Law and the German Universal Healthcare System: A Brief Contemporary Overview

*By Ursula Weide**

A. Introduction

How to reform the American health care system, now dominated by a decreasing number of multi-billion dollar managed care corporations, has occupied the public debate for many years. Recent news reports hefty increases in managed care premiums, benefit reductions, and an ever-growing number of managed care organizations refusing to treat Medicare patients. Numerous "patients' bills" have been submitted in Congress, attempting to rein in some of the managed care cost containment practices. None have been adopted so far.[1] At best, such bills would superficially treat some of the symptoms of an ill-functioning health care delivery system, poorly serving the population, insured and uninsured, and creating a plethora of ethical conflicts for providers battling to preserve an acceptable standard of care. Since the Clinton health care reform efforts failed in 1994 , no one has proposed a fundamental revision of the system[2], and the United States remains the only industrialized nation without a universal health care system. The literature mainly reports on those - English-language - countries whose cost containment measures have resulted in overburdening the public health care

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[1] *For Patients' Rights, A Quiet Fadeaway.* Amy Goldstein, WASHINGTON POST, Sept. 12, 2003, At A4.

[2] "Patients' Rights Bills … have unintended consequences because they deal with the effects, rather than the underlying causes, of the system's failure. … what many americans don't realize is that our employment-based health care system is entirely voluntary. … the fundamental problem is that it is impossible to regulate a strictly voluntary system. attempts to do so lead to the paradox of less rather than more coverage. … the answer is a single-payer system that covers everyone and more efficiently uses the resources we allocate to health care." Martha Angell, *A Wrong Turn On Patients' Rights,* N.Y. TIMES, June 23, 2001, At A13.

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system. There are, however, numerous European governments which succeed in stabilizing health care expenditures by mandating some sacrifices by all participants in the health care system while preserving universal access, comprehensive coverage, and the standard of care.

This article will provide a brief overview of the historical origins of the German health care system, define the main concepts of the current universal access/universal coverage system as codified in Title Five of the Social Code (SGB V – *Sozialgesetzbuch* V)[3], describe the role of the *Bundessozialgericht* (BSG – Federal Social Court)[4] with jurisdiction over the health care system, address some of its most influential rulings, and outline major reform bills. It will be shown that providers' clinical autonomy, including the operationalization of medical necessity, and compensation are protected by law. Current German proposals aimed at a better allocation of health care resources in the future will also be discussed.[5]

B. The History of Social Insurance in Germany

The protection of the working population from the consequences of illness, work-related accidents, unemployment, and the provision of services such as adequate housing, all raising the dignity of workers and their dependents, represent a longstanding German social tradition. [6]
As early as the 15th and16th century, the Fugger family, influential merchants in Augsburg, built housing settlements for its workers. In the 19th century, industrial entrepreneurs increasingly recognized the value of their labor force, the need to

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[3] *Sozialgesetzbuch Fünftes Buch*, SGB V (Title Five, Social Code*), "The Health Care Reform Act" (Gesundheitsreformgesetz, GRG),* Adopted In 1988 (Hereinafter SGB V). The Social Code today consists of 11 titles which include job pPlacement, Retraining And Unemployment Benefits (Title Iii: *Arbeitsförderung*), Social Security (Title Vi: *Gesetzliche Rentenversicherung*), Workers Compensation (Title Vii: *Gesetzliche Unfallversicherung*), and Longterm Care Insurance (Title Xi: *Soziale Pflegeversicherung*).

[4] The Court Is Located In Kassel, In The State Of Hesse.

[5] In the present article, comparative German-American comments are mostly limited to the footnotes. For a comprehensive discussion of comparative German and American Health Care Law, see already Ursula Weide, *Coverage And Medical Necessity Determinations: U.S. Managed Care Treatment Decisions Vs. German Administrative Rulemaking,* 8 ILSA JOURNAL OF INTERNATIONAL AND COMPARATIVE LAW 508 (2002); *id., Health Care Reform and the Changing Standard of Care in the United States and Germany*, In: 20 JOURNAL OF INTERNATIONAL AND COMPARATIVE LAW 249 (2000); *id., 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 TULANE EUROPEAN AND CIVIL LAW FORUM 47 (1998).

[6] This section is based on HEINZ LAMPERT, LEHRBUCH DER SOZIALPOLITIK [Compendium Of Social Policy] 1998 *[Hereinafter Lampert].*

protect it from major life risks, and to ensure an improved environment for the next generation. Health, disability and retirement plans were introduced. In addition, the tradesmen's guilds, as of 1845, required mandatory membership in local health plans and plans by profession. To this day, the structure of the universal healthcare system reflects these historical plan categories.

1881 became the year of social insurance[7] on a national level: draft bills for disability and health insurance, workers' compensation and retirement benefits were either submitted to parliament or announced and supported by a message from the Kaiser. The state chose social insurance over higher wages because voluntary insurance was considered too risky in light of the horrifying images of women surrounding factory gates on payday to prevent their husbands from spending their wages in the nearest pub. According to Rousseau, "Social insurance is the state's decision to force its workers to be free."[8] In 1883, Chancellor Otto von Bismarck submitted the "Health Insurance Act,"[9] integrating all then existing health insurance plans into national law. All plans were now uniformly regulated and premiums, to be shared by employers and workers, assessed according to income. In addition to prepaid medical care, coverage included sick pay and maternity benefits. The act was part of a comprehensive national social insurance system also covering workers' compensation, disability and retirement plans.

The *Reichsversicherungsordnung* of 1911 (RVO – National Insurance Code) combined all social insurance plans and added survivors' and orphans' benefits. Its health care chapter was amended numerous times over the years, as medical practice was changing, and cost containment increasingly became an issue. On December 20, 1988, replacing most health care sections of the RVO the parliament of the Federal Republic of Germany[10] adopted Title Five of the Social Code, the SGB V[11], and established the foundation for the current universal health care system. Four major revisions followed in 1992, 1997, 2000 and 2004[12], codifying with increasing specificity coverage, health care delivery, and standard of care.

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[7] This section is based on MICHAEL FREUND, DEUTSCHE GESCHICHTE [German History] 811 (1974).

[8] *Id.*, 813.

[9] *Krankenversicherungsgesetz.*

[10] *Bundestag.*

[11] *Sozialgesetzbuch Fünftes Buch. Gesundheitsreformgesetz (Grg).* BGBl. I 2477 (Dec. 20, 1988).

[12] *Gesundheitsstrukturgesetz (GSG)*, published in BGBl. (Federal Gazette) I 2266 (Dec. 21, 1992). *Neuordnungsgesetz I Und Ii* (Nog I, BGBl. 1518; Nog Ii, BGBl. 1520, June 23, 1997). *Gkv-Gesundheitsreformgesetz 2000.* BGBl. I 2626 (Dec. 22, 1999). *Gkv-Modernisierungsgesetz (Gmg) 2004.* BGBl. I 2190 (Nov. 14, 2003).

C. Health Insurance and the Socially Responsible State

According to Art. 20(1) of the *Grundgesetz* of 1949 (GG – Basic Law), the Federal Republic of Germany is a democratic and socially responsible federal state.[13] The statutory system of health care can be considered synonymous with the socially responsible state[14] established by the Basic Law.[15] The state thus has a formal duty to care for its citizens derived from Art. 20(1), which operates in conjunction with Art. 1(1) (the inviolability of human dignity), Art. 2(2) (the right to life and health), and Art. 104(1) (the protection of individual physical and psychological integrity).[16] This duty of care includes the provision of the material minimum for a dignified existence,[17] the preservation of health, the control of pain, and the restoration of health in case of illness.[18] The underlying principles of all social policy are solidarity, subsidiarity, and self-governance.[19]

I. Solidarity

Solidarity is expressed through the union movement, collective associations,[20] and the social insurances, including the universal health care system. For individuals as members of the community, solidarity implies not only rights but also obligations towards other citizens in order to prevent free-loading and the disabling of the

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[13] Grundgesetz [Bacis Law] Art. 20(1) (May 23, 1949). "Die Bundesrepublik Ist Ein Demokratischer Und Sozialer Bundesstaat." [The Federal Republic of Germany is a parliamentary democracy].

[14] *Sozialstaat.* English translation provided by Robert Gerald Livingston in: P.R. Range & R.G. Livingston, *The German Welfare Model That Still Is,* Wash. Post, Aug. 11, 1997, At C2.

[15] Gudrun Eberle, *Die Entwicklung der GKV zum heutigen Stand [The History Of The Statutory Health Care System],* 47 SOZIALER FORTSCHRITT 53 (1998).

[16] Decision of the Federal Administrative Court *(Bundesverwaltungsgericht)* of 24 June 1954, published in BVerwGE, Vol 78, 159 [161], June 24, 1954. Decision of the Federal Constitutional Court *(Bundesverfassungsgericht*) of 18 June 1975, published in BVerfGE 15, 121 [133].

[17] BVerfGE 7, 187 [228], of 21 June 21 1977.

[18] Erwin Deutsch, *Ärztliche Berufspflichten Im Konfliktfeld Zwischen Artzhaftung And Sozialrecht [Conflicts Between Medical Liability And Social Law: Physicians' Professional Duties],* RICHTERWOCHE, BUNDESSOZIALGERICHT (1996).

[19] *Solidarität, Subsidiarität, Selbstverwaltung.* This section is based on LAMPERT, *supra* note 6.

[20] *Genossenschaften Und Körperschaften (Associations, Cooperatives, Corporate Entities Under Public Law)* are both terms used in OTTO VON GIERKE, DIE GENOSSENSCHAFTSTHEORIE UND DIE DEUTSCHE RECHTSPRECHUNG [The Law of Associations and German Jurisprudence] (Weidmann, 3. Nachdruck der Ausgabe Berlin 1887) (Third Reprint Of The Edition Of 1887). These concepts have survived several consecutive systems of government and are the foundation of the public system of self-governance of the federal republic.

system. Solidarity is considered a concept of social ethics, occupying the position between individualism and collectivism.[21] Individualism implies the interpretation of freedom as "freedom from," especially from the interference of government, and the absence of submission to persons and institutions. It is "[t]he right to be left alone," as phrased by Justice Brandeis in *Olmstead v. United States*.[22] Economic freedom follows from individualism, allowing market forces to dominate. The social approach to society, however, interprets freedom as the material independence to enjoy "freedom to." Human beings, by nature, are members of society, able to attain this freedom only "when government is directly responsible for furthering both the economy and society."[23]

Solidarity, under the SGB V, Art. 1, entitles "Patients"[24] to comprehensive medical care but also holds them responsible for contributing to their health status through a preventive lifestyle or, whenever required, through active participation in their medical treatment. Sickness funds (insurers)[25] will provide members with the requisite information and benefits.[26] Funding of health care delivery, also based on solidarity, relies on mandatory membership up to a certain level of personal income[27], and on premiums (currently 14.2%[28]) not exceeding a certain level of

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[21] For an in-depth discussion of the influence of individualism in the United States and communitarianism in germany on the respective contemporary legal systems and the resulting differing approaches to health care, See Weide (Note 5), 47 TULANE EUROPEAN AND CIVIL LAW FORUM 94-104.

[22] 277 U.S. 438 (1928)

[23] Prof. Dr. Jürgen Wasem, *Sozialpolitische Grundlagen der gesetzlichen Krankenversicherung (Social-Political Foundations of the Universal Health Care System)*, in: HANDBUCH DES SOZIALVERSICHERUNGSRECHTS 90, VOL. 1, [HANDBOOK OF SOCIAL INSURANCE LAW] (BERTRAM SCHULIN, ED., 1994).

[24] The common german term is "*patient*" since most of the population receives cradle-to-grave coverage by the statutory health care system, making everyone a patient as of the first day of life. the term is used in this article interchangeably with "members, insured, subscribers."

[25] *Krankenkassen.*

[26] SGB V, Art. 1) *Sozialgesetzbuch – Fünftes Buch* (SGB V). BGBl. 2477, 20 December 1988.

[27] *Pflichtversicherungsgrenze.* In 2005, membership is mandatory up to an annual income of the insured of $46,800 euro ($57,000 at $1.22 per euro). benefits for dependents are included.

[28] The universal health care revenue surplus of 2004 and 2005 prompted the minister of health to call on the sickness funds to lower their premiums. A 13.3% average is expected for 2005. *Hartz-Reform sichert krankenkassen überschuß (Hartz-Reform provides surplus for sickness funds).* FRANKFURTER ALLGEMEINE ZEITUNG, 3 June, 2005, at 13. By law, sickness funds are required to return surplusses to the insured by lowering rates.

gross income[29], covering dependents for free.[30] Premiums are shared almost equally between employers and the insured.[31]

II. Subsidiarity

Subsidiarity signifies the resolution of issues by social entities – including self-help - on the lowest appropriate level. It also implies that aid be provided by larger entities to enable the smaller ones to accomplish their tasks, once again according to the principle of solidarity.[32] Within the universal system of health care, many aspects of health care delivery are resolved by associations[33] on local and regional levels without involving federal sickness fund and physician associations or the national government. This includes administering the regional health care budgets and setting physician compensation while taking into account regional and practitioners' patient population characteristics. In keeping with subsidiarity, the federal government will intervene only to ensure adequate and appropriate health care for the insured population should the system of self-governance fail.[34]

III. Self-Governance

Self-governance is a basic element of the German system of government. In accordance with the principle of subsidiarity, the administration of the social system components is delegated to corporate entities under public law[35] whose charters confer rulemaking authority to them. The SGB V mandates the joint administration of the universal system of health care by regional and national sickness fund and physician associations[36], all self-governed corporate entities

[29] *Beitragsbemessungsgrenze.* For 2005, it was set at 42,300 euro ($51,600 at an exchange rate of $1.22 per euro).

[30] SGB V, Art. 3)

[31] As of 2006, members will be assessed an additional 5%, resulting in a 55/45% split.

[32] Subsidiarity is also an important principle of the european union, leaving as many tasks as possible to localities, regions and individual states, while the eu itself is focussed on economic integration and the harmonization of legislation.

[33] All association members are elected according to the democratic process.

[34] So far, this has remained hypothetical.

[35] *Körperschaften des öffentlichen Rechts. V*on Gierke's historical concept of "associations" was recognized under public law which endows them with normative functions. Other examples are municipalities and counties. See also, supra, note 20.

[36] Sgb V, Art. 77(5)

under public law. They renegotiate compensation collectively on an annual basis, using a national fee scale for physicians. To promote the efficacy and cost-effectiveness of the statutory system of health care, the sickness funds and their associations cooperate closely with each other as well as with all other components of the health care delivery system.[37]

"Physician associations and sickness fund associations contract to jointly ensure the adequate, appropriate and cost-effective delivery of health care for all members according to the generally accepted medical standard of care.[38] The quality and efficacy of the benefits to be provided by the sickness funds must correspond to the generally accepted medical standard of care and must be in accordance with the progress of medical science."[39]

D. The SGB V

The SGB V is a federal health care act, providing comprehensive coverage for the prevention of illness and all medical procedures available. Illness is considered a major adverse event, and the SGB V seeks to limits its impact on patients and their immediate social environment. Coverage also includes home care, household help, prescription drugs, adjunct therapies, alternative care, and personal and home health equipment.

The SGB V thus codifies an all-payer, prepaid, means-tested, pay-as-you-go, universal access/universal coverage health care system, refining some of the unique elements developed as of the beginning of the 19th century. Continuing the tradition, care is delivered not according to wealth but according to need. The system covers 90% of the population (welfare and unemployment recipients as well as retirees receive full coverage but do not pay premiums as these are contributed by other agencies), the remaining 10% are privately insured. Private insurance, by law, must provide as a minimum the same level of coverage as the universal system, creating a disincentive to opt out for those whose income exceeds the level of mandatory membership but who may remain voluntary subscribers. Ninety percent of all physicians are licensed to participate. They may treat privately

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[37] *Id.,* Art. 4(1), (4)

[38] Id. Art. 72(2) *Sicherstellungsauftrag*. SGBV, Art. 72. This concept has been the subject of heated public debate for several years as some have suggested to limit the mandate of adequate health care delivery to the sickness funds. This would provide them with bargaining power similar to managed care companies in the united states and eliminate most of physician influence.

[39] Id. Art. 2

insured patients as well. The current high rate of unemployment in Germany and the rising number of retirees are considered the main reasons for the continuing need for reforms and cost containment efforts.[40]

I. Major Elements of the SGB V

1. Health Care Delivery

Chapter Four[41] of the SGB V mandates that sickness funds, physicians, hospitals, and other providers jointly[42] deliver the care to which members are entitled to as required by and detailed in Chapter Three.[43] The provision of health care is based on the consensus negotiated by physicians and sickness funds, resulting in several contracts. A federal framework agreement for physicians[44] is collectively negotiated by federal associations representing both parties. This agreement has normative character and is the most important instrument of self-governance of the health care system by physician and sickness fund associations.[45] As such, it regulates, for example, physician compensation through use of a fee scale, assigning relative value units (RVUs) to individual procedures; physician qualifications required for specialized diagnostic and therapeutic procedures; quality control measures; claims submission procedures; and plausibility checks to prevent fraud. Because of its normative character, the federal agreement is binding on third parties as well, i.e. individual sickness funds and patients, even though these do not participate in the negotiations.[46]

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[40] *Kein Wunder (No Miracle Yet).* FRANKFURTER ALLGEMEINE ZEITUNG, 21 August 2004, at 1.

[41] *Leistungserbringerrecht, Vertragsarztrecht.* Sgb V, Chapter Four (Health Care Delivery), Arts. 69-140.

[42] *Id.* Relationships between sickness funds and physicians, dentists and psychotherapists (Arts. 72-76); hospitals (arts. 107-114); providers of adjunct and alternative therapies (Arts. 124-125); providers of personal and home health equipment (arts. 126-128); pharmacists and pharmaceutical manufacturers (Arts. 129-131); other providers (household help; home care; social therapy; patient transportation; midwives, Arts. 132-134). Chapter four also covers the system of self-governance (associations, contracts between associations, compensation), Arts. 77-94.

[43] *Leistungsrecht. Id.*, Chapter Three (Coverage), Arts. 1-65. Medical care must reflect the current standard of care and the progress of medical science. Arts. 28, 2(1).

[44] *Bundesmantelvertrag. Id.*, Arts. 82- 83.

[45] HERMANN PLAGEMANN, VERTRAGSARZTRECHT - PSYCHOTHERAPEUTENGESETZ 33 [SGB V: Health Care Delivery - SGB V Plan Physician Sections – SGB V Psychotherapy Sections] (1998).

[46] Decision of the *Bundessozialgericht* (Federal Social Court) of 5 May 1988, published in BSGE 81, 73 (May 5, 1988).

The details of the federal agreement are implemented regionally[47] based on the consensus negotiated by the regional associations, making allowances for local particularities and needs.[48] All collective regional contracts then become integral parts of the federal agreement. (Similar agreements are concluded on a regional level only between regional hospital and sickness fund associations.[49]) A major element of the regional contracts is the regional global fund available for physician compensation,[50] negotiated by the regional sickness fund and physician associations, and paid to the physician associations by the sickness funds which then process and pay the claims submitted by their physicians on a quarterly basis. Factoring in regional particularities, the physician associations, when allocating the global regional funds, determine the combination of fee-for-service, capitation[51] and diagnosis-related payments, calculate reference values according to specialty expressed in total numbers of RVUs per year (taking into consideration, for example, the cost of running physicians' offices and the time required for specific procedures) [52], and budgets for prescription drugs.[53] The latter are also negotiated collectively by regional physician and sickness fund associations, adjusted annually according to changing needs, patient number and demographics, prescription drug prices, and coverage as amended by law.

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[47] *Gesamtverträge.* SGB V, Arts. 82, 83.

[48] If the United States were to introduce a universal system of health care in order to remedy the deficiencies of the current system, medicare would provide an excellent model. "The answer is a single-payer system… that is tantamount to extending medicare to all americans. Medicare is not perfect, but it provides a uniform set of benefits to nearly everyone who qualifies, and it does so much more efficiently than the private employment-based system." Martha Angell, *A wrong turn on patients' rights,* N.Y. TIMES, 23 June 2001, at A13.

[49] SGB V, Art. 112.

[50] *Gesamtvergütung. Id.*, Art. 85.

[51] SGB V, Art. 92. *Kopfpauschale.* Compensation for standard care is a flat fee per patient per quarter.

[52] *Honorarverteilungsmaßstab (Hvm - Unterschiedlicher Verteilungspunktwert Nach Facharztgruppe).* Sgb V, Art. 85(4).

[53] *Arzneimittelbudget.* SGB V, Art. 84.

2. Benefit Guidelines: The Joint Federal Committee (JFC)[54]

In the course of successive SGB V reforms, increasing authority for coverage decision-making ("guidelines" [55]) has been delegated to the Joint Federal Committee,[56] also dating back to the 19th century. Originally, the JFC guidelines were intended to guarantee a high standard of care for certain types of medical services. The pregnancy care guideline, already part of the RVO of 1911, is so detailed as to serve as a clinical practice guideline; the early childhood screening guideline also has aspects of a clinical practice guideline. Neither of them has ever been contested as they set a high standard of care serving all parties concerned. JFC coverage guidelines are normative components of all national and regional agreements between physician and sickness fund associations, and are binding on participating physicians.[57]

Today, the JFC, under neutral chairmanship, is composed of two independent members, four representatives of the National Physician Association, one representative of the National Association of Dentists, four representatives of the German Hospital Association, and representatives of all national sickness fund associations. Depending on the committee agenda, membership is adjusted to guarantee proper representation of all parties concernced and the required level of expertise. The expanded Committee mandate includes health care quality control,[58] defined as the effectiveness assessment of traditionally covered services, and the evaluation of innovative diagnostic and therapeutic procedures[59] for potential

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[54] *Gemeinsamer Bundesausschuss.* SGB V, Art. 91. Originally, the term denoted several committees, individually responsible for ambulatory care physicians, dentists, and hospitals. all were composed of representatives of the respective federal specialty associations and the sickness fund associations. The health care reform bill of 2004 (the *GMG*) merged all of these into one committee under one chairmanship, with uniform rules of procedure and independent funding.

[55] *Richtlinien der Bundesausschüsse.* SGB V, Art. 92.

[56] Established in *id.,* Art. 91.

[57] For a comparison with benefit and medical necessity determination procedures by managed care organizations, see Weide, *Coverage And Medical Necessity Determinations: U.S. Managed Care Treatment Decisions Vs. German Administrative Rulemaking*, 8 ILSA JOURNAL OF INTERNATIONAL AND COMPARATIVE LAW 508 (2002), at 514, 556.

[58] SGV, Arts. 135-139. Arts. 137-137(c) cover the quality control of hospitals and hospital care.

[59] This is comparable to the evaluation of what managed care organizations would consider "experimental treatments." Sickness funds, however, do cover many treatments and procedures considered "experimental" by managed care standards. Furthermore, in contrast with the german notice and comment administrative rulemaking procedure, managed care organizations often make coverage decisions behind closed doors, according to in-house "proprietary" criteria. See Weide, *Health*

reimbursement. Coverage guidelines are issued after public notice of the subjects under consideration, and comments by interested parties and experts enter into the decision-making. After approval by the Federal Ministry of Health, the guidelines are promulgated as addendum to the SGB V.

JFC decisions on procedures are made according to evidence-based criteria. These range from randomized, controlled clinical studies to consensus conferences and expert opinions. While clinical studies are preferred, their unavailability or limited feasibility is recognized, and lower evidence levels are allowed. Since care under the SGB V must correspond to the generally accepted standard of medical knowledge and the progress of medical science, clinical practice guidelines and prevailing practices are highly relevant for coverage guideline validity. In case of individual sickness fund denials of reimbursement of a treatment not yet addressed by a JFC guideline, patients may appeal to the social courts. Some authors urge that the JFC allow additional research methods for treatment validation and reimbursement since many generally recognized procedures, in particular those of primary care, do not meet the evidence-based requirements. Furthermore, evidence-based criteria ignore physicians' supportive and suggestive role in providing encouragement and compassion. As an essential element of humane medicine (humane care is a specific requirement of the SGB V[60]), it should be exempt from such criteria.

Additional checks on the newly acquired power of the JFC to limit clinical autonomy have come from the courts. Two rulings of the BSG[61] questioned the comprehensive authority of the JFC to issue coverage exclusions for medication treating illnesses meeting the statutory definition, and emphasized that the SGB V reserves the delegation of such wholesale power to the legislator. The JFC had excluded payment for a drug,[62] arguing that sickness funds would be prevented from delivering care in a cost-effective manner. The BSG, however, emphasized that cost-effectiveness was an administrative concept under the SGB V and as such an inadequate justification for the wholesale exclusion of a drug for treatment of an illness with differing etiologies.

Care Reform and the Changing Standard of Care in the United States and Germany, In: 20 JOURNAL OF INTERNATIONAL AND COMPARATIVE LAW 249 (2000).

[60] SGB V, Art. 70(2).

[61] Decision of the Federal Social Court of 30 September 1999, published in BSGE 85, 36, at 45. See also the decision of 16 November 1999 (Reg. No. BSG B 1 Kr 9/97 R), unpublished.

[62] Viagra for erectile dysfunction.

Much criticism has been leveled at the JFC. First, the constitutional legitimacy of the delegation of rulemaking authority to the committee has been questioned. Certainly, all member associations are built on democratic structures, but because of staggered elections passing from the local to the national level, democratic legitimacy may eventually be diluted to a merely "homeopathic dosage."[63] Second, the transparency of the decision-making process is considered inadequate. In 2000, the JFC, itself dissatisfied with the rules of procedure as legislated by the government, adopted its own, more stringent rules.[64]

3. The Cost-Effectiveness Mandate and Economic Utilization Reviews

The cost-effectiveness mandate is an administrative law concept and, as an expression of the fiduciary duty of the state, applies to budget policies on federal, state and local levels. Historically, the requirement to practice medicine economically was first mentioned in a physician-sickness fund contract in 1887, was expanded in the RVO of 1911, and became a standard term applied to all aspects of care in 1955.

Micro-allocation decisions have always been inherent in clinical decision-making, and today the law assumes that all physicians practice in a cost-effective manner, adhering to the SGB V general cost-effectiveness mandate.[65] Retrospective economic reviews[66] of practices therefore focus on reference values (individual practice values may be negotiated under certain circumstances), calculated according to specialty and regional particularities. Random reviews and reviews of outlier practices may take place at any time. Reviews are conducted by joint physician-sickness fund committees, and different sanctions apply. Physicians may appeal by justifying overruns demographically, by the number of chronically ill patients and of patients with serious conditions. Such above-average circumstances[67] will be taken into consideration and compensated accordingly.

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[63] Thomas Clemens, *Verfassungsrechtliche Anforderungen An Untergesetzliche Rechtsnormen (The Constitutionality Of Rulemaking By Non-Legislative Bodies)*", 9 MEDIZINRECHT 436 (1996).

[64] Karl Jung, *Rechtliche Grundlagen des Bundesausschusses auch nach der GKV-Reform 2000 unzureichend* (*Inadequate Legal Foundations For The Federal Committee Persist After Adoption Of TheSGBv Reform 2000*), 3 KRANKENVERSICHERUNG 52 (2000).

[65] SGB V, Arts. 4, 12.

[66] *Id.*, Art. 106.

[67] *Praxisbesonderheiten.*

Economic utilization reviews do require practitioners to apply economic considerations to resource allocation. There are, however, no waiting lists, acute cases receive immediate treatment by both physicians and hospitals, less acute conditions receive a lower priority - as has always been the case when micro-allocating health care. There is no rationing, and when necessary to stay within budgets, physicians refer to colleagues covering for them during vacation. Thus, some care is voluntarily distributed among practices. "When services are provided in an economically reasonable fashion, budgets are adequate."[68]

E. Physicians and the Law

I. Choice of Physician

Patients are free to choose their physicians including specialists,[69] and physicians have the obligation to treat insured patients.[70] They may, however, exercise discretion in cases of geographically unacceptable home visits (unless no other physician is available or in an emergency), prior patient refusals to comply with treatment, physician-patient conflicts, and practice overload. The reform of 2004 introduced the "family-physician centered" insurance plan as an option for the insured.[71] This corresponds to voluntary general practitioner gate-keeping. For one year, the plan member may not switch family physician and referrals to specialists are mandatory. In return, premiums and co-pays or deductibles are reduced. The main novel element of this approach, however, is the independent contracting option between gate-keeping providers and sickness funds. So far, all provider-insurer contracts had been collective, and the compensation agreement retains some collective elements. The impact of such independent contracts on providers and the standard of care remains to be seen.

II. Compensation

Physicians are entitled to proper compensation under Art. 12 (professional independence) and Art. 4 (protection of property) of the Constitution, and under SGB V, Art. 72(2) (physicians must be compensated "adequately" to ensure the sufficient, appropriate delivery of health care in accordance with the generally

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[68] Dr. Med. Gisela Groscurth-Galm, Personal Communication (28 April 2002). On file with the author.

[69] *Freie Arztwahl.* SGB V, Art. 76.

[70] *Id.*, Art. 75(1)

[71] *Hausarztzentrierte Versorgung. Id.*, Art. 73(B).

accepted standard of care). As "adequate compensation" is considered subject to joint interpretation by the sickness fund and physician associations, the BSG has ruled that physician compensation must provide sufficient incentives for physicians to become licensed to practice within the universal health care system.[72] The Court added, however, that this does not entitle physicians to specific levels of fees or income.[73] Furthermore, physicians are considered self-employed but point out that tax law does not apply to them accordingly, prohibiting deductions and cost-accounting methods accorded to other self-employed professions.[74]

Social law restricts physician income through budgets, capitation and diagnosis-related payments. These have been shifting some or all of the morbidity risks to the physicians, often resulting in lower or no payment for services.[75] Social law also prohibits practices such as balance billing and patient selection; physicians are required to accept payment according to the national fee scale and provide services which could be delegated to qualified staff. If shifting the morbidity risk to physicians resulted in a considerable loss of income, it could no longer be considered adequate under the SGB V, Art. 72(2).[76] This may then amount to a "taking" and require just compensation under Arts. 12 and 4 of the Basic Law,[77] accomplished through regional or global agreements between the sickness fund and physician associations, limiting the overall number of physicians practicing under the universal system,[78] or through measures to ensure the regionally appropriate availability of practitioners by specialty. The BSG has ruled that

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[72] BSGE 68, 291, 298. Also see HEINRICH LANG, DIE VERGÜTUNG DER VERTRAGSÄRZTE UND PSYCHOTHERAPEUTEN IM RECHT DER GESETZLICHEN KRANKENVERSICHERUNG 44 [Physician And Psychotherapist Compensation Under The Universal Health Care Law] (2001).

[73] BSG Soz-R 3-2500, § 85 SGB V, No. 30, at 228; BSGE 77, 279, at 288. HEINRICH LANG, DIE VERGÜTUNG DER VERTRAGSÄRZTE UND PSYCHOTHERAPEUTEN IM RECHT DER GESETZLICHEN KRANKENVERSICHERUNG (2001), at 45.

[74] Dr. Med. Klaus Schnetzer, Rastatt (Germany), personal communication, 28 April 2002. On file with the Author.

[75] HEINRICH LANG, DIE VERGÜTUNG DER VERTRAGSÄRZTE UND PSYCHOTHERAPEUTEN IM RECHT DER GESETZLICHEN KRANKENVERSICHERUNG 51 (2001).

[76] *Id.*, at 45.

[77] *Id.*, at 114, also at note 583.

[78] *Bedarfsplanung*. SGB V, Arts. 99-101. The main purpose of these articles is to ensure adequate access to care by making available the appropriate number of physicians but restrictions are permitted as well. See also LANG, at 120. Today, there are 375,000 physicians for close to 80 million inhabitants, yielding a statistical average of one physician per every 276 residents (1992: 321; 1970: 616). Heinz Stüwe, *Traumberuf Ade? (A Dream Profession No More?)* FRANKFURTER ALLGEMEINE ZEITUNG of 30 April 2002, at 1.

restrictions on the admission to the universal health care system are constitutional in order to promote its financial stability.[79]

By abolishing the regional global funds (budgets) available for physicians, the reform of 2004 is gradually shifting the morbidity risk away from the providers and to the sickness funds.[80] By 2007, these budgets will be replaced by "care capitation" by physician group[81] and by individual physician.[82] Based on a formula to be jointly developed by local provider and sickness fund organizations, the respective population morbidity risk and corresponding care requirements by medical specialty will be calculated. Sickness funds will then continue to make payment to the provider associations but now based on claims for prior services, up to the agreed-upon volume of care for each physician group. Provider associations will settle individual provider claims up to the volume of care provided by the practitioner during the preceding year. In all instances, compensation can be adjusted upward in case of morbidity fluctuations. The national fee scale[83] will now consist of predetermined fees instead of unpredictably floating relative value units, calculated after the fact within the limits of the global regional budget.

III. Physician Autonomy

Art. 12(1) of the Basic Law guarantees the freedom to choose and exercise one's profession. The Constitutional Court has interpreted this to include the autonomy of medical judgment and the responsibility for its consequences.[84] According to the Annotated Federal Medical Practice Act, "Autonomous clinical decision-making must be guaranteed, independent of the setting within which medicine is

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[79] Soz-R 3-2500 § 103 Nr. 1 (10 February 1996); B 6 Ka 35/97 R (18 March 1998). This includes capping the number of admissions to medical school, nothing out of the ordinary since many fields limit the number of students.

[80] "Physician compensation may not primarily depend on the financial situation of the sickness funds but on morbidity and therefore the subscribers' need for care." Bt-Dr. 15/1525, at 74 (*GMG* Draft Bill, 2003).

[81] *Arztgruppenbezogene Regelleistungsvolumina.* SGB V, Art. 85(A).

[82] *Arztbezogene Regelleistungsvolumina. Id.*, Art. 85(B).

[83] *Einheitlicher Bewertungsmasstab. Id.*, Art. 87.

[84] Thomas Clemens. *Ärztliche Berufsfreiheit aus juristischer Sicht: Der niedergelassene Kassen- bzw. Vertragsarzt. (Legal Aspects of Physicians' Professional Autonomy: Physicians Practicing under the SGB V)*, in: DIE ÄRZTLICHE BERUFSAUSÜBUNG IN DEN GRENZEN DER QUALITÄTSSICHERUNG 17 [PRACTICING MEDICINE WITHIN QUALITY CONTROL LIMITS] (A. WIENKE, H.D. LIPPERT, EDS., 1998).

practiced."[85] Physicians feel that medical decisions should be grounded in medical science, especially as the gap is widening between what is medically reasonable, humanely appropriate and technically doable.[86] Social law, however, requires physicians to observe the budgets, imposing micro-allocation decisions infringing on their autonomy to choose the most appropriate treatment for each individual patient.

But despite the growing pressures on physicians' autonomy, reliance on clinical decision-making remains firmly anchored in the SGB V. The BSG continues to interpret the coverage sections of the Act (Chapter Three), codifying members' material claims to all procedures as needed for the prevention, diagnosis and treatment of illness, as merely setting the framework for medical care. Based on clinical judgment, the attending physician must suspect or diagnose illness, an "exceptional physical or mental condition necessitating treatment."[87] Only then does the patient's coverage translate into an entitlement for individual benefits which are to be specified by the physician and to be reimbursed by the sickness funds.[88] A 1993 landmark case had confirmed providers' entitlement to treat according to their independent clinical judgment and the patient's preferences.[89] Treatment must, however, be in accordance with the regional contracts, the benefit determinations or clinical practice guidelines of the Joint Federal Committee, the cost-effectiveness mandate, and the generally accepted standard of care.

IV. Physician Liability

Medical malpractice law is mainly case law. According to SGB V, Art. 76(4), providers under the SGB V (including physicians, hospitals and others[90]) have a

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[85] Adolf Laufs, *Immer Weniger Freiheit Ärztlichen Handelns. (Increasing Limitations On Physicians' Activities)*, 37 NEUE JURISTISCHE WOCHENSCHRIFT 2717 (1999), citing: Haage, BUNDESÄRZTEORDNUNG, KOMMENTAR [FEDERAL LAW REGULATING THE PRACTICE OF MEDICINE ANNOTATED], (DAS DEUTSCHE BUNDESRECHT, 824. LIEFERUNG, 1999).

[86] 24 DEUTSCHES ÄRZTEBLATT 1 (1994).

[87] KARL HAUCK, SGB V: GESETZLICHE KRANKENVERSICHERUNG, KOMMENTAR [SGB V ANNOTATED], 50th Addition To The SGB V Annotated. K § 27, at 4 (July 2000).

[88] BSGE 73, 271, at 279; BSG Sozr 3-2500 §30 No. 8, at 32. Contrary to American physicians practicing under managed care requiring "preauthorization" for many procedures, the "medical necessity" determination of treatment lies exclusively with the physician, not with the insurer. For a comparative german-american analysis of the constraints imposed on physicians' exercise of clinical judgment, see Ursula Weide, "*Health Care Reform and the Changing Standard of Care in the United States and Germany.*" 20 JOURNAL OF INTERNATIONAL AND COMPARATIVE LAW 249 (2000), at 348.

[89] BSG 14a Rka 7/92, 8 Sept. 1993 ("Amalgam Decision"), leaving the choice of filling with the dentist.

[90] Under the SGB V, the same social, civil and criminal law norms apply to all providers.

contractual obligation under the Civil Code[91] to use customary care.[92] The physician-patient relationship therefore is based on contract law (service contract) and tort law standards. Compensatory damages are available under contract law while only tort law allows for damages for pain and suffering. Punitive damages are not a concept of German law. Jurisdiction rests with the state courts for civil and criminal law and the *Bundesgerichtshof* (BGH -- Federal Court of Justice for civil and criminal matters).

Providers owe only reasonable care, and an unfavorable treatment outcome is insufficient to infer negligence as the human body escapes total control by practitioners.[93] Reasonable care is an objective standard, reflecting generally accepted practices and state of medical knowledge at the time of treatment. Clinical practice guidelines (CPGs) may help to determine the applicable standard of care if they have been generally accepted, and expert witnesses may base their testimony on them.[94] JFC guidelines and CPGs, however, do not excuse physicians from exercising independent judgment and acting as prudent professionals. Their autonomous clinical judgment, reflecting personal experience and skills, is protected, and they must choose a course of treatment responsive to the individual circumstances of each patient and in accordance with prevailing practices.[95]

Physicians complain that their relationships with patients originate in social law, increasingly requiring them to micro-allocate care through budgets, capitation, and the cost-effectiveness mandate while civil law liability standards remain unchanged. Some authors suggest that social law should preempt civil law.[96] While CPGs are accepted by malpractice law as indicative of the standard of care,[97]

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[91] BGB, Sec. 611. *Dienstvertrag (German Civil Code, Service Contracts).*

[92] *Id.*, Sec. 276. *Haftung für eigenes Verschulden (Liability For Individual Negligence).*

[93] BGH, in: VERSICHERUNGSRECHT 428 (1980).

[94] For an in-depth discussion of the role of u.s. practice guidelines and a comparative german-american analysis of guideline legal and clinical relevance, see Ursula Weide, *Coverage And Medical Necessity Determinations: U.S. Managed Care Treatment Decisions Vs. German Administrative Rulemaking,* 8 ILSA JOURNAL OF INTERNATIONAL AND COMPARATIVE LAW 508 (2002).

[95] BGH, VI ZR 171/80 (11 May 1982); BGH VI ZR 56/87 (2 February 1988); BGH VI ZR 132/88 (12 June 1988).

[96] Dieter Hart, *Ärztliche Leitlinien und Haftungsrecht (Clinical Practice Guidelines and Malpractice Liability),* in: ÄRZTLICHE LEITLINIEN: EMPIRIE UND RECHT PROFESSIONELLER NORMSETZUNG [MEDICAL GUIDELINES: EMPIRICAL AND LEGAL FOUNDATIONS FOR SETTING PROFESSIONAL NORMS] (DIETER HART, ED., 2000).

[97] Dieter Hart, *Ärztliche Leitlinien und Haftungsrecht (Clinical Practice Guidelines and Malpractice Liability),* in: ÄRZTLICHE LEITLINIEN: EMPIRIE UND RECHT PROFESSIONELLER NORMSETZUNG [MEDICAL GUIDELINES:

social law so far has failed to integrate them in a systematically normative fashion.[98] They do, however, enter into the norm-setting coverage determinations of the Joint Federal Committee[99] while the Federal Social Court continues to exercise "judicial prudence" in its so far limited reliance on CPGs as novel concepts of legal relevance.[100]

Physicians have a powerful, polemic voice in the public debate. [101] "Problems may no longer be relegated where they do not belong: to the level of the physician-patient relationship. In the long run, this will destroy the trust which is the foundation of any therapeutic relationship."[102]
Physicians are bound by the duty of undivided loyalty to patients; hence, it is argued, society must protect their legal status, and should not burden them with unresolved ethical conflicts and excessive financial risk bearing. Since medical ethics are unrelated to cost containment, responsibility should rest with policy makers who control health care expenditures and the law, and who should issue allocation and coverage guidelines.[103]

F. The Federal Social Court (BSG)

The Federal Social Court was established in 1954[104] in order to fulfill the constitutional mandate of the creation of a federal court with jurisdiction over

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EMPIRICAL AND LEGAL FOUNDATIONS FOR SETTING PROFESSIONAL NORMS] (DIETER HART, ED., 2000), at 92-93.

[98] Dieter Hart, *Einleitung und Kommentare,* in: CLINICAL PRACTICE GUIDELINES, at 7, 16.

[99] Thomas Clemens, *Leitlinien und Sozialrecht (Clinical Practice Guidelines and Social Law)*, in: CLINICAL PRACTICE GUIDELINES, 147, 156.

[100] *Id.*, 147, 161.

[101] For a discussion of the extremely limited bargaining power of American physicians, see Ursula Weide, *Health Care Reform and the Changing Standard of Care in the United States and Germany*, 20 JOURNAL OF INTERNATIONAL AND COMPARATIVE LAW 249 (2000), at 286.

[102] Jörg-Dietrich Hoppe, *Wirtschaftliche Zwänge belasten zunehmend das Arzt-Patienten-Verhältnis (Economic Pressures Increasingly Burden the Physician-Patient Relationship),* available at http://www.bundesaerztekammer.de (27 October 2000). (Statement by the President of the Federal Physicians' Chamber)

[103] Lothar Krimmel, *Was Ist "Medizinisch Notwendig"?* (*What Is "Medically Necessary"?*), 94 DEUTSCHES ÄRZTEBLATT C16 (1997).

[104] 25 JAHRE BUNDESSOZIALGERICHT, CHRONIK 1954-1979 [The Federal Social Court - 25 Years, Chronic 1954-1979] (1979).

social law.[105] It succeeded the National Social Insurance Agency[106] which was eliminated in 1945 after its sixty-year existence by the countries then occupying Germany. Today, the court consists of 13 panels ("Senates") with one presiding judge sitting with two or three judges, assisted by one deputy, and honorary lay judges representing those subject to panel jurisdiction. Among them are the insured, employers, providers, and representatives of the sickness funds. Jurisdiction over the universal health care system rests with Panel One (all aspects of the SGB V not covered by other panels, including suits brought by patients); Panel Three (home care, long-term care, adjunct therapies and alternative care); and Panel Six (system of self-governance, relationships between physicians, psychologists, dentists, dental technicians and sickness funds).

I. Major Rulings

In addition to the important BSG decisions cited above, other cases have had a major influence on health care delivery as well. The following decisions constitute a paradigm shift in health care law.

Chapter Three of the SGB V stipulates the patients' comprehensive and universal right to coverage, Chapter Four details providers' obligations to deliver care in cooperation with the sickness funds, and the development of the Joint Federal Committee coverage guidelines. Until recently, the patients' right to coverage and treatment under Chapter Three were interpreted as controlling, the guidelines as mere internal administrative rules for sickness fund and physician associations. In 1996, however, Panel Six of the BSG ruled that the JFC is an "institution" under public law with rulemaking authority limited to specific interpretations of the law.[107] The BSG thus strengthened the position of the JFC under public law, giving its guidelines normative status, now binding individual patients and providers as well.[108] Five decisions by Panel One followed in 1997,[109] reversing the primacy of

[105] Germany has a system of limited jurisdiction. different state courts have jurisdiction over Administrative, Social, Labor, and Civil and Criminal law cases. Each field of law has one Federal Court for Appeals from the State Supreme Courts.

[106] *Reichsversicherungsamt.*

[107] *Anstalt des Öffentlichen Rechts mit begrenzter Rechtsfähigkeit mit der Aufgabe der Konkretisierenden Rechtssetzung.* BSG 6 Rka 62/94, 20 March 1996 (*Methadonurteil)*, 3 MEDIZINRECHT 123 (1997).

[108] Decision of the Federal Social Court of 20 March 1996, published in BSGE 78, 70.

[109] 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 (all 16 September 1997). Panel one rejected patients' claims for reimbursement of acupuncture treatment of Neurodermitis, and for Immuno-Augmentative therapy for Multiple Sclerosis. according to the Court, neither therapy was considered covered under the SGB V, the latter having been specifically excluded by the JFC.

patients' rights under Chapter Three over the administrative sections of Chapter Four. In 1998, Panel Six reconfirmed that the JFC guidelines bind sickness funds, providers and patients, as they are issued under the charter-based rulemaking power of a corporate entity under public law, and are components of the normative state and federal contracts concluded between physician and sickness fund associations. The BSG thus confirmed as constitutional the democratic legitimacy of the Joint Federal Committee's rulemaking power.[110] This decision can be appealed for final determination to the Federal Constitutional Court.

As a result, physicians still must translate patients' right to coverage into individualized medical services, but the JFC guidelines for innovative and traditional procedures may now set limits to practitioners' former almost unrestrained clinical autonomy. The JFC was thus made the "arbiter" of medical progress under social law,[111] contingent on the consensus between sickness funds and physicians as represented on the Committee. The Court's novel interpretation turned on SGB V, Art. 2, as the linchpin linking both Chapters and requiring physicians and sickness funds to deliver care to patients according to generally accepted standards, and in keeping with the progress of medical science. But standards of care rest on physicians' expertise, also entered into the clinical practice guidelines issued by medical specialty societies. By tying coverage guidelines to clinical standards and the progress of medical science under Art. 2, the BSG has preserved the medical profession's autonomy to define clinical competence. This was recognized by the neutral JFC chairman when he announced the intent to seek cooperation with the professional societies, possibly to incorporate their practice and quality control guidelines into the coverage guidelines.[112]

In the era of macro- and meso-level[113] cost containment measures, increasing pressure on physicians to micro-allocate care considered the cause of ethical conflicts, friction among the members of the system of self-governance, expanding authority of executive bodies to evaluate novel and traditional procedures under effectiveness considerations and thus influence the standard of care, and rising patient discontent with premiums and the care provided, the BSG is relied on for clarification of the norms adopted by all norm-setting components of the health

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[110] Decision of the Federal Social Court of 18 March 1998 (Reg. No. B6 Ka 37/97).

[111] SGB V, Art. 135 (evaluation of novel diagnostic and therapeutic procedures).

[112] 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: MEDICAL GUIDELINES, *supra*.

[113] Budget and compensation decisions made by sickness fund and physician associations are called "meso-level" allocation within the German universal system of Health Care.

care system. The limited jurisdiction of its individual panels ensures the competency of its judges, dedicated to the preservation of the social spirit of German health care legislation dating back to the 19th century, and to the evolution of social law.

G. Reforms of the Universal Health Care System[114]

Cost containment reform began in 1977,[115] based on the principles that expenditures should not exceed revenues, premiums should remain stable, and the current level of coverage and prevailing standard of care should be preserved.[116] The next major reform effort, aimed at structural changes, followed in 1988 with the adoption of the Health Care Reform Act[117] which became Title Five of the Social Code, the SGB V. The most fundamental element of the act was the introduction of reference prices for prescription drugs,[118] determined for non-patented drugs by the federal sickness fund associations.[119]

The act also added co-payments for several benefits, raised some of the already existing ones (for prescription drugs not subject to the reference price system, dental prosthetics, taxi fares for medical visits), and excluded some medications such as treatments for the common cold from coverage.[120] Co-pays so far had been either inexistent or absolutely minimal.[121] Retrospective economic utilization

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[114] For a comparative german-american analysis of health care cost containment approaches, 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*, in: 13 TULANE EUROPEAN AND CIVIL LAW FORUM 47 (1998).

[115] *Krankenversicherungskostendämpfungsgesetz.* BGBl. 1069 (27 June 1977).

[116] HEINRICH LANG, DIE VERGÜTUNG DER VERTRAGSÄRZTE UND PSYCHOTHERAPEUTEN IM RECHT DER GESETZLICHEN KRANKENVERSICHERUNG 44 (2001).

[117] *Gesundheitsreformgesetz (GRG).* BGBl. 2477 (20 December 1988).

[118] *Festbeträge.* SGB V, Art. 35. Before SGB V limitations on reimbursement, drugs were sold in Germany subject to one of the highest profit margins in the world. even though per capita spending on health care in the united states was almost twice that of germany, in 1988, german prescription drug expenditures per patient exceeded those of the United States. General Accounting Office, German Health Care Reforms (Gao/Hrd-93-103, 1993).

[119] SGB V, Art. 213(2)(3).

[120] *Bagatellarzneimittel.*

[121] To this day, compared with current co-payments and deductibles in the united states, the German patient contributions remain negligible.

reviews of physicians' offices were expanded in order to ensure the more stringent implementation of the cost-effectiveness mandate.[122]

The second reform effort followed in 1992.[123] Voluntary and hence ineffective provider spending targets had been in force when the then Christian-Democratic government, alarmed by what was considered a health care cost explosion, adopted non-negotiable, mandatory sector budgets for ambulatory care, hospitals, and prescription drugs, effective from 1993 to 1995. In order to introduce some elements of competition, members were enabled to switch sickness funds during periods of open enrolment, eliminating the traditional mandatory membership by profession.[124] Because of cherry-picking (contracting with a younger and healthier population), however, risk adjustment payments were required to protect sickness funds left with a (more expensive) high-risk population.

In 1997, two additional reform acts were adopted.[125] They further strengthened the system of self-governance, permitted premium reimbursements to members as incentive to reduce the utilization of medical services, allowed sickness funds to add additional benefits to the comprehensive coverage mandated by law to increase competition, excluded some dental benefits, and levied a small charge on all members for the renovation and maintenance of hospitals.[126] The floating relative value units for fee-for-service physician payments were now fixed again within the regionally negotiated global funds for physician compensation.[127]

In 1998, the newly elected Social-Democratic government immediately began to draw up a temporary revision of the SGB V,[128] specifying some of the allowable budget increases, expanding the role of primary care physicians, reducing co-payments, optional benefits offered by the sickness funds (in part reversing some of

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[122] this mandate applies to the entire public sector and is deeply rooted in administrative law.

[123] *Gesundheitsstrukturgesetz (Gsg)*. BGBl. 2266 (21 December 1992).

[124] Historically, sickness funds had developed to cover members according to their profession (farmers, miners, office employees, merchant marine, public service, tradesmen's guilds, company-sponsored plans, and local/regional plans for those not covered by any other sickness fund.)

[125] *Neuordnungsgesetz I und II* (NOG I, BGBl. 1518; NOG II, BGBl. 1520, 23 June 1997).

[126] *Krankenhausnotopfer*.

[127] This eliminated the reduction in RVU value occurring with increasing services provided, making physician incomes once again predictable.

[128] *GKV-Solidaritätsstärkungsgesetz [Law on Strengthening Solidarity within the Statutory Health Care System)*, BGBl. I 1998, at 3857 (19 December 1998).

the "market-oriented" elements of the prior Christian Democratic reforms), and replacing indemnity payments for some dental services by prepaid reimbursement. This was followed by the "Reform 2000"[129] which became law on January 1, 2000. A draft had envisaged a global budget for all health care sectors and a prescription drug formula but both were withdrawn because of Christian-Democratic opposition in the *Bundesrat* (Federal Council of the States),[130] and vehement physician association protests. On February 15, 2002, the SGB V amendments to limit prescription drug expenditures were enacted.[131] In essence, physicians will continue to prescribe the desired active ingredient and dosage while pharmacists, also contractual providers under the SGB V, are held to choose the least costly drug among all those of equal quality and with the same active ingredient if the physician has not already done so.

I. Recent Reforms

The health care system and additional reform efforts perceived as necessary were dominating subjects of the campaign for federal elections on September 22, 2002. The Christian-Democrats wanted to introduce more market-oriented elements, including competition between sickness funds and consumer choice, while the Social Democrats preferred to adhere to improved regulatory solutions: more stringent quality-control measures, mail-order pharmacies, and revised prescription drug sales regulations. Neither party platform addressed the inclusion of income other than wages and salaries when assessing premiums. Additional proposals focused on cementing solidarity-based financing by raising the income cap for mandatory membership.[132] Both parties agreed on novel selective sickness fund-provider contracting and the continued joint mandate for sickness fund and physician associations to deliver all care as required by and detailed in the SGB V.[133] Some had suggested that the mandate be restricted to the sickness funds. This, however, would empower them to interfere with medical treatment similar to

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[129] *GKV-Gesundheitsreformgesetz 2000 (GRG).* BGBl. I, at 2626 (22 December 1999).

[130] Members of the *Bundesrat* are not elected but appointed by state governments, Representing the majority parties. only legislation affecting state sovereignty must receive *Bundesrat* approval. Therefore, as in the case of the "Reform 2000", only some sections of the act had to be ratified.

[131] *Arzneimittelausgabenbegrenzungsgesetz (Law On Prescription Drug Cost Containment),* BGBl. I Nr. 11, 22 February 2002. SGB V, Arts. 73(5), 92, 115b, 129, 130(1), 131(4), 300(2), 302(2).

[132] While politicians were arguing over raising the mandatory income cap, 325,000 voluntary subscribers with higher incomes preventively switched to private insurances, causing the universal system to lose 1 Billion Euros in revenue. *Ausgaben für Arzneimittel steigen stark (Prescription drug expenditure increases),* FRANKFURTER ALLGEMEINE ZEITUNG, 10 May 102002, at 15.

[133] *Sicherstellungsauftrag.* SGB V, Art. 72.

managed care organizations in the United States, and met with considerable opposition.

Also proposed was the creation of a new institute for the development of clinical practice guidelines, followed by immediate protests by participants of the National Physician Assembly objecting to "checklist medical care" and the introduction of disease-management programs.[134] The assembly, not denying the value of scientifically developed CPGs, wanted to ensure their use by physicians according to their patients' individual circumstances only. "Restrictions by norm-setting bureaucratic entities and health experts focussed exclusively on economic considerations jeopardize the patient-physician relationship based on trust."[135]

The next major reform bill, the GMG[136] which became law on January 1, 2004, resulted from consensus negotiations among all parties represented in parliament. It affects both coverage (by reducing benefits but awarding bonuses for prevention) and the health care delivery system (by introducing elements of structural reform).[137] The main amendment affecting providers is the promotion of individual sickness fund-provider contract options to facilitate the development of new delivery structures and competition. In addition to the family-physician centered (gate-keeper) plan option, interdisciplinary team practices resembling the former East German "polyclinics"[138] and integrated delivery systems, bridging the current gap between in- and outpatient care[139], may be established. Furthermore, separate contracting options for specialty care facilities requiring particular standards of quality and expertise such as dialysis and cardiac care were introduced.

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[134] *Ärztetag lehnt "Checklisten-Medizin" Ab (National Physician Assembly Opposes Checklist Medical Care),* FRANKFURTER ALLGEMEINE ZEITUNG, 31 May 2002, at 15.

[135] *Id.*

[136] *GKV-Modernisierungsgesetz* (GMG) 2004. BGBl. I 2190 of 14 November 2003.

[137] Till-Christian Hiddemann/Stefan Muckel, *Das Gesetz zur Modernisierung der Gesetzlichen Krankenversicherung (The Law Modernisizing The Universal Health Care System*, in: NEUE JURISTISCHE WOCHENSCHRIFT 7 (2004).

[138] *Medizinische Versorgungszentren.* SGB V, Art. 95.

[139] *Integrierte Versorgung. Id.,* Art. 140(A). Once established, these delivery systems could resemble ambulatory care centers but also potentially involve case managers. the law allows incorporation and the involvement of management companies. again, individual contracts outside of the collective system may be concluded with the sickness funds. although already permissible under the reform of 2000, this alternative so far has found few takers. *See* Hiddemann/Muckel, *supra*, note 137, at 8.

H. Future Reforms

The reform of 2004 has opened the door for future structural changes in the German universal health care system and thus for the introduction of managed-care type cost-containment approaches, weakening provider bargaining power.[140] Just as in the United States, increasing interference into clinical decision making, dimishing financial rewards for providers, and the necessity to enter into alliances with large delivery systems may eventually lower the standard of care.

Numerous controversial reform proposals have been introduced into public debate by the governing Social Democratic/Green Party coalition and the CDU/CSU opposition. The Social Democrats and Greens were unable to agree as the latter advocated a basic, premium-funded benefit package which was rejected by the Social Democrats.[141] Even within the minority coalition of Christian Democrats and the Christian Social Union, the proper reform approach was hotly contested.[142] Left untouched but subject to heated debates since 2003 was the base for assessing premiums, limited to salaries and wages, thus burdening labor costs and restricting revenue due to high unemployment (above 10%).

The unanticipated early scheduling of federal elections for September 2005 has forced the parties to crystallize their health care financing reform proposals but is preventing them from submitting well-thought out projects to the electorate.[143] The Social Democratic/Green Party coalition now advocates mandatory public insurance for everyone[144], including those who currently are subscribers of private plans: self-employed individuals, members of the civil service[145], and those whose annual income exceeds the cap for mandatory membership. Premiums are expected to drop as they would be based in addition on earnings other than wages and salaries (returns on investments, rental income, etc.).

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[140] The SGB V expressly rejects an "any willing provider" stipulation.

[141] *Clement lehnt Ausweitung der Einnahmen für das Gesundheitssystem ab (Minister Clement Rejects Increasing The Revenue Base Of The Universal Health Care System)*, in: FRANKFURTER ALLGEMEINE ZEITUNG, 4 August 2003.

[142]. "Peoples' heads are still spinning from the heated debate between CDU and CSU how to best reform the Health Care System." *Die Basis ist Vertrauen (Confidence is the Foundation).* Frankfurter Allgemeine Zeitung, 28 May 2005.

[143] This section is based on Nico Fickinger, Andreas Mihm and Manfred Schäfers, *Gesundheit, Arbeitsmarkt, Steuern – Was die Parteien ihren Wählern anbieten (Health Care, Labor Market, Taxes – What The Parties Are Offering Their Voters).* FRANKFURTER ALLGEMEINE ZEITUNG, 24 May 2005, at 16.

[144] *Bürgerversicherung.*

[145] *Beamte.*

The coalition of CDU and CSU proposes a "premium model"[146] which would maintain the current dual system of universal and private insurance. Premiums would no longer be assessed according to income but every adult would contribute 169 Euro, 60 of which would be paid out of a fund financed by employers. Members unable to afford the premium would receive aid from the same fund. The Free Democrats – they will most likely form a coalition with the CDU/CSU should these win the elections – submitted the most radical reform proposal: away with the public system. A privately insured basic benefit package would be mandatory, and insurance carriers would be prohibited from cherry-picking. Employees would receive the employer's share as taxable income, and the resulting revenue would in turn be paid in for those unable to afford the premiums.

All proposals have been critiqued because they continue to rely at least partially on employment relationships and hence on the strength of the labor market. Currently, no predictions as to the future course of German health care reform are possible. There is one certainty, however: during the elections campaign, "social policy will be an important subject."[147] And, as the governor of Saxony-Anhalt put it, "I am not sure which solutions we will arrive at, but, in light of the current constraints, solutions will be arrived at."[148]

I. The Economics of German Health Care

Health care expenditures had remained stable at around ten percent of GDP (8% or less for the universal health care system, 2% for private insurance) for many years but rose to 11.1% in 2003.[149] (United States health care expenditures in 1995 absorbed 13.6% of GDP[150] and rose to 15.4% by 2003.[151]) Net administrative expenditures have been stable for many years at slightly over 5% of total German

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[146] *Prämienmodell.*

[147] *Sozialpolitik wird wichtiges Thema (Social Policy will be an important subject).* SÜDDEUTSCHE ZEITUNG, 24 May 2005, at 1.

[148] *Steuermittel Für Krankenkassen (Subsidies For Sickness Funds).* FRANKFURTER ALLGEMEINE ZEITUNG, 23 May 2005, at 5.

[149] OECD Gesundheitsdaten 2005 (OECD Healthcare Data). 8 June 2005, available at http://www.oecd.org/dataoecd/14/16/34987469.pdf.

[150] THOMAS S. BODENHEIMER/KEVIN GRUMBACH, UNDERSTANDING HEALTH POLICY 116 (1998).

[151] Highlights, National Health Expenditures. Centers For Medicare and Medicaid Services. Available at http://www.cms.hhs.gov/statistics/historical/highlights.asp. Last modified 11 January 2005.

health care spending.[152] (Managed care organization in the United States spend between 20 and 30 cents per premium dollar on administration.) In 1997, Germany spent $2,339 per capita on health care, compared to $4,090 by the United States without any correspondingly superior population health status.[153] By 2003, these numbers had risen to $2,996 and $5,635 respectively.[154]

During the first quarter of 2005, the universal healthcare system achieved a surplus of 156 million Euro ($190 million), down from over 936 million Euro ($1.14 billion) during the last quarter of 2004[155] and over 2 billion Euro ($2.5 billion) during the first half of 2004.[156] A surplus of approximately 2 billion Euro is projected for all of 2005.[157] This is achieved despite the fact that the current German percentage of individuals aged sixty-five and over will be reached by the United States in 2018-2020 when the baby-boomers retire. Furthermore, the increased demand for health care since German unification in 1990 could be roughly compared to the United States absorbing Mexico.[158]

It has been suggested that the current system may have more of a cost-benefit problem than one of excessive health care expenditures, actually making major structural changes unnecessary. Increased transparency and quality control measures may yield considerable savings while applying the premium to additional sources of income other than salaries and wages may sufficiently broaden the revenue base of the sickness funds for many years to come.[159] The reform proposals currently on the table, major topics during the election campaign for federal elections in September 2005, will subject the above considerations to public debate.

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[152] 1991: 5.13.%, 2002: 5.7%, 2005: 5%. *Kassen Sollen Verwaltungskosten Senken (Sickness Funds Must Lower Administrative Expenditures).* Frankfurter Allgemeine Zeitung, 5 August 2003, at 13. *Hartz-Reform Sichert Krankenkassen Überschuß (Hartz-Reform Provides Surplus For Sickness Funds).* Frankfurter Allgemeine Zeitung, 3 June 2005, at 13.

[153] Uwe Reinhardt, *'Mangled Competition' And 'Managed Whatever.'* 18 HEALTH AFFAIRS 92 (1999).

[154] OECD Healthcare Data, *supra* note 149.

[155] *Hartz-Reform Sichert Krankenkassen Überschuß (Hartz-Reform Provides Surplus For Sickness Funds).* Frankfurter Allgemeine Zeitung, 3 June 2005, at 13.

[156] *Id.*

[157] *Id.*

[158] Uwe Reinhardt, *'Mangled Competition' And 'Managed Whatever.'* 18 HEALTH AFFAIRS 92 (1999).

[159] Uwe Reinhardt, *Managed Care - An Imperative For German Health Care?* Presentation to the Federal Association for Managed Care, Berlin (12 September 2000). On file with the author.

K. Conclusion.

The German universal health care system under Title Five of the Social Code continues to guarantee access, coverage, and a high standard of care for everyone. Policy makers are accountable to the public for any health care spending decisions, and the still mostly consensus-based physician-sickness fund system of self-governance translates these into the delivery of care while subject to judicial review by the BSG. Proposed reform acts always give rise to a heated debate and are frequently withdrawn or revised in the face of opposition by the public and provider and sickness fund associations.

Complaints by providers and members about cost-containment measures are often triggered by the unwillingness to accept increasing restrictions on and more financial responsibility for a health care system which had delivered unlimited, comprehensive, prepaid care for decades without any cost-awareness on the part of subscribers who never received invoices nor were required to contribute through co-payments and deductibles. Only now the realization has sunk in that health care is a scarce resource and must be preserved due to an aging population and evermore sophisticated medical technology while unemployment is high and the revenue base still entirely contingent on labor. Most reform measures implemented so far, true to the historical principle of solidarity, have required some sacrifices on the part of all system participants. After the reform of 2004, however, provider bargaining power may weaken increasingly as sickness fund power rises.

Physicians will continue to have collective influence on the quality of health care services. Their clinical autonomy is protected by a complex system of checks and balances, anchored in constitutional and social law, and revisions are subject to judicial scrutiny by the BSG. Coverage and practice guideline development is a public notice and comment process with many opportunities for formalized physician input, perhaps eventually leading to benefit determinations based on sufficient empirical evidence while leaving appropriate room for individualized clinical decision-making.

Physicians' uneasiness arising from growing pressures to combine economic considerations with clinical judgment is certainly well-founded, considering medical ethics and the resulting focus on the individual circumstances of each patient.[160] Social law and its successive reforms mandate the delivery of care

[160] these concerns are similar to those of american practitioners, and the supreme court has coined the term "Mixed Treatment and Eligibility Decisions", implying the inseparable link between therapeutic and administrative (cost-saving) decisions, necessary for the "rationing" of health care, seen as natural by a conservative Court. Pegram V. Herdrich, 86 U.S.L.W. 4501 (12 June 2000) (No. 98-1949). 2000 U.S.

according to social and civil law standards while increasingly burdening practitioners with micro-allocation decisions. But their call for legislated coverage determinations to limit the liability arising from the perceived growing gap between social and civil law may be incompatible with the laws protecting their autonomy.

The recently legislated opening to market forces and competition as well as the potentially growing chinks in the system of self-governance, one of the main pillars of the consensus-based German health care system, may create a situation similar to the United States where managed care has severely hampered independent clinical decision-making and engendered conflicts for all those endeavoring to practice in keeping with traditional medical ethics.

By better understanding the strengths and weaknesses of their respective health care systems, the United States and Germany may be able to reduce current system deficits and prevent deficiencies from widening in the future.

Lexis 3964. In the United States, Managed Care Organizations often preauthorize or deny care, seriously limiting the clinical decision-making autonomy of providers, which is protected by law in Germany.