential Ins. Co. of Am.*, (N.Y. App. Div., Dept. 1, Index No. 97-107881, IAS Part 49) (filed 1997), *aff'd in part, rev'd in part by Batas v. The Prudential Ins. Co. of Am.*, 281 A.D.2d 260 (N.Y. App. Div. 2001), *motion granted by Batas v. The Prudential Ins. Co. of Am.*, 721 N.Y.S.2d 856 (N.Y. App. Div. 2001) (attending physician, Dr. Vetere, for plaintiffs Batas and Vogel, stated in his affidavit that a Prudential Concurrent Review Nurse called his office two days after Ms. Vogel's surgery and "informed us that there was *no medical reason* (emphasis added) to keep the patient hospitalized, stating that Prudential would not cover any further expenses arising from the patient's hospitalization." The physician instructed his staff to inform the nurse that he "adamantly disagreed with her medical opinion" and would refuse to discharge Ms. Vogel.

In her trial testimony, Dr. Linda Peeno explained that a Humana case manager nurse has the authority to tell a board certified pediatric neurologist what to do. "That's exactly what a health plan does . . . and that is part of the difference between managed care and traditional insurance that now the plan holds itself out as doing that, and that's one of the requirements that they have to meet in order to be accredited." Record at 1902, 1903, in *Chipps v. Humana Health Ins. Co. of Fla.*, (15th Jud. Cir., Palm Beach County, Fla.) (Case No. CL 96-00423 AE) (unreported, filed 1996). See also *supra* note 69.

178. Amicus Curiae Brief of the American Medical Association and The Medical Society of the State of New York at 2 (March 30, 2000), *Batas v. The Prudential Ins. Co. of Am.*, (N.Y. App. Div., Dept. 1, Index No. 97-107881, IAS Part 49) (filed 1997), *aff'd in part, rev'd in part by Batas v. The Prudential Ins. Co. of Am.*, 281 A.D.2d 260 (N.Y. App. Div. 2001), *motion granted by Batas v. The Prudential Ins. Co. of Am.*, 721 N.Y.S.2d 856 (N.Y. App. Div. 2001) [hereinafter Amicus Curiae Brief of the American Medical Association].

qualifications or by medical management department physicians not specialized in their respective areas.¹⁷⁹ Furthermore, long delays in obtaining approval for medical procedures are common. In cases of denial, the appeals process for what is considered essential treatment can be even more time-consuming. As a consequence, patients' conditions have deteriorated irreversibly and some have died.¹⁸⁰ Even though delays and denials are generally classified as "administrative" in nature, they often have medical consequences and thus represent de facto medical decisions not to treat.

1. Guidelines

Cost containment in health care and the standardization of medical practice for quality control are generally not disputed in today's health care delivery environment. Because of the extensive use of guidelines for such purposes, guideline validity is essential. Guidelines developed by medical specialty societies according to scientific and evidence-based criteria, reflective of prevailing practices, and in agreement with Institute of Medicine and Agency for Healthcare Research and Quality standards, would most likely meet with little resistance on the part of practitioners. Commercial guidelines, however, derived from data considered "proprietary" and judged by physicians as endangering patients and in violation of the standard of care, are rejected as "straightjackets" and "cookbook medicine." Furthermore, the perceived economic motives for such guideline development and their indiscriminate use by MCOs undermine the guidelines' credibility with the medical community.¹⁸¹

Physicians have also expressed concern about practice guidelines stretching the definition of primary care beyond what practitioners should responsibly perform in their offices. According to the M&R guidelines, large, potentially malignant facial lesions can be removed by general practitioners,¹⁸² avoiding a referral to a plastic surgeon. Furthermore, as reported by the director of an emergency room, MCOs have recently

179. MARK GREEN, WHAT AILS HMOS—A CONSUMER DIAGNOSIS AND Rx, 63 (1996) (a report by the Public Advocate for the City of New York).

180. *Crum v. Health Alliance Mid-West, Inc.* 47 F. Supp. 2d 1013 (C.D. Ill. 1999) (stating that triage hotline nurse denied patient's admission to emergency care resulting in cardiac arrest); *Pappas v. Asbel*, 724 A.2d 889 (Pa. 1998), *reh'g denied* (Feb. 12, 1999) (stating that patient became paraplegic because of delayed admission to the appropriate neurological facility).

181. Myerson, *supra* note 44, at C1 (stating that Dr. Doyle, chief author of the M&R guidelines, has stressed that the guidelines are goals not rules but that "the more rigorous the application, the greater the savings").

182. MARK GREEN, *supra* note 179, at 64 (quoting *Pushing the Definition of Primary Care to the Limit*, MED. ECONOMICS, Aug. 7, 1995, at 60).

instructed patients to see their primary care provider instead of visiting an ER. "I find this worrisome, many PCPs have little suturing experience and wouldn't know one tendon from another."¹⁸³ The M&R hospitalization length-of-stay guidelines were called unrealistically optimistic by the AMA because treatment and recovery often do involve considerable complications since patients do not respond optimally, as the guidelines assume.¹⁸⁴ Even though M&R points out that physicians should use their own judgment, doctors are "worn down by constant bickering with insurance companies that use guidelines such as M&R. A clerk with no knowledge of medicine is often the one telling the doctor what the recommended treatment is, and doctors have no idea the guidelines were written by an actuarial firm."¹⁸⁵

2. Cost Containment

MCOs, physicians' offices and hospitals require an elaborate administrative infrastructure for the preauthorization and concurrent review of individual medical decisions. Disputes with providers over delays and denials, frequent arguments over payment for tests or necessary equipment, and excessive paperwork¹⁸⁶ absorb additional resources. Hospitals may dedicate entire office suites to on-site personnel conducting concurrent review for numerous MCOs. Managed care companies may have eighteen nurses on staff for treatment reviews, a full-time medical director, twenty-seven customer service representatives, and four part-time medical directors. On the business side, there may be eight representatives to recruit providers, fifteen salespeople to sell to employers, and roughly one-hundred clerical workers for claims processing.¹⁸⁷ In addition, major data processing centers are required for the wealth of medical and business information generated by a large MCO. Humana, for example, has four-hundred in-house application programmers for the development and maintenance of its own application systems. "The information systems support marketing, sales, underwriting, contract administration, billing, financial . . . customer service, authorization and referral management,

183. *Id.*

184. Amicus Curiae Brief of the American Medical Association, *supra* note 178, at 9.

185. *Cost-Cutting Guide Used by HMOs Called "Dangerous," supra* note 152.

186. MARK GREEN, *supra* note 179, at 63.

187. *Id.* at 81 (stating that this was the infrastructure of an HMO with 110,000 members in New Jersey).

concurrent review, physician capitation and claims administration, provider management, quality management and utilization review.”¹⁸⁸

Whether the immense administrative apparatus for controlling and “standardizing” the micro-allocation of health care funds through managed care treatment decisions at the bedside absorbs whatever “efficiencies” may have been achieved, often at the patients’ expense, remains unanswered.¹⁸⁹ With health care expenditures stabilized on a macro level, the traditional providers’ hands-on clinical judgment might be just as “efficient” while much more patient-friendly.¹⁹⁰

188. Reply Memorandum of Law in Support of Plaintiff’s Motion for Class Certification. Attachment 1, Section 1, in *Price et al. v. Humana Inc.*, (S.D. Fla.) (Case No. 9:99-8763 CIV-Moreno) (unreported, filed 1999), *transferred and consolidated In re Humana Inc. Managed Care Litig.*, 2000 U.S. Dist. LEXIS 5099 (2000), *aff’d* 2002 U.S. App. LEXIS (11th Cir. 2002). (stating that Humana’s centralized management services include “management information systems, product administration, financing, personnel, development, accounting, legal advice, public relations, marketing, insurance, purchasing, risk management, actuarial, underwriting and claims processing”).

189. MCOs on the average spend close to 30% of every premium dollar on administration. Administrative expenditures by German sickness funds do not exceed 6% even though recent health care reforms are pushing costs upward.

190. *See, e.g., Dave Barry, Wit’s End, Managed Care*, THE WASH. POST MAGAZINE, Oct. 15, 2000, at 36 (stating that the complex, bureaucratic administration of MCOs is certainly perceived by the public and solutions are proposed. “All we have to do is get in a time machine and go back to 1957. In those days we had a great health care system. The way it worked was, every family had a doctor, who wore a white coat and a head reflector, and who had an aquarium in his waiting room . . . In those days, medical paperwork was simple: The doctor gave you a bill. That was it. Whereas today, if you get involved with the medical care system in any way, including sending flowers to a hospital patient, you will spend the rest of your life wading through baffling statements from insurance companies. I speak with authority. At some point in the past, some member of my family apparently received medical care, and now every day, rain or shine, my employer’s insurance company sends me at least one letter, comically entitled “EXPLANATION OF BENEFITS,” which looks like it was created by the Internal Revenue Service From Hell. It’s covered with numbers indicating my in-network, out-of-pocket deductible; my out-of-network, nondeductible pocketable; my semi-pocketed, nonworkable, indestructible Donald Duckable, etc. For all I know, somewhere in all these numbers is a charge for Dr. Cohn’s fish food. What am I supposed to do with this information? . . . Let’s demand some action! Let’s track down the people sending out these EXPLANATION OF BENEFITS letters and have them arrested! Let’s bring back head reflectors!”); Carey Goldberg, *State Referendums Seeking to Overhaul Health Care System*, N.Y. TIMES, June 11, 2000, at A1 (stating that it may come as no surprise that states such as Maryland, Massachusetts, and Oregon are gearing up for referendums on the introduction of universal health care systems); Gina Kolata, *For Those Who Can Afford It, Old-Style Medicine Returns*, N.Y. TIMES, March 17, at A1 (stating that at the same time, increasing numbers of physicians accept self-paying patients only, adding another tier to the already multi-tiered American health care system).

III. GERMANY: ADMINISTRATIVE RULEMAKING

A. *Introduction to the German Statutory Health Care System*¹⁹¹

The German health care system is an all-payer, pre-paid, non-profit, universal access/universal coverage system of social health insurance which is currently embodied in Title Five of the Social Code (SGB V) of 1988.¹⁹² It originated at the beginning of the 19th century when tradesmen's guilds and industrialists began to introduce health care coverage for the protection of their members and workers. In 1883, under Chancellor Bismarck, the National Health Insurance Act was adopted which integrated all individual plans into a single national social insurance plan. The administrative structure which had grown out of seven categories of corporate sickness funds and sickness funds by profession was preserved and continues to be one of the foundations of the SGB V.¹⁹³ Within these categories, a total of over 500 plans offering by law almost identical comprehensive coverage is available. Originally, members were required to obtain coverage for life under their professional plans. In 1996, open enrollment was introduced as an element of competition among the different plans.

Premiums are assessed at a uniform percentage (13.8% in 2000)—premiums are split evenly between employers and members—up to a certain level of annual income (currently approximately \$40,000). This represents an element of income redistribution since half of the premium is spent on a member's health care, the remaining half on family members (covered at no additional charge, independent of their number) and on the elderly. The unemployed and the elderly continue to receive the same comprehensive benefits without paying premiums. Care is therefore provided according to need, not according to income. Those whose incomes exceed the legal maximum may opt out of the statutory plan. But

191. 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. FOR. 47 (1998); Ursula Weide, *Health Care Reform and the Changing Standard of Care in the United States and Germany*, 20(3) N.Y. L. SCH. J. OF INT'L & COMP. L. 249 (2000).

192. 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].

193. *Krankenkassen Betriebskassen* (individual 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). Certain groups of blue and white collar workers also could choose one of the so-called substitute funds (*Ersatzkassen*) instead.

90% of all Germans remain covered as private coverage by law must correspond at a minimum to statutory coverage, creating little incentive to engage in private insurance contracting. Furthermore, most universal system members have private secondary insurance covering additional benefits such as private instead of semi-private hospital rooms. Ninety percent of all physicians are public plan providers but may also deliver care under private indemnity insurance.

While the government sets the overall legal framework for the health care system and its administration (the SGB V has been amended numerous times since its adoption in 1988 when it replaced the venerable Insurance Code of 1914,¹⁹⁴ also amended and fine-tuned over time), the delivery of care is subject to joint physician and sickness fund self-governance by associations. The principle of self-governance was officially announced by Bismarck in the “Imperial Message” on November 11, 1881, read during an opening session of the National Parliament, and announcing the introduction of the Social Insurances Act. The delegation of power to associations was intended to achieve “a greater closeness to the real forces of the citizens’ lives by concentrating those forces within corporate entities protected and supported by the State, permitting the resolution of tasks which the State would be unable to accomplish to the same extent.”¹⁹⁵ In 1972, the Constitutional Court of the Federal Republic rephrased in modern language the stated purpose of the delegation of rulemaking authority to associations, now corporate entities under public law. Subgroups of society should be allowed to regulate their own affairs based on their special expertise and knowledge of local particularities, often difficult to discern for the legislator, thus reducing the distance between those who adopt norms and those bound by them, and permitting more rapid adjustment to change.¹⁹⁶

Sickness funds are self-governed corporate entities under public law,¹⁹⁷ and deliver health care in cooperation with the providers (physicians,

194. This Act contained several titles covering health insurance, workers’ compensation and retirement benefits. A separate act for health insurance was adopted in 1988, the SGB V.

195. INGWER EBSSEN, *AUTONOME RECHTSSSETZUNG IN DER SOZIALVERSICHERUNG* [AUTONOMOUS RULEMAKING IN SOCIAL INSURANCES], VSSR 57 (1990) (quoting Kaiserliche Botschaft, Verhandlungen des Reichstags, 5. Legislaturperiode, Erste Session 1881, Bd. 1, S. 1 ff [Deliberations of the National Parliament, Fifth Term, First Session 1881, Vol. 1, at 1]). Associations as the expression of society’s communitarian spirit have been analyzed at length by German jurists. See, e.g., OTTO VON GIERKE, *DAS DEUTSCHE GENOSSENSCHAFTSRECHT* [THE GERMAN LAW OF ASSOCIATIONS] (1887). In opposition to the economic liberalism of Kant, von Gierke’s approach was labeled “economic communitarianism.”

196. BverfGE 33, 125, 156.

197. *Körperschaften des öffentlichen Rechts*, Art. 4, SGB V. Self-governance and status as corporate entities under public law are particularities of the delegation of rulemaking authority

dentists, psychologists, hospitals and pharmacists). These operate as independent businesses but are subject to regulation.¹⁹⁸ Both sickness funds and physicians are represented by regional associations (plan physician membership is mandatory)¹⁹⁹ with elected assemblies and boards. All associations are corporate entities under public law. While there are several federal sickness fund associations representing the different fund categories, there is only one Federal Physician Association.²⁰⁰ The federal associations of both parties to the system of self-governance annually renegotiate a collective national agreement²⁰¹ stipulating the framework for the provision of care and provider compensation. This agreement includes a fee scale based on relative value units for fee-for-service payments, and capitation for certain basic services. It also lists quality control guidelines in agreement with SGB V, Art. 135, for specialized diagnostic and treatment procedures such as MRI, dialysis, radiology and nuclear medicine, pace makers, ultrasounds, and the cytological diagnosis of female reproductive carcinomas. It further integrates the coverage guidelines as adopted by the Joint Federal Committees of the Sickness Funds and Physician Associations under SGB V, Art. 92. These guidelines are intended to guarantee a high standard of care, not to limit benefits. So far, nineteen guidelines apply, most prominent among them the pregnancy care guideline, the early childhood screening guideline, the prescription drug guideline, and the guideline for the evaluation of diagnostic and treatment procedures for coverage purposes.²⁰²

Regional agreements, incorporating all elements of the national agreement but allowing for regional adjustments, are concluded among the regional physician and sickness fund associations. The regional agreements emphasize provider compensation, random plausibility checks

under the German system of government. Other entities enjoying this status are municipalities and counties, universities, chambers of industry and trade, public radio and television. All may autonomously promulgate charters for the regulation of their affairs, and no enabling legislation is required. HARTMUT MAURER, *ALLGEMEINES VERWALTUNGSRECHT* [GENERAL ADMINISTRATIVE LAW] 64 (12th ed. 1999).

198. The German health care delivery system does not employ anyone and in that sense is not a "national health system" as found in Great Britain and Canada.

199. *Landesverbände der Krankenkassen; Kassenärztliche Vereinigungen*.

200. *Spitzenverbände der Krankenkassen; Kassenärztliche Bundesvereinigung (KBV)*.

201. *Bundsmantelvertrag*, reprinted in *VERTRÄGE DER KASSENÄRZTLICHEN BUNDESVEREINIGUNG (DIENSTAUFLEGE DER KBV)* [CONTRACTS OF THE FEDERAL PHYSICIAN ASSOCIATION, OFFICIAL EDITION] (1998).

202. Respectively, *Mutterschaftsrichtlinie* (for pregnancy); *Kinderrichtlinie* (for early childhood screening); *Arzneimittelrichtlinie* (for prescription drugs); and *Bewertung von Untersuchungen und Behandlungsmethoden* (for diagnostic and treatment procedures). The latter guideline is applied in conjunction with the stipulations of Art. 135, SGB V.

on claims filed, and the retrospective economic review of care delivered by office, based on medical specialty. On a quarterly basis, physicians bill their associations which process and pay the claims with assets received from the sickness funds. Sickness fund revenues correspond to the premiums paid by their members. Members are not invoiced except for copayments and some dental indemnity claims.

B. Coverage, Benefits and Medical Necessity

Historically, the German health care code guaranteed the coverage of members²⁰³ but did not yet bind sickness funds and providers. Due to poor economic conditions in the 1930s, a comprehensive system of contracts between these two parties and their associations was added to the code to safeguard the health care delivery system.²⁰⁴ Today, the Coverage (Art. 1 to 66) and Health Care Delivery sections (Art. 69 to 140) are found in Chapters Three and Four of the SGB V.²⁰⁵ Coverage is comprehensive and identical for all members, and physicians and sickness funds together must ensure the delivery of care. Under SGB V, Art. 11, coverage is to be provided:

for the prevention, early diagnosis, treatment and stabilization of illness; contraception, elective sterilization, and legal abortions.²⁰⁶ Included are medical and adjunct services for rehabilitation to prevent disability or illness requiring longterm care, and services to reverse, improve or stabilize such conditions. In case of hospitalization, coverage extends to the presence of a patient's companion whenever medically necessary.

Art. 27 specifies:

Members are entitled to benefits for the diagnosis, treatment and stabilization of an illness or to control its symptoms. Coverage includes medical and dental treatment, psychotherapy, drugs, durable medical equipment, medical/surgical dressings and supplies, adjunct therapies, home care and household help,

203. *Leistungsrecht*.

204. *Leistungserbringungsrecht*.

205. The extent of future coverage may depend on the priority BSG—Bundessozialgericht, the Supreme Social Court—jurisprudence may accord to one or the other Chapter. For further discussion, see *infra*.

206. Abortions are reimbursed whenever “medically and socially” indicated. A recent amendment extended coverage to medication-induced abortions.

hospitalization, medical and other services for rehabilitation, stress testing and occupational therapy. The needs of mental health patients must receive particular attention, including adjunct therapies and rehabilitation. Fertility treatment . . . is covered.²⁰⁷

Several SGB V sections define what would correspond to the medical necessity definition in managed care plan documents:

- The quality and efficacy of the benefits to be provided by the sickness funds must correspond to the prevailing medical standard of care and be in accordance with the progress of medical science. (Art. 2)
- Contracts between physician and sickness fund associations must ensure the sufficient, appropriate and cost-effective²⁰⁸ delivery of

207. United States. General Accounting Office, 1993 German Health Reforms New Coast Control Initiatives: Report to the Chairman, Committee on Governmental Affairs, U.S. SENATE, GAO/HRD 93-103, at 25. (stating the German health care system is one of the “most comprehensive health insurance benefits programs in the world”).

208. KARL HAUCK, SGB V: GESETZLICHE KRANKENVERSICHERUNG, KOMMENTAR [SGB V ANNOTATED], K § 12, at 7, 8 (Sept. 1999) (stating that cost-effectiveness expresses the fiduciary function of the State and applies to all levels of German government: federal, state and local. Cost-effectiveness under social law, as related to health care for individual members, is of relevance only when several equally effective but more or less costly treatments are available. Cost is (basically) irrelevant when a single procedure would produce the desired outcome. (Art. 1, SGB V, entitles members to the preservation, restoration or improvement of their health.) Benefits are cost-effective when the desired outcome can be achieved with an acceptable minimum of resources. “Such a cost-benefit analysis, however, is not purely economic. Qualitative medical considerations, especially the kind, duration and sustainability of the outcome, must be balanced with cost. How to quantify quality is the underlying issue, unresolved under current law, perhaps defying any kind of resolution. In a prepaid system of health care, only increasing standardization may provide a satisfactory answer.”) Hauck’s loose-leaf edition is continuously updated, reflecting all amendments to the code.

According to Art. 103, SGB V, cost-effectiveness reviews of physicians’ practices are conducted by both physician and sickness fund associations, based on economic utilization criteria, determined by the various and changing cost containment approaches adopted by the government. Examples are sector budgets (for all of ambulatory vs. in-patient care), prescription drug budgets, and practice budgets by specialty. Penalties for violations generally are of a collective nature and, even though stipulated by the SGB V, have not been enforced in any consistent fashion. Art. 116, SGB V, provides for (economic utilization) cost-effectiveness review of hospitals to be conducted by the sickness fund associations. This application of the social law concept of cost-effectiveness has been criticized for ignoring costs incurred in cases of undertreatment requiring more expensive care later on. “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.” Thomas Clemens, *Abrechnungsstreitigkeiten, Wirtschaftlichkeitsprüfung, Schadensregreß* [Claims Processing Disputes, Cost-Effectiveness Audits, Sanctions], in HANDBUCH DES SOZIALVERSICHERUNGS-RECHTS, BAND 1,

medical care for all insureds under the plan, in accordance with the law and the coverage guidelines established by the Joint Federal Committees (JFC)²⁰⁹, and correspond to the generally recognized level of medical expertise.(Art. 72)²¹⁰

- Sickness funds and providers must ensure care for all members as needed, in a consistent fashion, and in accordance with the generally recognized level of medical expertise. The delivery of care must be sufficient and appropriate, it may not exceed whatever is necessary, it must correspond to the professionally required level of quality, and must be cost-effective. (Art. 70)

The BSG (Bundessozialgericht, Supreme Social Court) considers Art. 27 to represent a general guarantee of coverage but no entitlement to individual benefits.²¹¹ Due to the complexity of medical care, additional decisions must follow to establish the eligibility for benefits. First, a plan physician, authorized under public law to determine “eligibility” must suspect or find illness in accordance with Art. 27, defined as an “exceptional physical or mental condition necessitating treatment.”²¹² (Benefits for prevention and early screening are guaranteed under Arts. 11, 20 to 26). Once this requirement of the SGB V Coverage Chapter has been satisfied, the patient is eligible for benefits necessary for the diagnosis, cure or stabilization of an illness, or to control its symptoms. Individual treatment decisions are delegated to the attending physician who provides or orders the services required to translate the general material claim to coverage into individual benefits.²¹³ These must correspond to the prevailing standard of care and reflect the progress of medical science. (Art. 2) The delivery of care must be sufficient, appropriate and cost-effective, not exceeding what is necessary for the individual circumstances of the patient. (Arts. 70, 72) Benefits, however, may also be specified by coverage guidelines issued by the Joint Federal Committee under the SGB V Health Care Delivery Chapter (Arts. 92, 135). These guidelines are considered general and abstract criteria, to be translated into specific

KRANKENVERSICHERUNGSRECHT [HANDBOOK OF SOCIAL INSURANCE LAW, VOL. 1, HEALTH INSURANCE LAW] 918 (Bertram Schulin, ed., 1994).

209. *Bundesausschüsse der Ärzte und Krankenkassen*. For further discussion, see *infra*.

210. This article stipulates the joint contractual provider-sickness fund mandate to assure access to and the provision of medical care for all insureds. *Sicherstellungsauftrag*.

211. BSG 4 Rk 5/92, E 73, 271, 277, 290 (Dec. 12, 1993).

212. HAUCK, *supra* note 208, K § 27, at 4 (50th addition to the Annotated Code, July 2000).

213. BSGE 73, 271, 279; BSG SozR 3-2500 §30 No. 8, at 32.

benefits by the attending physicians, both in office and hospital environments.²¹⁴

C. The Joint Federal Committee

The institutions of the German universal system of health care have remained remarkably stable in spite of several successive systems of government.²¹⁵ The earliest embodiment of the Joint Federal Committees was the then-called Central Committee, established by the Berlin Agreement of 1913 as a response to a long period of conflict between sickness funds and physicians. After a series of physician strikes, the Berlin Agreement for the first time established a joint sickness fund-physician committee with equal representation, under neutral chairmanship, with the participation of neutral members, and a mandatory arbitration procedure. The private Hartmann Bund (roughly comparable to the American Medical Association) had been founded in 1900 to strengthen the physicians' position vis-à-vis the sickness funds which contracted individually with providers, thus creating total dependency. The Hartmann Bund had demanded patients' independent choice of physicians and any willing provider contracting with licensed physicians only. The joint Central Committee's initial mandate was to improve the representation of physicians' interests but also to protect the people from a collapse of the health care system. In 1923, after the expiration of the voluntary Berlin Agreement, many of its clauses were integrated into the National Social Insurances Act (RVO)²¹⁶ by the National Ministry of Labor.²¹⁷

The Central Committee, now safely anchored in public law, evolved into the National Committee mandated to further develop the mechanisms embodied in the original Berlin Agreement. The Committee subsequently received rulemaking authority and refined the law regulating the relations

214. Robert Francke, *Richtlinien, Normsetzungsverträge und neue Behandlungsmethoden im Rechtskonkretisierungskonzept des Bundessozialgerichts* [Coverage Guidelines, Norm Contracts and Innovative Procedures as Interpreted in Rulings of the Supreme Social Court], 1 DIE SOZIALGERICHTSBARKEIT 5 (Jan. 1999) (citing BSGE 73, 271, 280 and BSG SozR 3-2500 §39 No. 3).

215. This section is based on Marian Döhler and Philip Manow-Borgwardt, *Kontinuität durch Wandel: Zur Institutionsgeschichte des Bundesausschusses der Ärzte und Krankenkassen* [Continuity Through Change: The Institutional History of the Federal Committee of Physicians and Sickness Funds], in GESUNDHEITSRISIKEN, INDUSTRIEGESELLSCHAFT UND SOZIALE SICHERUNGEN IN DER GESCHICHTE [HEALTH RISKS, THE INDUSTRIALIZED SOCIETY, AND SOCIAL SAFEGUARDS IN HISTORY] 119 (Dietrich Milles, ed., 1993).

216. *Reichsversicherungsordnung*. This act was adopted in 1914 and covered health insurance, workers' compensation and retirement benefits.

217. Historically, oversight over health care has alternated between the Ministry of Labor and the Ministry of Health.

between physicians and sickness funds. This included the adoption of licensing procedures for physicians and the first coverage guidelines for the “cost-effective” dispensation of drugs and “electro-physical treatments” in 1925. The Hartmann Bund, willing at times to break the law to represent physicians’ interests and accused by the government of practicing “terrorism,” was now cooperating with the National Committee. Years of such cooperation between physicians and sickness funds pursuing common goals had already resulted in a much improved relationship between the parties. The National Ministry of Labor supported the development of sickness fund and physician associations and recognized their national federations as the “legal representatives of the parties’ interests” in the RVO. In 1931, the physician associations received their status as corporate entities under public law. The government had “domesticated unruly” private law associations by recognizing the importance of their contribution.

In spite of the normative authority of the National Committee, the definition of its legal relationship with the state remained amorphous—the Committee was at times designated as an “entity of the system of self-governance under agency oversight” or as a “national agency with elements of self-governance.”²¹⁸ The legal status of its guidelines, including the adoption of rules for the medical licensing boards, was equally contested but a consensus developed eventually, according the guidelines *de facto* normative status but not the force of law.

In 1931, in the middle of the international economic crisis, the National Ministry of Labor issued an RVO emergency regulation defining the relationship between sickness funds and physicians in accordance with Committee guidelines, the logical next step in the continued development of the cooperation between sickness funds and physicians. The social health insurance code thus incorporated licensing rules, patient choice of providers, capitated payments (adopted with the physicians’ approval), collective agreements, and the equal representation of sickness funds and physicians on administrative entities under public law. As a consequence of the adoption of the licensing regulations, physicians now had a public law entitlement to a contract to practice, the first step towards extending the RVO to individual physicians. The emergency regulation also provided the National Committee with *de jure* authority to promulgate binding rules under the act, a delegation of rulemaking authority unique among all social insurance laws. Government regulatory authority was preserved under default provisions. This democratic process collapsed, however, when the physicians refused to participate in Committee activities

218. Marian Döhler and Philip Manow-Borgwardt, *supra* note 215, at 125.

under the Nazi regime, and regulation reverted back to the National Ministry of Health by default.²¹⁹

After World War II, the influential pre-war role of the now-called Joint Federal Committee was not restored. Only when coverage was expanded in the sixties, the JFC adopted the pregnancy care guideline, the children's guideline and the rehabilitation guideline. The focus then was on ensuring a high standard of care, and the guidelines served the detailed interpretation of the health care code. But beginning in 1977, when the first health care cost containment provision was passed, the entities of the system of self-governance began to be instrumentalized for cost-effectiveness purposes. The JFC was now charged with the implementation of several cost control mechanisms, such as the development of a list of medications for minor ailments (common cold, headaches) to be excluded from coverage, and of the guideline for the cost-effective use of major medical equipment. Over time, the Committee thus has assumed different roles: initially, it served the collective interpretation and implementation of the first agreements between sickness funds and physicians, evolved into the regulatory entity of the system of self-governance, further refining the contractual relationship between the parties, then issued guidelines to uphold a high standard of care, and in recent years has increasingly provided assistance with cost containment.

D. Coverage Rulemaking under SGB V, Arts. 92, 135, and 137

Today, the Joint Federal Committee,²²⁰ as established by SGB V, Art. 91, and mandated to issue coverage guidelines under Art. 92, has a total of twenty-one members: a neutral chairperson, two neutral members, nine members representing physicians (and dentists or psychologists), three representatives of the Local Funds, two of the Substitute Funds, and one member each representing the corporate-sponsored plans, the plans by trade, and the agricultural workers, merchant marine, and mine workers plans. Should the parties be unable to agree on the neutral chairperson and the two neutral members, these are appointed by the Federal Secretary of Health in cooperation with the Federal Physician Association and all sickness fund associations. Each member has five deputies of which no more than two may participate in meetings. Whenever psychotherapy guidelines are to be drafted, the nine physician members are replaced by

219. *Id.* at 127.

220. Even though the singular is generally used, there are three JFCs covering medicine, dentistry and psychology.

five psychologists and five physicians practicing psychotherapy.²²¹ Members may not receive instructions from their associations. Proposed coverage decisions are referred to JFC working groups with generally nine members each, representing the physician and sickness fund associations. Decisions are submitted to the plenary and must be adopted by majority vote. JFC membership is uncompensated, only travel expenses and time spent working on JFC-related activities are reimbursed.

The Federal Ministry of Health has oversight over the JFC but is concerned only with the proper implementation of procedures, not the actual decision making. Coverage guidelines adopted by the JFC must be submitted to the Ministry which may object within two months to matters of law. Objections may not reflect political considerations. The Committee may cure objections within the time frame set by the Ministry, if it fails to do so, the Ministry may promulgate its own guideline. The JFC may then bring an action before the social courts. So far, however, the Committee has resolved all issues in a timely fashion, avoiding further action by the Ministry.²²²

1. Committee Activities

Since the adoption of the SGB V in 1988, the JFC's task has been the development of coverage guidelines²²³ under Art. 92 as necessary to ensure the "sufficient, appropriate and cost-effective" delivery of outpatient health care. (The JFC for dentists issues guidelines limited to dental procedures, dental prosthetics, and orthodontics.) Art. 92 mirrors the coverage members are entitled to under Art. 27 and may be expanded (the original act of 1988 did not include items 10 and 11):

The Federal Committees adopt guidelines as necessary for the delivery of health care in order to ensure sufficient, adequate and cost-effective services for the insureds; the

221. Psychologists fought for many years to be recognized and reimbursed as independent providers since reimbursement was allowed only after referral from and while under supervision by a physician. With equal representation of psychologists and physicians on the JFC for matters psychological, physicians are still able to block psychologists' decisions.

222. Karl Jung, *Leitlinien aus der Sicht des Bundesausschusses der Ärzte und Krankenkassen—Rechtspolitische und rechtspraktische Probleme* [Clinical Practice Guidelines Viewed by the Federal Committee of Physicians and Sickness Funds—Problems of Law, Application and Policy], in *ÄRZTLICHE LEITLINIEN: EMPIRIE UND RECHT PROFESSIONELLER NORMSETZUNG* [MEDICAL GUIDELINES: EMPIRICAL AND LEGAL FOUNDATIONS FOR SETTING PROFESSIONAL NORMS] (Dieter Hart, ed., 2000) [hereinafter *Clinical Practice Guidelines Viewed by the Federal Committee*].

223. Coverage guidelines are defined as "norms addressing acts or omissions, issued by a rulemaking entity as mandated by the SGB V."

needs of mental health patients must receive particular attention . . . Guidelines must be adopted *in particular*²²⁴ [emphasis added] for:

1. medical treatment
2. dental treatment including dentures and orthodontics
3. the early diagnosis of illness
4. pregnancy and maternal care
5. the coverage of innovative²²⁵ diagnostic and treatment procedures
6. the prescription of drugs, medical/surgical dressings and supplies, medial equipment, prosthetic devices, adjunct therapies, hospitalization, home care and socio-therapy
7. disability determination
8. the provision of medical care as required by individual circumstances, and of medical, occupational and complementary rehabilitation benefits
10. the determination of number of physicians required for adequate health care delivery
11. medical services in cases of infertility
12. contraception and legal abortions.

Examples of current guidelines (nineteen have been adopted so far) are the pregnancy care guideline (dating back to 1965), the early childhood screening guideline, and guidelines for prescription drugs (originating in the 19th century), early cancer screening, disability determination, psychotherapy and fertility treatment. Their main purpose is to guarantee the standard of care. The pregnancy care guideline is as detailed as a

224. This term indicates that the above list is not exclusive. *Ein Verwaltungstiger erhält Zähne [An Administrative Tiger Gets Its Teeth]*, 23 DER KASSENARZT 31 (1997).

225. The German term is “new” procedures. The author, however, prefers to use “innovative” because the issue concerns some of the same diagnostic and treatment services dubbed “experimental” by managed care companies.

clinical practice guideline (CPG) and sets a high standard for medical services during pregnancy. Practitioners must apply the guideline and may not undertreat. The early childhood screening guideline also has elements of a CPG.

Art. 135, in conjunction with Art. 92(1)(5), further clarifies the mandate for innovative treatment coverage determinations, introducing specific evidence-based requirements. When the NOG 2²²⁶ became law on July 1, 1997, Art. 135 was significantly expanded:

Innovative medical and dental diagnostic and therapeutic procedures are covered by the sickness funds only if the Joint Federal Committee has issued guidelines under Art. 92(1)(5) recommending the acceptance of the diagnostic and therapeutic usefulness of the new procedure, its medical necessity and cost-effectiveness—also in comparison with already covered benefits—in agreement with the current state of scientific knowledge of the specialty concerned.

The JFC's scope of action now included the examination of the sufficiency, appropriateness and cost-effectiveness of innovative diagnostic and therapeutic procedures as compared to already covered benefits, in accordance with each medical specialty's state of the art. (Concerns were raised at the time that the application of internal specialty standards would lead to automatic "self-validation" but the JFC chairman, in agreement with members of the health care committee, clarified that this phrase expressed a requirement for comment by experts in the respective fields.²²⁷) Applications for such coverage determinations must be submitted by a regional physician association, the Federal Physician Association, or one of the sickness fund associations. Innovative procedures are not covered until the JFC has pronounced their diagnostic and therapeutic "usefulness."²²⁸ The revised Art. 135²²⁹ was further extended to the

226. 2 Neuordnungsgesetz NOG. BGBl. S. 1520; Bonn, 30. Juni 1997 [Health Care Code Revision Act II, German Code, June 30, 1997, at 1520].

227. *An Administrative Tiger Gets Its Teeth*, *supra* note 224. Wording was also added to include alternative therapies. *Resolution of the Health Care Committee, Art. 135(1)(1)*, in GESETZLICHE KRANKENVERSICHERUNG [SGB V ANNOTATED] 84 (Wilhelm Schmidbauer and Bernhard Schmidbauer, eds., 2000).

228. *Nutzen*. The BSG has interpreted this clause as an "exclusion of a procedure from coverage until approved by the JFC" for purposes of quality control. It also considers the JFC to hold a decision making monopoly for the coverage of innovative services. Rolf-Ulrich Schlenker, *Das Entscheidungsmonopol des Bundesausschusses für neue medizinische Verfahren und Außenseitermethoden* [The Decisionmaking Monopoly of the Federal Committee for

evaluation of already covered benefits to ensure their continued usefulness and appropriateness under the evolving standard of care. No application by a third party is required, the Committee must act *ex officio* whenever information indicative of the need for reevaluation of a covered procedure or service is received. The JFC has thus become the major coverage decision maker for outpatient treatment.²³⁰

Furthermore, a Hospital Committee²³¹ for the evaluation of current and innovative diagnostic and treatment procedures in hospitals, modeled after the JFC, was created by the Social-Democratic Reform 2000 under SGB V, Art. 137(c), thus eliminating an important legislative gap. Evaluations must be based on the current state of scientific knowledge, and the Art. 92 criteria, "sufficiency, appropriateness and cost-effectiveness," continue to apply.

Contrary to Art. 135, however, no mention is made of "diagnostic and therapeutic usefulness," resulting in a less stringent evaluation standard. This was criticized by the JFC chairman, also sitting on the Hospital Committee, who expressed concerns related to the absence under Art. 137(c) of adequate procedures and a sufficient organizational structure for the initiation and implementation of evaluations, and the promulgation of Hospital Committee decisions.²³² Art. 137(e) established a Coordinating Committee,²³³ a working group of all associations represented on both the JFC and the Hospital Committee. Its task is the coordination of committee activities resulting in a uniform set of criteria for the appropriate and cost-effective delivery of in- and outpatient care, relying on evidence-based clinical practice guidelines. The Committee is expected to issue such guidelines for at least ten illnesses per annum for which there are indications of the delivery of inadequate, inappropriate or excessive care, the elimination of which may affect population morbidity and mortality.²³⁴ Conceived as a working group, the Coordinating Committee lacks independent legal status but its decisions will bind the sickness funds,

Innovative Medical Procedures and Alternative Treatments], 9 NEUE ZEITSCHRIFT FÜR SOZIALRECHT 411 (1998).

229. Art. 135(1)(3), SGB V.

230. For further discussion, including some of the limitations of the scope of the JFC's rulemaking authority and resources, see *infra*.

231. *Ausschuss Krankenhaus*.

232. Karl Jung, *Rechtliche Grundlagen des Bundesausschusses auch nach der GKV-Reform 2000 unzureichend* [*Inadequate Legal Foundations for the Federal Committee Persist after Adoption of the Reform 2000*], KRANKENVERSICHERUNG 52 (March 2000) [hereinafter *Inadequate Legal Foundations*].

233. *Koordinierungsausschuss*.

234. Art. 137(e)(3)(1), SGB V.

hospitals and plan physicians.²³⁵ So far, neither the Hospital Committee nor the Coordinating Committee have promulgated guidelines. Whether and how they will be able to accomplish their mission remains to be seen.

2. Rulemaking Procedures

Art. 92, as of its earliest version in 1988, has mandated notice and comment procedures for JFC coverage guideline development. Initially limited to the prescription drug guideline, the article required that experts in pharmacology, representatives of the pharmaceutical industry and the pharmacist associations were to be heard.²³⁶ It was amended to currently include the medical specialty associations for alternative treatments, the midwives association, the organizations representing the manufacturers and service providers for prosthetic devices, hearing aids, other medical devices and equipment, the providers of preventive and rehabilitative services, both public and private home care providers, and dental technicians. At the Committee's discretion, additional parties may be heard. All opinions must be duly considered and included in the final coverage guideline decision. Deliberations are not open to the public.

The neutral JFC chairman has criticized the absence of a coherent legislative concept covering all procedural aspects of the hearing process such as the scope of notice and comment, the specific parties to be heard, whether comments should be presented orally or in writing, when and to which extent documentation should be made public and responses to requests for information be provided, and the absence of a well-defined obligation of the JFC to justify its decisions.²³⁷ The Committee therefore issued additional, more stringent rules of procedure specifying, for example, that any interested party may be heard or submit comments, once appropriate notice of the subjects under consideration has been given. Comments are distributed to all Committee members.

235. The sickness funds and Social-Democratic members of Parliament would have preferred a corporate entity under public law, making the Coordinating Committee a strong umbrella organization for all federal committees.

236. This was the result of the lobbying onslaught on the federal government before the reference price system was adopted as one of the major innovations of the new SGB V. With drug profit margins for both manufacturers and pharmacies exceeding the international average by far, the government introduced reimbursement ceilings by drug, the so-called "reference prices." These do not apply across the board, exempting innovative and patented drugs, for example. Currently, 46.5% of total drug expenditures by the universal health care system cover medication subject to reference prices. *Bundeskartellamt stoppt neue Festbeträge für Medikamente* [Federal Antitrust Agency stays new Reference Prices for Drugs], FRANKFURTER ALLGEMEINE ZEITUNG, Jan. 29, 2001, at 13. In spite of the price regulations, drug supply shortages as currently experienced in the United States are unlikely in Germany.

237. *Inadequate Legal Foundations*, *supra* note 232, at 53.

Art. 135, contrary to Art. 92, does not contain any notice and comment clauses, considered to be a serious legislative omission since the Art. 135 process leads to coverage exclusions while the Art. 92 process rarely does. Once again critical of the legislators' abdication, the JFC issued its own procedural guidelines.²³⁸ Medical services to be evaluated must be clearly defined and their indication specified. The JFC working groups must give notice of the procedures to be evaluated in the Federal Register and in the *Deutsches Ärzteblatt*.²³⁹ Comments are solicited from medical experts, specialty societies, and, whenever relevant, from associations of manufacturers of medical products and equipment. The working groups may hear expert testimony, and both written and oral opinions should be based on a questionnaire developed by the respective working group. Adequate time must be provided for the submission of comments.

Applications for innovative procedure coverage under Art. 135 must describe the usefulness of the new procedure, its medical necessity, and its cost-effectiveness compared to already covered care. The "usefulness" of the procedure must be supported by effectiveness studies for the specified indication, evidence of the therapeutic results of a diagnostic procedure, outcome evaluations including side-effects, and usefulness data in comparison with other procedures used for the same purpose. "Medical necessity" is to be shown through data detailing the relevance of the clinical issue, the epidemiology of the syndrome, the spontaneous course of the illness, and diagnostic and therapeutic alternatives. "Cost-effectiveness"²⁴⁰ must be addressed by estimating costs per patient, balancing costs and benefits per patient, balancing costs and benefits for the insured community, including follow-up costs, and by balancing costs and benefits in comparison with other treatment approaches.

Because the JFC must prioritize applications, data showing the diagnostic/therapeutic relevance for certain illnesses, the inherent risks of the procedure and its likely economic impact should also be submitted.

238. *Richtlinien des Bundesausschusses der Ärzte und Krankenkassen über die Einführung neuer Untersuchungs und Behandlungsmethoden und über die Überprüfung erbrachter vertragsärztlicher Leistungen gemäß §135 Abs. 1 i. V. m. §92 Abs. 1 Satz 2 Nr. 5 SGB V, 1. Jan. 1998* [Guidelines of the Joint Federal Committee of Physicians and Sickness Funds for the Coverage of Innovative Diagnostic and Therapeutic Procedures and the Evaluation of Covered Medical Services Under §135(1) in Conjunction with §92(1)(5)], in HAUCK, *supra* note 208, C 455, at 1 (Jan.1, 1998).

239. This is the official publication of the Federal Physician Association.

240. The JFC cost-effectiveness definition strives to avoid being "one-eyed," *see Bundesausschüsse der Ärzte und Krankenkassen, supra* note 209, by requiring the "balancing" of costs and benefits and by addressing follow-up costs.

The JFC then classifies applications for therapeutic innovations according to: (I) evidence based on at least one randomized, controlled study, conducted and published in agreement with internationally recognized standards (good clinical practice, such as GCP according to Consort); (IIa) evidence derived from other prospective studies with clinical intervention; (IIb) cohort or case-controlled studies, preferably involving more than one group of subjects; (IIc) time-series studies or comparisons between sites with and/or without clinical intervention; (III) opinions of recognized experts, correlational observations, pathophysiological discussions or descriptions; expert committee reports, consensus conferences, case studies.

Diagnostic procedures are classified by considering: (I) evidence based on at least one randomized, controlled study, conducted and published in agreement with internationally recognized standards; (IIa) evidence based on prospective diagnostic studies using validated numerical targets (so-called "gold standards"), conducted under routine clinical conditions accompanied by sensitivity, specificity and predictive value calculations; (IIb) evidence derived from studies using populations with a health status determined at the outset of the study using validated numerical targets (gold standards), indicating at least sensitivity and specificity data; (IIc) evidence from studies of populations with a predetermined health status using non-validated diagnostic coefficients resulting in at sensitivity and specificity data; (III) opinions of recognized experts, correlational observations, pathophysiological discussions or descriptions; expert committee reports, consensus conferences, case studies.

Whenever the JFC has approved an innovative therapeutic or diagnostic procedure, recommendations for required provider qualifications, equipment standards and quality control measures are published simultaneously in order to ensure the appropriate application of the new method. The national sickness fund and physician associations may then jointly issue additional detailed quality control requirements. Procedures rejected as not meeting the statutory coverage criteria are publicized as well.

Should the JFC have failed to rule on a new procedure or have done so in a timely fashion²⁴¹ but treatment was provided and reimbursement denied by the sickness fund, patients may bring an action before the social courts under Art. 13, SGB V, allowing payment for care required by

241. *Systemversagen*. Whenever the JFC has failed to rule on the coverage of a new method in a timely fashion, the reimbursement of services will be permitted under Art. 13, contingent on case-by-case medical necessity determinations by the sickness funds and their Medical Services.

individual circumstances. The social court will then apply the “acceptance” standard to determine whether the procedure has become part of medical practice and is supported in the literature. Sickness fund payment decisions, however, are based on effectiveness and appropriateness criteria, a contradiction not yet resolved by the BSG.²⁴² Since the Court has concluded that the judiciary lacks the competence to make “medical-scientific” determinations²⁴³, and the legislative has conveniently delegated most of the responsibility for politically difficult choices to the JFC, patients, according to some authors, are left without the protection of the law.²⁴⁴

3. Conclusion

In spite of the remaining procedural weaknesses, the coverage determination process is public and transparent. Both Arts. 92 and 135 refer to generally recognized or prevailing standards of medical knowledge as standard for currently covered and innovative benefits. Patients are entitled to care in keeping with the progress of medical science (Art. 2), and physicians are obligated to provide it (Art. 70). According to the JFC chairman, coverage guidelines should therefore be based on the expertise of competent organizations and institutions²⁴⁵, and on evidence-based criteria reflecting the prevailing standards and scientific progress inherent in clinical practice guidelines (CPGs). These are also relied upon by experts whose comments on proposed coverage guidelines are required by law or JFC statutes. CPGs are developed by medical specialty societies, the Federal Physicians’ Chamber,²⁴⁶ and the AWMF (Working Group of Scientific-Medical Societies). The Chamber and the Federal Physician Association²⁴⁷ (represented on the JFC) have jointly established a

242. Schlenker, *supra* note 228, at 415.

243. BSGE 81, 54, 70, 72.

244. Ruth Schimmelpfeng-Schütte, *Richtlinienggebung durch den Bundesausschuß der Ärzte und Krankenkassen und demokratische Legitimation [JFC Guidelines and Democratic Legitimacy]*, 11 NEUE ZEITSCHRIFT FÜR SOZIALRECHT 530, 534 (1999).

245. *Clinical Practice Guidelines Viewed by the Federal Committee*, *supra* note 222.

246. *Bundesärztekammer*. Its regional member chambers (*Landesärztekammern*), corporate entities under public law, represent physicians’ interests, and adopt and implement the rules for the practice of medicine. They are roughly comparable to U.S. state boards monitoring the application of the professional code of ethics, continuing education requirements, and other rules and regulations controlling the exercise of the medical profession. All are components of the system of health care self-governance.

247. *Arbeitsgemeinschaft der wissenschaftlichen medizinischen Fachgesellschaften*. The AWMF’s website is available for view at <http://www.uni-duesseldorf.de/WWW/AWMF>.

Clearinghouse for Medical Quality Control.²⁴⁸ It develops CPGs for in- and outpatient delivery of care, supports both federal associations when contracting with sickness funds and hospitals, and coordinates the quality control activities of all associations on the federal level. It has also issued a “checklist for guidelines,” a step-by-step roadmap to ensure guideline quality and validity. In 1999, all federal entities of the system of self-governance representing physicians, sickness funds and hospitals adopted a joint project to promote the quality of guidelines in cooperation with the AWMF. Based on both Clearinghouse and AWMF criteria, a Guideline Manual for the development, adaptation or implementation of guidelines was published in October 2000.²⁴⁹ Increasing cooperation among all parties will contribute to quality of care improvements since valid CPGs translated into coverage guidelines would influence the daily practice of medicine.²⁵⁰

E. The Democratic Legitimacy of the Federal Committee Guidelines

1. The Guidelines' Legal Status

Public law associations autonomously adopt charters which have the force of law. But laws must result from a democratically legitimate process: associations, representing a limited number of citizens for a particular purpose, must have democratically constituted rulemaking bodies such as elected assemblies and boards. Sickness fund and physician associations meet this requirement but the democratic legitimacy of the Joint Federal Committee and its coverage guidelines has been a matter of much dispute. The SGB V of 1988 strengthened the normative force of the guidelines by integrating them into the federal collective agreements negotiated by the federal associations of sickness funds and physicians, and thus into the regional collective agreements as well. But the legal status of the guidelines and their external application to the insureds continues to be discussed and questioned in the literature.

Until 1996, the BSG had held that guidelines were only internal administrative rules binding the JFCs' member associations, without

248. *Ärztliche Zentralstelle Qualitätssicherung*. This organization considers and uses standards and definitions of the Institute of Medicine (IOM) and the former Agency for Healthcare Policy and Research (AHCPR).

249. *Leitlinien-Manual*, at <http://www.uni-duesseldorf.de/AWMF/II/IImanual.htm>. The Manual, with 2001 updates, is available at this site for purchase or for download in Adobe Portable Document File format.

250. Whenever clinical practice guidelines become part of the social law coverage guidelines, the physicians' conflict between the cost-containment requirements of social law and the civil law malpractice standard is resolved as CPGs represent the civil law standard of care.

normative effects on individual sickness funds and providers. Guidelines could be applied to such third parties²⁵¹ only through their integration into the regional association charters.²⁵² Furthermore, guidelines could not limit members' material claims to comprehensive health care under Art. 27.²⁵³ The BSG thus gave clear precedence to the coverage and benefit entitlement sections (Chapter Three, Arts. 11-66) of the SGB V over its administrative health care delivery sections (Chapter Four, Arts. 69-140), emphasizing the rights of patients to treatment over administrative decisions by the JFC (established by Art. 91 of Chapter Four).²⁵⁴ This approach also helped bridge the inconsistencies between the coverage and health care delivery aspects of the law, enabled the providers to provide legal individualized services, protected the patients, and required the sickness funds to accept medical judgment. Concurrently, physicians were bound by the coverage guidelines and all collectively agreed upon contractual conditions of health care delivery.

On March 20, 1996,²⁵⁵ however, the Supreme Social Court ruled that the JFC is an "institution" under public law with rulemaking authority limited to specific interpretations of the law.²⁵⁶ Even though such institutions, contrary to corporate "entities" under public law, are established to fulfill a certain purpose without the democratic representation of members, they too may adopt charters and participate in a system of self-governance. Relying on SGB V, Art. 92(8) (the JFC coverage guidelines are components of the federal collective agreements between sickness fund and physician associations), Art. 82 (the federal collective agreements determine the terms of the regional agreements), Art. 83 (the regional agreements are binding for the sickness funds), Art.

251. *Drittwirkung; Aussenwirkung.*

252. Prior to 1988, guidelines were declared "binding" in the charters of the regional sickness fund and physician associations, endowing them with only questionable applicability to third parties. This issue had never been resolved. Ebsen, *supra* note 195.

253. Peter Hinz, *Der Bundesausschuss der Ärzte und Krankenkassen—Status and Aufgaben [The Joint Federal Committee—Status and Mandate]*, 7 DIE LEISTUNGEN 385 (July 2000).

254. This was also a reflection of the historical development of German health care law: one of the original purposes of the contractual arrangements between physicians and sickness funds was the delivery of health care for favorable fees. Wolfgang Gitter & Gabriele Köhler-Fleischmann, *Gedanken zur Notwendigkeit und Wirtschaftlichkeit von Leistungen in der gesetzlichen Krankenversicherung und zur Funktion des Bundesausschusses der Ärzte und Krankenkassen [Reflections on the Necessity and Cost-Effectiveness of Benefits under the SGB V and the Function of the Joint Federal Committee]*, 1 DIE SOZIALGERICHTS BARKEIT 1 (1999).

255. BSG 6 Rka 62/94, March 20, 1996, *Methadonurteil* ["The Methadone Ruling"], 3 MedR 123 (1997).

256. *Anstalt des öffentlichen Rechts mit begrenzter Rechtsfähigkeit mit der Aufgabe der konkretisierenden Rechtssetzung.*

95 (the regional agreements bind individual providers), and Art. 81 (the regional physician association charters must contain clauses to make the guidelines binding on association members), the Court reversed its earlier interpretation of the law and held that the JFC guidelines have the same normative effect on sickness funds and physicians as the federal and regional collective agreements concluded by their associations. This confirmed the separate rulemaking authority of the Joint Federal Committee, independent of its constituent corporate entities under public law governing the health care system. Furthermore, the BSG reversed the primacy of the SGB V coverage and benefit entitlement sections over the sections regulating the administration of the health care delivery system, thus permitting administrative interventions in an area so far mainly controlled by physicians.

The applicability of the new approach to the patients as third parties was resolved by analyzing the internal consistency of the law.²⁵⁷ Chapter Three (coverage and benefits) of the SGB V calls for JFC guidelines detailing the material claims for benefits by members under SGB V, Arts. 27 (a)(4) for fertility treatment, and Art. 29(4) for orthodontics in agreement with Art. 92 of Chapter Four (the health care delivery system). Without such a specific mandate, Art. 92(1) was considered the default clause granting general JFC rulemaking authority (“Guidelines must be adopted to ensure the sufficient, adequate and cost-effective delivery of care”). According to the BSG, Art. 92(1) is logically related to Art. 12(1) of Chapter Three, requiring the “sufficient, adequate and cost-effective” provision of benefits to individual patients. Art. 72(2) of Chapter Four once again reiterates these terms when stipulating the joint obligation of sickness fund and provider associations to deliver care. The BSG thus found the guideline application to patients to be implied in the SGB V.

Five BSG decisions, announced on September 16, 1997,²⁵⁸ confirmed the far-reaching delegation of rulemaking authority to the JFC,²⁵⁹ dubbed “one of the traditional components of German health care law” by the Court. In all five cases, the BSG denied patients’ claims for reimbursement by the sickness funds of treatments not considered covered

257. BSG 6 Rka 62/94, March 20, 1996; Hinz, *supra* note 253.

258. BSG 1 RK 28/95, SozR 3-2500 §135 No. 4.; BSG Az 1 RK 17/95; 1 RK 14/96; 1 RK 30/95; 1 RK 32/95.

259. The BSG assumed the constitutionality of the scope of the delegation by declaring that the Constitution does not contain a *numerus clausus* provision, limiting the categories of rulemaking approaches. Still, the constitutionality of the Committee rulemaking authority is hotly contested by constitutional law scholars and experts. The final arbiter, the Constitutional Court, has not yet been seized with the issue.

by the SGB V. Three decisions relied on the exclusion by the JFC of immuno-augmentative therapy for multiple sclerosis from coverage.²⁶⁰

Building on the March 3, 1996, opinion, the Court considered the binding normative effect of the JFC guidelines on patients as flowing from the systematic unity of SGB V Chapters Three and Four. The analysis turned in particular on Art. 2, entitling members to the provision of benefits in accordance with the prevailing state of medical knowledge and the progress of medical science. The JFC was thus given a central role in coverage decision making under the SGB V, shifting more of the complex application of the SGB V from legislators to a body of experts. This responsibility is shared with federal and regional physician and sickness fund associations which must initiate the innovative treatment evaluation but may not block nor delay such proceedings which are subject to the Art. 2 provisions.²⁶¹ But in light of the multitude and complexity of prevailing and innovative practices, and the resources required for their evaluation, the current capacity of the JFC to rule on comprehensive coverage while ensuring adequate transparency and the rule of law is in doubt.

Furthermore, the scope of the JFC rulemaking authority has been successfully challenged in court. The BSG, even though recognizing the Committee's authority to issue guidelines to "concretize" the general health care entitlement clauses of the SGB V, limited the Committee's ability to adopt exclusions.²⁶² It rejected the JFC Viagra coverage exclusion argument that sickness funds would be prevented from "appropriately managing" the cost-effective provision of health care as merely addressing administrative difficulties, insufficient justification for a coverage exclusion reserved to the legislator under Art. 34, SGB V.²⁶³ Because erectile dysfunction meets the statutory definition of illness of Art. 27, SGB V, and can have differing etiologies (in this case a chronic, age-unrelated condition), the JFC may not prohibit reimbursement of a drug approved for its effectiveness independent of a patient's individual circumstances. Relying on the BSG opinion, a state court approved

260. In another case, the treatment received by one of the plaintiffs was not considered the prevailing standard of care since practiced by one physician only. In the fifth case, the reimbursement of acupuncture for neurodermitis was denied because medical science had not increasingly relied on such treatment for this indication.

261. Schlenker, *supra* note 228, at 415.

262. BSGE 85, 36, 45, Sept. 30, 1999. 37 NEUE JURISTISCHE WOCHENSCHRIFT 2764 (Sept. 2000).

263. Art. 34, SGB V, excludes from coverage most over-the-counter medication. It also allows the Secretary of Health to exclude by regulation additional drugs, adjunctive therapies, and durable medical equipment of questionable usefulness.

coverage for a patient afflicted with diabetes.²⁶⁴ In another case before the BSG, the Court reversed the JFC exclusion of medically indicated podiatric services, referring to the authority of the Secretary of Health to regulate adjunct therapies under Art. 34.²⁶⁵ Both BSG rulings clarify that the guidelines may “concretize” adequate, appropriate and cost-effective care but may not exclude from coverage a particular illness nor adjunct therapies and specific drugs, a power reserved to the Secretary of Health.

In addition, one state court, ruling in three cases brought by three pharmaceutical companies, imposed temporary injunctions against the prescription drug guideline in 1999.²⁶⁶ A state supreme court, finding that all provisions of the guideline applicable to the products of a pharmaceutical manufacturer violated antitrust law, issued an injunction in January 2000.²⁶⁷ The JFC chairman deplored these actions leading to a temporary stay of the development of guidelines potentially subject to further antitrust actions, accused physicians and the pharmaceutical industry of jointly stymieing all efforts to “clean up” the drug market, and called for a legislated solution.²⁶⁸ He also advocated exclusive social court jurisdiction over guideline-related issues as matters of public not civil law. The national legislature under Social Democratic leadership agreed and amended Art. 69, SGB V accordingly. Since sickness funds and their associations are exercising a public law function, they do not act as private law corporations, and antitrust law does not apply.²⁶⁹

2. Legal Norms Based on Contract?

As most elements of the German health care system, collective norm setting based on contract is rooted in history.²⁷⁰ Many of the provisions of

264. SG Lüneburg, S 9 KR 97/99, Feb. 2, 2000. 37 NEUE JURISTISCHE WOCHENSCHRIFT 2766 (Sept. 2000).

265. BSG B 1 KR 9/97 R. Nov. 16, 1999.

266. LG Hamburg, AZ 315-0-115/99, 129/99, 143/99 (March 31, 1999).

267. OLG München (Jan. 1, 2000).

268. *Inadequate Legal Foundations*, *supra* note 232. Before the adoption of the SGB V in 1988, more than 60,000 prescription and OTC drugs were on the German market, often combining different active ingredients without therapeutic justification but favored by the “consumer” and the drug companies. Currently, 40,000 drugs remain.

269. HAUCK, *supra* note 208, at Art. 69. *See also* GESETZLICHE KRANKENVERSICHERUNG [SGB V ANNOTATED] 44 (Wilhelm Schmidbauer et al., eds., 2000) (discussing legislative intent). In addition, the relationships between sickness funds and their associations and providers and their associations are regulated exclusively by Chapter Four, SGB V. *See generally* Art. 69, SGB V.

270. This section is based on Klaus Engelmann, *Untergesetzliche Normsetzung im Recht der gesetzlichen Krankenversicherung durch Verträge und Richtlinien* [Rulemaking Through

the civil law Berlin Agreement of 1913, regulating the relationship between physicians and sickness funds, were entered into the national insurance act of 1923. The Joint Committee of Physicians and Sickness Funds, one of the historical predecessors of the current JFC, was instituted to resolve the details of health care delivery by plan physicians through the issuance of (then indirectly normative) "guidelines." Their main purpose was to facilitate the cooperation between physicians and sickness funds, with only minor references to coverage. Eventually, the contractual relationships between physicians and sickness funds began to evolve into collective agreements which became the foundation of the health care system of self-governance when the national insurance act was revised in 1932.

Furthermore, medical care has always been prepaid.²⁷¹ Sickness funds as the "arrangers" of health care contracted with providers for the delivery of services. Therefore, norms based on contracts helped specify the details of the provision of prepaid care, a process carried forward through successive versions of the national health care law. Today, the SGB V requires collective contracts between physician and sickness fund associations as corporate entities under public law, mandated to jointly guarantee and govern health care delivery. JFC guidelines are seen as collectively agreed-upon norms characteristic of the German health care system.²⁷² But how legitimate are the guidelines?

On September 16, 1997,²⁷³ the BSG ruled that patients' claims to health care are limited by the coverage definition of Chapter Four of the SGB V, regulating the delivery of health care and the issuance of coverage guidelines. "This Chapter determines the extent of coverage materially and formally; the insureds may not claim benefits beyond coverage as defined herein." The general statutory claim to comprehensive coverage in case of illness of Chapter Three (Art. 27) thus was made subject to interpretation by rulemaking as delegated to the JFC.²⁷⁴ Opponents of the now expanded normative character of the coverage guidelines consider the delegation of such rulemaking authority to the JFC a violation of fundamental constitutional rights, based upon the non-delegation

Collective Contracts and Coverage Guidelines as a Component of the Health Care Act, 1 NEUE ZEITSCHRIFT FÜR SOZIALRECHT 1, (2000).

271. This system was preferred over indemnity plans as guaranteeing more "social protection" but also more control over the appropriate, adequate and cost-effective delivery of care for the country. *Id.*

272. *Rechtssetzung durch Vertrag*. Engelmann, *supra* note 270, n.255.

273. Engelmann, *supra* note 270, n.241 (citing BSG 1 RK 28/95, SozR 3-2500 §135 No. 4).

274. Health care has now joined environmental protection and other complex technical and scientific fields for which traditional laws have become inadequate mechanisms of control.

doctrine.²⁷⁵ Fundamental rights and values, including “freedom, life and physical inviolability”²⁷⁶, are subject only to the legislative powers of parliament. Whether a fundamental right has been violated is to be analyzed case-by-case by the Constitutional Court. It has been argued,²⁷⁷ however, that the coverage and health care delivery sections (Chapter Four) of the SGB V are complex, and legislating details of the provision of medical services exceeds the resources of parliament. For decades, “the judiciary has proven that it is capable of construing vague statutory terms and clauses without diminishing the protection of the law afforded to the people.”²⁷⁸

Even when accepting the validity of rulemaking delegation to the JFC on behalf of physician and sickness fund associations, some authors question the applicability of JFC guidelines to the patients. In 1996, the 6th Senate of the BSG ruled that patients were “passive beneficiaries”, not active participants in the implementation of the health care law, and no separate justification for the extension of guideline applicability to them was required. But are violations of the non-delegation doctrine really contingent on individuals’ active or passive role within a norm setting process, or isn’t it rather the degree to which the ensuing norm affects their rights?²⁷⁹ The 1st Senate, in 1997, concurred with the 6th Senate while dissenting from its analysis: JFC guidelines as norms based on collective contracting are integral elements of a system of rules intended to ensure the provision of medical care, and thus applies to all patients. Some authors, however, consider the patients’ absence from the rulemaking process as undermining its democratic legitimacy.²⁸⁰

Another strand of criticism cuts even more deeply. It disputes the norm setting authority of physician and sickness fund associations, partners

275. Raimund Wimmer, *Verfassungsrechtliche Anforderungen an untergesetzliche Rechtsetzung im Vertragsarztrecht*, [Constitutional Limitations to Normsetting Procedures under the SGB V Health Care Provider Sections], 9 MEZINRECHT 425 (1996).

276. Constitution of the Federal Republic, Art. 2(2). In combination with Art. 20 (“The Federal Republic is a democratic, socially responsible state”), the rights to an existential minimum, health care and informed consent (“patient autonomy”) have been inferred by the Constitutional Court.

277. Klaus Engelmann, *Das Rechtskonkretisierungskonzept des SGB V und seine dogmatische Einordnung durch das Bundessozialgericht* [The Construction of the SGB V and its Dogmatic Classification by the Supreme Social Court], in *ÄRZTLICHE LEITLINIEN: EMPIRIE UND RECHT PROFESSIONELLER NORMSETZUNG* [MEDICAL GUIDELINES: EMPIRICAL AND LEGAL FOUNDATIONS FOR SETTING PROFESSIONAL NORMS] (Dieter Hart, ed., 2000). Justice Engelmann is Chief Justice of the 6th Senate of the Supreme Social Court.

278. *Id.*

279. Schimmelpfeng-Schütte, *supra* note 244, at 533.

280. *Id.*

to the collective agreements. Hence none of the institutions established by them, including the JFC, may issue any generally applicable rules or coverage guidelines. The legislator should remedy this "legal vacuum" because of guideline impact on the constitutional rights of patients, providers, and of those who sell to the health care system.²⁸¹

Others argue alternatively that the increasing complexity of allocative and medical decision making requires an effective intermediate-level system of norms, consisting of collective agreements and guidelines, constituting flexible elements of law with limited applicability, and promoting the interplay between the state, the legislator, administrative entities, and other relevant institutions such as public and private associations.²⁸² While funding was not an issue, health care laws could be executed satisfactorily through the application of professionally and medically-scientifically derived standards, preserving the quality of the provision of care. But at a time when health care cost containment measures are considered unavoidable, decision making must be delegated to administrative rulemaking entities of the system of self-governance to ensure the continued availability of "sufficient, appropriate and cost-effective" care,²⁸³ respecting the standard mandated by law.

IV. CONCLUSION

Two more divergent approaches to coverage and "medical necessity" are difficult to conceive. The German health care code, the SGB V, may appear overly complex to American readers, "big government" seemingly practicing medicine and limiting individual freedom. But the code was drafted to protect the dignity and autonomy of patients and their families at times of need, the autonomy of providers to practice medicine according to the standards and values of their profession, and to guarantee a high standard of care for everyone. In this spirit, the SGB V mandates comprehensive universal coverage for the prevention, diagnosis, and treatment of illness. Only physicians can translate these general material claims to care into specific benefits. They must assess each individual patient's circumstances and provide or arrange for needed procedures and

281. Raimund Wimmer, *Grenzen der Regelungsbefugnis in der vertragsärztlichen Selbstverwaltung* [Limits of Rulemaking Authority within the System of Physician Self-Governance], 3 NEUE ZEITSCHRIFT FÜR SOZIALRECHT 3 (1999).

282. Robert Francke, *Richtlinien, Normsetzungsverträge und neue Behandlungsmethoden im Rechtskonkretisierungskonzept des Bundessozialgerichts* [Coverage Guidelines, Norm Contracts and Innovative Medical Procedures: New Approaches to Interpreting Legislation as seen by the Supreme Social Court], 1 DIE SOZIALGERICHTSBARKEIT 8 (Jan. 1999).

283. *Id.*

services. The SGB V thus relies on physician autonomy for the appropriate case-by-case delivery of health care, according to the prevailing standards of medical practice and in keeping with the progress of medical science.

Clinical decisionmaking, however, must respect the boundaries set by budgets for practices by specialty, adjusted for regional variations of risk, and for prescription drugs.²⁸⁴ Furthermore, capitation for some basic services shifts part of the morbidity risk to providers who, just as their American colleagues, must now micro-allocate care. Sickness funds and physician associations jointly conduct economic reviews of individual physicians' practices. Individual or collective monetary sanctions are imposed for expenditures exceeding a predetermined range. National coverage "guidelines" for innovative treatments and technology result in another, increasingly weighty, limitation on physician autonomy. But guidelines by law are jointly negotiated by sickness funds and physician organizations, just as aspects of quality control, standards of care, and physician compensation. Through their participation in the collective self-governance of the health care system, physicians therefore have a formal role in the decision making process affecting the exercise of their profession. Resulting from the communitarian German tradition of social insurance, the health care system enjoys a high degree of acceptance among both members and providers, and proposed amendments trigger a heated, sometimes acrimonious, public debate. Recent reform and cost control efforts have met with general discontent, and any fundamental modifications would be rejected by all parties concerned.

In the United States, coverage for a majority of the population is negotiated between private managed care companies and employers. Policies list benefits and exclusions, while internal guidelines and criteria subject physicians' treatment proposals to stringent corporate "medical necessity determinations,"²⁸⁵ effectively transferring medical decision making to a third party outside of the physician-patient relationship. Many

284. The current system of funding health care by assessing personal income up to a specific bracket has been criticized because sickness fund revenue becomes insufficient at times of high unemployment, early retirement to promote job creation, and an aging population. Health care fund availability is thus limited by external factors such as labor market policies and demographics. Sickness funds may not raise premiums as the law mandates "premium stability."

285. See M. Gregg Bloche, *Medical Care and the Enigma of Efficiency*, in SOCIAL SCIENCE RESEARCH NETWORK ELECTRONIC PAPER COLLECTION 71 (1999), available at http://papers.ssrn.com/paper.taf?abstract_id=184275. See also Lothar Krimmel, *Was ist "medizinisch notwendig"?* [What is "Medically Necessary"?], 94 DEUTSCHES ÄRZTEBLATT, at C16 (1997) (stating that "medical necessity" is considered "vacuous" and a "meaningless metaphor" in both countries). Dr. Krimmel is past president of the Federal Physician Association.

physicians' clinical autonomy is subject to additional corporate control through payment arrangements (financial incentives and capitation) and provider profiling. Practitioners exceeding corporate utilization and appeals benchmarks are dropped from the managed care network. Physicians, lacking the protection of national health care legislation and an effective system of self-governance, are prohibited by antitrust law from forming unions to negotiate quality of services, working conditions, and payment with managed care corporations. Considerable nationwide dissatisfaction with the current health care delivery system has led to the adoption of several contradictory "patients' rights bill" by Congress and increasingly comprehensive state legislation regulating managed care practices.

Common to both countries are cost containment efforts through standardized practice guidelines. Managed care guidelines, both corporate and commercial, are often considered "proprietary," and the methodology for their development is not available for public scrutiny. German guidelines, promulgated according to social law requirements, result from a notice and comment administrative rulemaking procedure relying on expert input but criticized because not yet completely transparent. In both countries, guidelines developed according to scientific and evidence-based criteria by medical societies do not yet have a major influence on medical practice. "A negative consequence of being sponsored by a voluntary professional organization is the lack of financial support to widely distribute information."²⁸⁶ In Germany, however, efforts are under way to develop the growing number of guidelines adopted by the Joint Federal Committee through formal cooperation with medical societies.

In both countries, there is also a clear recognition that guidelines alone can not resolve the dilemma of how to increase cost-effectiveness without compromising the delivery and quality of necessary care. "How to quantify quality is the underlying issue, unresolved under current law, perhaps defying any kind of resolution."²⁸⁷ Many prevailing practices have not been evaluated and many are not amenable to empirical validation. Furthermore, some of the most fundamental aspects of good medical care, effective clinical support and comfort at the bedside, can not be cast into standardized practice guidelines or subjected to a cost-effectiveness analysis. Any efforts to remove such "waste" from health care to increase efficiency would be misguided and ignore one of the basic purposes of medicine.²⁸⁸

286. GARTNER & MEE-LEE, *supra* note 28, at 13.

287. HAUCK, *supra* note 208, K § 12, at 8.

288. Bloche, *supra* note 285.

In the United States, there is a growing awareness that universal access to health care would remedy much of the failings of the current market-dominated system, singular among industrialized nations. “If this moment—a moment of unprecedented economic prosperity and looming budget surpluses—is the wrong one for an aggressive move towards universal health insurance, when will it be right?”²⁸⁹ But any fundamental changes to the health care system would have to be supported by culture and societal values. In the United States, the emphasis traditionally has been on individualism, the protection of individual rights, and the protection from “government interference.” In Germany, solidarity among members of the national community—implying both rights and obligations—is the foundation of social insurance. Social law is seen as protective of the rights of individuals while codifying their obligations and those of society.

But laws, regulations and charters, drawn too complex and too restrictively, may impose excessive duties on individuals and the economy. Wherever there is reliance on market forces, society gains space, and government saves money. On the other hand, the market is cold, focused on profitability, blind to off-balance-sheet side-effects, and indifferent to politically defined concepts of justice. The state, predominant in the “magic triangle of state, market, and self-regulation”, can weight the instruments at its disposal: effective administrative law, self-governance, and the use of market forces. German health care reform efforts continue to search for the proper balance between them. The more weight is given to cooperative structures and flexible rulemaking, the more the market forces become instrumentalized, and the more apparent the ability of legal norms to protect freedom.²⁹⁰ In order to restore patient autonomy and choice of health care options, remove generic clinical decision making from distant commercial entities and return it to physicians focussed on their patients’ individual needs, a new conception of American health care law may be required.

289. *Toward Universal Coverage*, N.Y. TIMES, Sept. 24, 2000, at A14.

290. Udo di Fabio, *Verlust der Steuerungskraft klassischer Rechtsquellen* [*The Loss of Control of Classical Sources of Law*], 10 NEUE ZEITSCHRIFT FÜR SOZIALRECHT 449, 453, 455 (1998).