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# **Reshaping the regulation of the workforce in European health care systems**

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## **Introduction**

The nature of health care as a social and a private good means that it is the subject of intense regulation in most countries (Saltman et al. 2002). Over time, each society has established an array of institutions, laws and rules to regulate the practices of health care workers in the stated interest of protecting the public and ensuring high-quality services. Recently, in the wake of high-profile cases of poor performance and professional misconduct, health policy-makers have increasingly felt the need to strengthen or reform the regulatory mechanisms for the health professions. Yet overregulation can be as great a problem as underregulation, as it inhibits innovation and demotivates professionals.

Regulation is complex, requiring health policy-makers to balance a number of considerations related to the social, political and economic context of health care. This chapter sets out a framework for the analysis of approaches to professional regulation and applies it to the experience of reforming the regulation of doctors in a number of European countries.<sup>1</sup> The chapter aims to identify recent trends in regulatory reforms in order to increase understanding of what constitutes appropriate regulation – that is, how to ensure high standards and effective accountability without adverse effects on efficiency. It is hoped that it will assist policy-makers and regulators to select, from the vast range of options available, an optimal mix of regulatory instruments.<sup>2</sup>

Primarily, the chapter considers regulatory provisions that aim to protect the public from harm and to foster the provision of high-quality and efficient care. It does not deal directly with the regulation of supply, education and labour

relations, as these issues are examined in more detail elsewhere (Chapters 3, 4, 5 and 9). The following section sets out a theoretical framework for examining professional regulation. A number of case studies are presented, and these form the basis for an assessment of the general direction of regulatory reforms and the key strategies that have been used in Europe. These cases suggest that there is a shift towards greater political accountability and micro-regulation. Recent reforms go beyond traditional models based on professional self-regulation. They suggest a continual expansion of regulatory practices, a larger repertoire of policy instruments and increased oversight by external actors.

### **A framework for analysing regulation in the health labour market**

Occupational regulation in health care is nothing new and has been traced back to the earliest records of the healing professions. The legal code of Hammurabi, established in about 2000 BC in Mesopotamia, created a drastic remedy for malpractice: amputation of the surgeon's hand (Hogan 1979; Merry and Crago 2001). Here the primary public purpose of state intervention was to prevent harm from dangerous or unqualified medical practice. From another perspective the Hippocratic oath, originating in Greece in the fifth century BC, was based on the view that medicine is above all a vocation (Jacob 1999). Doctors operate within an ethical tradition and are subject to self-imposed codes of conduct accepted voluntarily by the professions. Regulation of the health care workforce within contemporary societies has evolved to become a complex and polymorphic system with multiple objectives. However, the main dilemmas remain: who should regulate, and how?

#### ***Degree of state intervention***

Regulation, by its very nature, requires a source of regulatory authority. However, the most appropriate locus of this authority remains the subject of intense debate in the health sector. Consequently professional bodies' degrees of involvement in the regulatory system and the role of external actors, such as state institutions, vary. The extent to which the state intervenes in the practice of medicine can be seen as a continuum from complete professional autonomy and self-determination to direct state control (Figure 10.1). In reality, the state may intervene more in certain aspects of regulation, such as remuneration, than



**Figure 10.1** Degree of state intervention in professional regulation.

in others, such as entry criteria, though this has been shown to vary between countries (Moran and Wood 1993).

The view that regulation should be the sole responsibility of the professional group concerned has long been a fundamental aspect of professionalism in medicine (Freidson 1970; Rottenberg 1980). Self-regulation of health professionals is justified on the basis that their services are experience goods and therefore they themselves have more knowledge about the quality and risks of receiving health services than do public authorities and consumers. Because of this information asymmetry between those who practise and those who seek to regulate, professional organizations argue that they are in the best position to ensure quality and prevent public harm.

Another argument in favour of self-regulation is that it is more efficient. Information to set, monitor and enforce standards is more easily acquired. The self-regulators' level of understanding of the professions gives them the flexibility to adapt to changes in practice and make voluntary compliance more likely (Baldwin and Cave 1999). Furthermore, the costs are lower than those that might arise from a more formal legalistic mechanism, and are borne by the profession instead of the government (or taxpayer). Yet the case for self-regulation is not accepted universally.

Economists in particular are wary about the virtues of self-regulation (Chapter 8), and emphasize self-regulation's economic benefits for the professions. As early as 1770, Adam Smith highlighted the ability of crafts to lengthen apprenticeship programmes and limit the number of apprentices per master, thus restraining free competition and ensuring higher earnings for persons in those occupations. Codes of ethics and standards of practice that are designed to ensure that professionals have appropriate competencies, deliver a high-quality service and continue to develop their skills and knowledge are seen as barriers to entry, as they are used to regulate the numbers of practitioners and the conditions under which they can participate in the market (Smith 1970).

More recently, analysis of regulation has observed regulatory capture, whereby the regulator comes to serve the interests of the group regulated rather than those of the public (Gellhorn 1956, 1976; Friedman 1962). *Capture theory* predicts that health professionals will structure regulations to keep out competition and thereby increase their incomes (Moore 1961; Coase 1974; Posner 1974). Such views are also consistent with the rent-seeking interpretation of interest group behaviour in the public choice literature and the economic theory of regulation (Stigler 1971; Becker 1983; Peltzman 1989; Lowenberg and Tinnin 1992; Zhou 1993). These posit that the demand for regulation comes primarily from practitioners looking for protective regulation, such as regulated prices and barriers to entry to the market. As such, regulation originates where supplier interest groups are concentrated and well-organized so that they can lobby effectively to influence the level and content of regulation to their benefit. However, such control may result in regulatory failures, including the creation of monopolies, a scarcity of certain necessary services and inefficiency.

Thus, where regulation is internalized fully by professionals, there is a danger that it will not serve the public interest. External forms of regulation are thus promoted as a means to achieve a better balance between professional and public interests, combat provider monopolies, avoid unjustified restrictions on

competition and prevent restrictions to access. In reality, most self-regulation is supported by a statutory framework – for example, compulsion or licensure powers – with some role for external actors (e.g. governments or statutory bodies).

The extremes of the continuum of state involvement can be characterized by two ideal types: the guild approach and the bureaucratic state approach.

### ***The guild approach***

This approach was foreshadowed in the guilds of the Middle Ages, organizations that possessed quasi-governmental authority to regulate their membership, using their monopoly power to decide who could practise, their prices and minimum quality standards (Hollings and Pike-Nase 1997). Although the guilds' authority diminished with the rise of the nation state, national medical societies, established in many countries between the sixteenth and nineteenth centuries, continued to reflect the medieval structures and in many respects still do so today.

Professional associations operate as primary regulatory institutions, benefiting from a triple monopoly: economic (control of recruitment, training and credentialing, protected contractual positions); political (control of the area of expertise, provision of expert guidance for legislators and administrators); and administrative (control of standards of practice, discipline) (Freidson 1994). Their activity emphasizes approaches that regulate new entrants rather than control those already in practice, as reflected in the low number of disciplinary actions in comparison with estimates of the incidence of incompetent practice (Institute of Medicine 1989).

Turf monitoring and turf protection occupy much of the regulatory bodies' energy as the various occupations battle among themselves about which parts of health care fall under their jurisdiction. Historically, professional associations sought to defend their practitioners' interests against irregular healers (Lindemann 1999); today, changes in professional boundaries are viewed as expansions, encroachments and infringements. Such fragmented, competitive and adversarial regulatory activity, based on exclusive occupational domains, is reflected in a high level of compartmentalization of health occupations that leaves little room for collaborative practice.

### ***The bureaucratic state approach***

The bureaucratic state approach dates back to the Enlightenment period of the seventeenth and eighteenth centuries, as nation states sought to reduce the powers and privileges of the guilds. This process accelerated in the aftermath of the French Revolution, as most European nations abolished those institutions that were seen as antipathetic to the ideals of egalitarianism and popular sovereignty (Burrage 1990; Bellis 2000).

During the second half of the twentieth century, with the expansion of the welfare state in both western and eastern Europe, this model of regulation

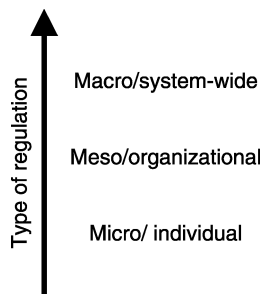
became more commonplace. The steady expansion of bureaucracy is seen as undermining professional sources of power, contributing to the bureaucratization of medicine and proletarianization of health practitioners (Braverman 1974; Larson 1977; Derber 1982). From this bureaucratic state approach, the case for state intervention is set within a welfare maximization framework. The state can legitimately exercise its power as part of its duty to protect the interests of the public as opposed to those of professional elites (Moran 1995). The government takes ultimate responsibility for care delivery and even clinical standards. Bureaucratic mechanisms are used by the state to exert administrative control over professional bodies and even individual practitioners.

### ***Types of regulation***

The other main decision for policy-makers is how to regulate. In particular, at what level should regulation be implemented and what tools should be used? The type of regulation can be understood as a continuum from the macro- through the meso- to the micro-level (Figure 10.2).

At one end of the spectrum there are macro forms of regulation. These shape the market for services and the characteristics and conduct of participants (Table 10.1). Regulation of this sort may influence the supply of health workers, control wages and prices, establish levels of services, harmonize qualifications and requirements or set and enforce common standards for practice. Macro-regulation tends to rely on hierarchy (bureaucratic or professional) and a variety of centralized state-run and professional agencies for its implementation. Usually negotiation is centralized (involving the state and organized representatives) and collective decisions are applied to all workers within a defined geographical area (e.g. country, state or region). Regulations are both prescriptive and comprehensive; that is, providing a detailed definition of scope, conditions of practice and codes of conduct under which professionals can be held accountable.

At the other end of the spectrum, micro-regulation focuses on the delivery of services and their outcomes. Regulatory influences are exerted primarily through devolved institutions or independent agencies such as insurance funds, consumer organizations or audit agencies. Instruments such as quality-based contracting are used to create incentives for practitioners to improve their



**Figure 10.2** Types of regulation.

**Table 10.1** Summary of macro- versus micro-regulation

	<i>Macro-regulation</i>	<i>Micro-regulation</i>
Purpose	Control of market structure, characteristics and conduct of participants	Management of delivery of services and outcome
Areas of action	Inputs and prices	Outputs and outcomes
Instruments	Numerus clausus Fee schedule Minimum qualifications Standards of practice	League tables Quality-based contracting Continuous quality improvement Risk management Benchmarking, quality circles and standardized treatment procedures
Nature and scope	Prescriptive and comprehensive	Flexible and tailored

performance and adopt the most cost-effective and evidence-based practices. Other interventions, such as continuous quality improvement, risk management, benchmarking, quality circles and standardized treatment procedures, are used *within* organizations to influence the practices of individual health workers. In line with the ideas of NPM (Osborne and Gaebler 1992; Bekke et al. 1996), this approach allows a certain degree of flexibility to tailor the regulations to the circumstances of each organization or group. Often micro-regulation is associated with deregulation and an easing of the degree of prescription imposed by regulations; however, it may instead reflect in practice a process of re-regulation with an increased sophistication of regulatory mechanisms.

The next part of this chapter examines the reforms to professional regulation in Norway, France, the United Kingdom and Germany, highlighting the trends moving away from the traditional approaches set out above or changes in the types of regulation employed.

## **New modes of regulation of the health labour force in Europe**

Within Europe, many countries have introduced reforms to the regulatory environment as it applies to the health workforce. Regulation has proved a highly versatile tool. It has been wielded to: influence the supply of health workers; monitor the process of production; facilitate mobility; stimulate changes in practices; increase responsiveness to consumer needs and expectations; and create incentives for improved performance and higher standards of service. Drawing on empirical data generated from five European case studies prepared for this book, this section explores the extent to which these reforms and concurrent changes in the wider health system have impacted on traditional modes of regulation.

***The medical profession in Norway: state capture or cooptive polity?***

Governance of the Norwegian health care system and of its workers has been shaped by traditional Nordic decision-making practices. Interest groups, organized around functional sectors, are granted privileges of self-governance but are integrated closely with the state and strongly involved in the process of formulating and implementing health policy (Blom-Hansen 2000; Peters 2000). In this context, the Norwegian medical profession has been able to take advantage of its institutional integration into the state machinery to dominate health care policy and safeguard its self-regulation privileges (Erichsen 1995). Physicians obtained hegemonic positions in shaping health care through their right of veto over policy changes, dominance of formal decision-making arenas and positions in many critical posts in the health bureaucracy.

Even now, the medical profession maintains authority over the context and content of its work and, to a certain extent, health policy-making as a whole. While a substantial part of state authority has been devolved to independent regulatory agencies as part of the structural devolution that took place during the 1990s (Christensen and Lægreid 2001a, b), physicians have remained dominant in the new health care supervisory agencies. For example, at national level the Norwegian Board of Health, an independent technical agency with lead responsibility for the supervision of health services, is heavily dominated by physicians and works in collaboration with 19 county medical officers. At local level, physicians are given primary responsibility for supervising health services and monitoring counties' and municipalities' compliance with national health policy (Feruholmen and Magnussen 2000).

However, recent reforms indicate that the medical profession's efforts to capture the power of the state, so as to maintain its influence over health policy-making, are increasingly counterbalanced by the Norwegian state's concurrent attempts to increase its influence over medical activity through cooptation of the professional elites.

Current developments suggest an active process of reshaping what has been called the 'professional state', creating a new balance of power between the medical profession and the state. Following recent changes in the institutional context, the medical profession has developed a more detached relationship with the state, as reflected in the Norwegian Medical Association's restricted participation in formal policy-making bodies and a reduction in physicians' power of veto. Other examples include recent initiatives involving decentralization and internal market experiments that have created new forms of external influence over medical activity and have coopted professional elites into state structures that control and regulate their peers on behalf of governments at both national and local levels.

Since 1984, municipal councils have been responsible for financing and providing primary health care. By 2001, most GPs (74%) were operating as contractors directly accountable to municipal offices (van den Noord et al. 1998). Consequently, the Norwegian strategy to enhance the quality of health care envisages a leading role for the political and administrative leaders of counties and municipalities (Norwegian Board of Health 2002). In addition, the



Norwegian Directorate for Health and Social Affairs and the Norwegian Centre for Health Technology Assessment (SMM) are developing medical guidelines, quality indicators, medical databases, strategic planning and performance-related budgeting tools; all formal instruments that are designed to reinforce political control over health care professionals.

Thus, although regulation of the Norwegian medical profession still reflects some key features of traditional Scandinavian corporatism, it appears that a reshaping of the corporate order is under way, creating new opportunities for public authorities to oversee professional activity, enforce improvement in quality standards and, more broadly, increase the state's influence over the health policy process.

### ***The case of la médecine libérale in France: self-regulation or a lost legacy?***

Despite the long-standing tradition of central state control that characterizes French polity, the French health care system is viewed as one of the most liberal in the world in terms of the autonomy enjoyed by patients and health professionals, particularly physicians (Poullier and Sandier 2000). Under the French model of liberal medicine secured by the *Charte médicale* of 1927, private practice is dominant in ambulatory care and private practitioners are free to set up practice wherever they choose. Doctors' prescriptions are neither monitored nor constrained. Professional status is based primarily on reputation. Physicians are granted considerable autonomy over the content of their work. There is a strong emphasis on professional confidentiality so that physicians are considered to be answerable primarily to their patients and themselves for the quality of their services (Rodwin 1981).

Implicit in this model is the view that self-governance is the preferred regulatory approach and that professional institutions should retain control over key aspects of health care work. Consequently, professional bodies have retained mandates for monitoring the performance and disciplining their members. Efforts to restrict the choice of patients and providers have been strongly and, to a certain extent, successfully resisted. One example is the recent failure to establish GPs as gatekeepers to secondary care (fewer than 1% of doctors signed up to the scheme). However, a closer look at the evolution of the regulation of health professions in France over recent decades suggests a dilution of the legacy of liberal medicine because of significant developments.

First, the French state has been able to tighten its grip over the activity of the health professions through the development of various forms of control and regulation operating at the macro level (Wilsford 1987). Since 1971, the French state has had direct control over the supply of health personnel through a *numerus clausus*. Through control of education funding, the government has the ability to create national training schemes for the health professions, establish quality norms for educational institutions and influence the location of training and the distribution of specialists in each specialty and region.

Another source of state control comes from contractual agreements between professional trade unions and the government. These agreements, initiated after

the Second World War, define the financial resources available for health care and the maximum fees that physicians may be reimbursed by the sickness funds (Maria and Ostrowski 2003). Since the 1996 Juppé reforms, the French Parliament has held the ultimate responsibility for determining the rate of increase in health care expenditures and setting annual targets for the growth of private practice medical fees and prescriptions.

Second, more recent efforts to improve the efficiency and quality of medical services have targeted the heart of the liberal practice itself, sanctioning prescribing practices and the behaviour of individual professionals at the micro level. The 1996 Juppé Plan introduced provisions for both collective and individual sanctions against overspending physicians. Similar objectives were pursued through mandatory universal practice guidelines known as *références médicales opposables*. These new tools explicitly sought to rationalize medical practices, standardize patient care and limit the unnecessary prescription of redundant and costly drugs, tests and procedures (Durand-Zaleski et al. 1997; Durieux et al. 2000).

New state-controlled bodies have been given new responsibilities for evaluating professional practice and quality assessment. For instance, ANAES (a government agency with statutory authority) has been given a clear mandate to establish the state of knowledge on diagnostic and therapeutic procedures, issue guidelines for clinical practice and provide technical recommendations to sickness funds. ANAES provides support and guidance to the 22 regional associations of independent doctors founded in 1993 to contribute to the improvement of health care quality and evaluate the practice of physicians.

The clinical practice of general practitioners is coming under increasing scrutiny (Maria and Ostrowski 2003). This role has been devolved to counsellor doctors (*médecins-conseils*) employed directly by the medical division of CNAMTS (National Health Insurance Fund for Salaried Employees), who have the right of access to all medical records and data held by local sickness funds. Although access to patient information remains a sensitive issue, the consolidation of all patient reimbursement claims in a single electronic database is proving to be an invaluable tool that enables the counsellor doctors to scrutinize patterns of clinical practice (Or 2002).

In summary, while the medical profession still holds tightly to the principles of liberal medicine, the introduction of a number of new policy tools at both macro and micro levels during successive reforms has extended the state's power and its capacity to exert control while eroding professional independence.

### ***The reform of self-regulation in the United Kingdom: professionally led regulation or managerial dominance?***

In contrast to many continental European countries, professions in the United Kingdom have historically developed independently of the state. In line with the guild approach mentioned above, the state-sanctioned model of self-regulation enshrined in the Medical Act of 1858 left the professions considerable authority to set standards for training and practice, control entry to the profession and monitor and enforce standards of practice (Irvine 1997). Responsibility for

ensuring that doctors were performing effectively was the exclusive responsibility of the General Medical Council (GMC) and the Royal Colleges (DoH 1999) until the 1990s.

However, the 1990s saw the emergence of more articulate consumerism in health care, a widespread perception of substantial inefficiencies in the use of health care resources and high-profile examples of clinical practice failures. These created both political and professional momentum for reform of professional regulation (BRI Inquiry Secretariat 1999). In the wake of the Bristol and Shipman cases (the former involving failure to act in response to high death rates among babies undergoing cardiac surgery, the latter a general practitioner convicted of murdering patients using overdoses of morphine), even the survival of the GMC with its system of medical self-regulation was questioned, creating a sense of urgency among medical profession leaders to tackle the perceived failures of self-regulation (CMO Review Group 1995; BMA et al. 1998; Klein 1998; Stacey 2000). A model of professionally led regulation was proposed as an alternative to self-regulation. This still places a strong emphasis on professional bodies' role in setting standards and assuring competency.

New mechanisms are being introduced with the goal of ensuring better monitoring of professional activity. For example, the GMC is developing methods for assessing the performance of allegedly poorly performing doctors (Southgate and Dauphinee 1998) and has introduced a requirement that physicians disclose evidence of inadequate medical practice. The introduction of revalidation for medical practitioners requires all registered doctors to demonstrate periodically that they are up-to-date and fit to practise in their chosen field (Catto 2003). In addition, a number of professional bodies have recently changed their structures and composition, increasing the proportion of lay representatives in order to integrate non-medical input into their decision-making process, making them more transparent and more accountable to the public (Hatch 2001).

Concurrently with these professional initiatives, governance of the health professions has become a highly politicized issue, prompting a wide range of initiatives by successive governments since the late 1980s. The White Paper *Working for Patients* (DoH 1989) introduced the internal market in the British health system; it signalled a greater role for managers in assessing the quality of health care services, a role previously reserved almost exclusively for clinicians. Contracts, and thus the distribution of funds, gave managers potentially strong levers to make professionals take account of specific purchaser or client demands. To some extent, clinical autonomy became circumscribed within the parameters of contracts, although in practice the inherent ambiguities of health care meant that the more ambitious managerial expectations were never fulfilled (McKee and Clarke 1995). More recently, *The New NHS, Modern, Dependable*, published in 1997, warned that self-regulation could be sustainable only if it became open to public scrutiny and responsive to changing service demands. To support such changes, the Council for the Regulation of Healthcare Professionals (rebranded as the Council for Healthcare Regulatory Excellence) has been established in order to coordinate approaches across the various professional bodies and build a common framework that explicitly allows for robust public scrutiny.

In addition to these various structural levers, clinical governance has given

managers statutory responsibilities for the quality of health care delivered by their organizations, together with the legitimacy and authority to monitor clinical services at the micro level. There have been attempts to involve groups of clinicians in management, so that managerial and fiscal discipline can be imposed on clinicians through more subtle clinical–managerial channels (Ferlie 1999). NHS targets, waiting lists, guidelines and protocols have stood out as valuable instruments to control clinical practice and have enabled managers to nibble at the edge of clinical decision-making through micro-management. Such developments have been underpinned by the creation of a number of new national standards agencies, such as NICE and the Health Care Commission, devoted to promoting the performance of health care providers and ensuring quality.

Thus, the reform of professional regulation in the United Kingdom clearly reflects a tension between professional efforts to perpetuate the patterns of self-governance within new arrangements and government attempts to develop a more actively managed, externally regulated system. While the government is using the NHS's strong structural levers and a series of new regulatory agencies to constrain clinical autonomy and achieve its policy objectives, professional elites are seeking actively to consolidate public confidence in self-regulation.

### ***Restructuring German legal corporatism: new corporate order or another version of self-governance?***

Regulation of the health care workforce in Germany has traditionally reflected the country's dominant policy style of legal corporatism, with extensive cooperation between governments and various associations granted official standing by law (Offe 1981; Lehbruch and Schmitter 1982; Dyson 1992; Aguilar 1993; Dryzek et al. 2002). In this system of interest mediation, large organized interests are granted formal sanction by the state and thus official status as legitimate participants in the decision-making process. In exchange for this monopoly, they commit to coordinate their actions and to contribute to the common public interest through the cooperation of their members (Dyson 1980; Jepperson 2000). Above all, the state's role is focused on providing a unified legal framework (set out in Social Code Book V) (Busse and Reisberg 2000). Within this broad framework, the corporatist actors benefit from significant constitutional autonomy and authority both to regulate the behaviour of their members and to shape the organization of health care (Altenstetter 1987; Bureau 1999). In many respects, a guild-like approach is evident in this system. Within the statutory health insurance scheme, professional associations operate as the main regulatory, administrative and financing bodies, acting as a buffer between individual professionals and the statutory funds, shielding the funds from direct surveillance of professional activity (Godt 1987; Busse and Reisberg 2000).

Responsibility for professional accreditation in ambulatory care is devolved to the regional associations of ambulatory care physicians, who also negotiate with sickness funds, private insurance companies and voluntary and public agencies. Their monopolistic and cartel-promoting behaviour is reflected in the sharp division between inpatient care and ambulatory care. Ambulatory care

has remained a monopoly of the associations of ambulatory physicians and, until 1993, hospitals (except university hospitals) were not allowed to provide even ambulatory surgery.

Outside the scope of the statutory health insurance system, professional chambers assume certain exclusive regulatory functions, notably in specialist training, continuing education, licensing, access to professional practice, development and enforcement of professional standards.

As in the United Kingdom, German professional bodies have been more proactive recently, taking steps to strengthen and modernize their self-regulatory mechanisms (Birkner 1998). For example, since 1993 the National Association of SHI-Accredited Physicians (physicians working in the ambulatory sector) has launched new quality assurance projects, developed quality control charts and promoted 'quality circles' (more than 1000 peer-based quality groups) (Gerlach et al. 1998). The *Arbeitsgemeinschaft zur Förderung der Qualitätssicherung in Medizin* (Working Group for the Advancement of Quality Assurance in Medicine), founded by the German Medical Association and the National Association of SHI-Accredited Physicians, has been operating as a clearing house for standards and practice guidelines.

This picture adds weight to the argument that the German health care system relies heavily on traditional self-regulation to govern the functioning of its professional elements and that many recent initiatives initiated by the professions seek primarily to secure public confidence in the guild system. However, after more than a century of strong professional autonomy, the German state has re-emerged as a major actor in health policy-making (Hinrichs 1995; Bura 1999; Altenstetter 2001). A series of cost-containment measures, introduced from the 1970s onwards, challenges the financial autonomy of doctors, their freedom to prescribe and their control of key areas of health policy. Capping mechanisms, such as a strict global prescribing budget and lump sum prospective budgets for sickness funds' payments to physicians' associations, were introduced despite vociferous and coordinated opposition by physicians.

In the early 1990s, a requirement that any overspend in the new drug budgets or in the global remuneration envelope be repaid by doctors was introduced (Busse and Howorth 1999). As physicians' associations became liable for overspending, they were forced to scrutinize more closely the practice profiles of their members, measured by such criteria as the number of drugs prescribed, office visits, laboratory tests per case and rates of certain surgical procedures. A number of additional structural changes, including limitation of the number and type of physicians who can practise in different regions of Germany, a reduction in the number of medical students, rationalization of the very fragmented system of sickness funds and the introduction of elements of managed competition, appear to confirm the prospect for further political and managerial encroachment on professional power and autonomy.

Furthermore, while quality issues traditionally were the domain of individual clinicians or professional organizations, actors external to the professional bodies (such as the Federal Committee of Sickness Fund Physicians, a body where doctors are in the minority) have been involved increasingly in the development and enforcement of clinical guidelines, medical audit and quality assurance (Busse and Reisberg 2000).

In summary, professional regulation in Germany is shifting from a system of self-governance towards one that secures a greater role for the state. The overall picture suggests a drive towards a more technocratic model of regulation led by external actors, and the use of more policy instruments by both professional bodies and government, including new micro-management tools such as diagnosis related groups (DRGs), computerized practice profiles, clinical practice guidelines and quality assurance systems.

## **Changing models of professional regulation**

For more than a century, the self-regulation of professionals in health care has provided a powerful tool, at least in western Europe, to guarantee minimum standards of health care delivery, ensure appropriate levels of technical and ethical practice and hold providers accountable when they slip below accepted standards. Statutory self-regulation has required health professions to develop a complex infrastructure that serves to keep professional services acceptable to society. It has also granted the medical profession legitimacy for authoritative advocacy on behalf of patients and autonomy to determine the clinical content of their practice at micro level and the terms of their practice at macro level.

Over recent years, the traditional mechanisms of self-regulation have been challenged by a number of well-publicized concerns about: clinical competence; growing evidence of unexplained variations in medical practice; pressure groups' increasing willingness to publicize information about sub-standard services; evidence of poor outcomes despite increasing expenditures; and changing attitudes within medicine itself. The evidence drawn from the case studies indicates that regulatory reforms broadly are driving changes in two ways.

### ***The growth of public accountability***

Increased politicization of the health care decision-making process has resulted in calls for closer public scrutiny of professional activities, the emergence of new externalized forms of control and the development of new reporting lines – upwards to governmental or independent regulatory agencies and downwards to consumers and citizens. The guild approach, evident in the various forms of corporatism in European health systems such as those of Germany and the United Kingdom, has come under attack. Other social actors, not only governments but also managers, parliaments and the general public, have assumed increased responsibility for overseeing professional activity and defining the framework of self-regulation. Many initiatives from governments, payers and consumers have focused on recasting the relationship with medicine in order to reduce its tight grip on policy, overcome its resistance to outside scrutiny and impose various forms of political and/or managerial control over medical care. Professional elites coopted into state structures in Norway, medical associations in Germany, counsellor doctors recruited by the sickness funds in France and clinicians with managerial functions in the United Kingdom have been used as channels for ensuring compliance with governmental and managerial

requirements. In many cases, self-regulatory organizations have been prompted to sacrifice voluntarily some aspects of their collective power in order to safeguard control over the core content of their work.

The perceived regulatory failure of professionally dominated self-regulation, as well as overly bureaucratic state regulation, has led to a growth in alternative forms of public accountability, either through more diverse representation on professional bodies (e.g. from other professions, consumer and patient groups or the state) or through the state establishing quasi-independent public bodies that are seen to be less bureaucratic. In all four countries examined, conventional approaches are being displaced in favour of a concept of regulation that is more pluralistic, drawing upon more diffuse sources of power and a greater diversity in the basis of control. A wide range of formal, externalized regulatory controls is used to ensure that health practitioners account for their performance to a range of stakeholders, including consumers, government agents, citizens' representatives, professional bodies, auditors, purchasers of care and regional and local health authorities.

The regional authorities in Norway, ANAES and the CNAMTS in France, the Federal Committee of Sickness Fund Physicians in Germany and NICE in the United Kingdom exemplify institutions that have been given prerogatives to hold health professionals accountable for their practices. These add to efforts developed in many recent reforms, particularly where there have been experiments with internal markets, to provide consumers and purchasers with the option to choose providers on the basis of their performance (Hibbard and Weeks 1989; Hannan et al. 1994; Edgman-Levitan and Cleary 1996; Lansky 1998; Rosenthal et al. 1998; Schneider and Epstein 1998).

The criticisms of self-regulation have provoked responses from the professions themselves. In the United Kingdom they have initiated reforms to offer reassurance that self-regulation fits the modern context of health care delivery. Such developments have suggested the emergence of a new guild, in which strategic elites within the health professions are attempting to maintain professional control over health care and forestall further managerial encroachment on professional activity by being more proactive and taking initiatives to modernize self-regulation (Tuohy 1976, 1988; Freidson 1994). Increasing lay representation on professional bodies and the changing composition of governance structures, as seen in the recent reforms of the GMC in the United Kingdom, are indicative of this trend.

To a certain extent, all these developments have altered the relationship between medicine and other health occupations such as nursing. Subordination to medicine is being replaced by direct accountability to the public, the government and the legislatures, and by direct access to the policy-making process (Chapter 4).

### ***The shift from macro- to micro-regulation***

Recent reforms of health care systems in Europe have shown a clear trend towards new regimes of regulation characterized by an increased emphasis on micro-efficiency and the application of a range of technical tools. The traditional

regulatory tools, favoured by both the bureaucratic state and professional bodies, which have featured mostly a concern for macro-managerial control, are being supplemented with a new generation of policy instruments: *références médicales opposables* in France, quality indicators in Norway, performance indicators in the United Kingdom and practice profiles in Germany.

The formalization and codification of performance standards is a key feature of recent regulatory reforms in the United Kingdom, reflected in the increasing use of business plans, contracts for service delivery and performance indicators and targets. Measures that target costs are complemented by micro-measures that affect clinical practice more directly in France and Germany. In all the countries examined there is an emphasis on the provision of information in the form of league tables, consumer reports, score cards, public performance reports, provider/practice profiles, billing patterns, utilization reviews and quality monitoring systems. These are used to: enforce individual practitioners' compliance with specific performance standards; monitor clinical services; foster provider organizations' and individual practitioners' accountability for their performance; and ensure that all stakeholders have adequate access to information on providers' performance. Such developments have been fostered by a number of technological developments, such as computerized databases, electronic systems for reimbursement and smart cards, all of which make it possible to scrutinize professional practice more closely.

The professions have been involved in this process and have sought actively to initiate innovative measures aimed at rationalizing and modernizing self-regulation. Guidelines, protocols, case mix measures, techniques of evidence-based medicine and other actions to systematize professional practice are promoted as tools that the professions can develop to ensure higher standards of care and protect patients from the consequences of poor practice. Medical audit and other forms of peer review, the development of measurable and auditable outcome indicators, often published as league tables or report cards (Marshall et al. 2003), and scrutiny of professional practice are introduced in order to facilitate early detection and correction of inappropriate care.

Reflecting a move from a reactive regime to a more proactive environment, continuing professional development and competence monitoring are promoted as ways to ensure that professionals regularly demonstrate evidence of their competence. This approach seeks to empower regulatory bodies not only to deal with a few high-profile cases where performance is clearly unacceptable, but also to reduce the tail of underperforming practitioners. Within this model, a significant element of professional control is exerted through local systems of monitoring but within a national framework of self-regulation. Local peers become the primary scrutinizers of professional practice (Sheaff et al. 2004). Although these professionally led measures have been incremental in nature, seeking jealously to safeguard many of the privileges of self-regulation, they have reflected a trend that is similar to the development of technical control mechanisms.

Thus, the evidence seems to suggest a dual process. First, the source of authority for control is shifting from traditional bureaucratic mechanisms and professional bodies towards a broader range of regulatory agencies, which operate at all levels of the health system and aim to enlarge health care workers' scope



of accountability. Second, there is the emergence of new policy instruments that operate mostly at micro level, introduced by both professional and governmental agencies to optimize the control of professional activity.

## Conclusion

Over recent decades developments in public administration, in both theory and practice, have challenged the two traditional ideal types of regulation: the guild and the state bureaucratic approaches. New models of regulation are emerging. No longer able to rely on their traditional privileged and trusted status, increasingly professionals have had to find rational and instrumental means to secure their position and ensure the continuation of the present balance of responsibilities for accountability, regulation and the management of professional activities. The principles of new public management, such as decentralization and consumer involvement, have had an important influence on government activity in many sectors and altered the respective roles of government and public service providers. Such trends are also apparent within regulatory structures, with greater diversification of regulatory bodies and delegation of regulatory authority. Changes can also be seen with the growth of lay involvement.

Despite self-regulation's failure to ensure public protection, no reform has attempted to replace it entirely with alternative regulatory forms. The aim of the reforms has instead been to consolidate, complement or renew the prevailing professional and bureaucratic mechanisms. Despite the powerful rhetoric in favour of deregulation, more often the reality has been expansion of the regulatory system through the adoption of new instruments, development of new channels of control and creation of new regulatory agencies, rather than a removal of professional regulatory authority.

Although these trends in regulatory reforms show some consistency between countries, not all countries are at the same stage of recasting their regulatory system. The post-communist countries of CEE are still at an early phase in rebuilding their professional institutions. Similarly, the pace of reform, the choice of regulatory tools and how they are implemented are constrained by the unique institutional history and the distinct corporate structure of each country.

## Notes

- 1 Within the scope of this chapter it is not possible to consider the regulation of all health professionals, such as dentists, nurses, pharmacists, allied health professionals or indeed some of the so-called complementary and alternative medical practitioners. Given the historical precedence of professional regulation for doctors, it is likely that many of the trends identified will apply to other health professionals in due course.
- 2 Regulatory instruments are defined here as procedural and substantive forms of public action that are used to influence the behaviour and functioning of health care personnel or to modify the production of health services (see Eliadis and Hill 2001).

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