The Police Power and the Regulation of Medical Practice: A Historical

Review and Guide for Medical Licensing Board Regulation of Physicians

in ERISA-Qualified Managed Care Organizations

8 Annals of Health Law 201, 1999

Edward P. Richards*

^{*} Edward P. Richards, III, J.D., M.P.H., is Professor of Law and Adjunct Professor of Business at the University of Missouri Kansas City. He received his undergraduate training at Rice University, post-graduate training at Baylor College of Medicine and the University of Michigan, his Juris Doctor from the University of Houston, and his Masters in Public Health from the University of Texas School of Public Health. [2003 - Professor Richards is now at the LSU Law Center. His website is: http://biotech.law.lsu.edu.

INTRODUCTION

The central health care regulatory issue facing the states is how to enforce a consistent regulatory environment over both ERISA-qualified managed care organizations ("MCOs") and those that are not covered by ERISA's limitations on state regulation. More generally, states are confronting substantial changes in the medical care delivery system, changes that are driven by private corporations and that are sometimes in conflict with state policy. These changes demand the quicker regulatory responses that are possible when decision making is delegated to an agency, rather than being expressed only through the legislature. The states, through their police power, have broad latitude to regulate the practice of medicine. Congress has provided few limitations on this power, and the United States Supreme Court has only limited it when it directly conflicts with certain limited constitutional rights of patients. In almost all cases where the extent of police power has been at issue, the state and federal courts have found in favor of the state. Unfortunately, state medical licensing boards have used these powers to exercise meaningful oversight of medical practice and MCOs and are thus ill-prepared to meet the challenge of regulating the practice of medicine in a managed care environment.

Regulation of medical practice through state licensing laws is a common pathway to control the medical aspects of patient care delivered by MCOs because every aspect of patient care depends on physician decision making. If the MCO does not allow physicians to practice consistent with state law, it will have no physicians and thus cannot function, yet this regulation should not run afoul of ERISA. The

¹ The Supreme Court has indicated that there would be constitutional issues if the state regulatory body acted arbitrarily or capriciously, or otherwise violated generally applicable constitutional or federal guidelines applicable to all state actions.

² "Our data on the response of the Board to complaints also raises questions as to the ability of medical licensure boards to address problems concerning the clinical competence of their licensees (and thus ultimately the problem of medical error) through disciplinary interventions. It is often assumed that the primary function of licensure boards is to assure clinical competence, and that the volume of their formal disciplinary actions is an appropriate measure for evaluating their success in accomplishing this task. Our study demonstrates that evaluating board success solely on the basis of formal disciplinary actions is inadequate because boards may be more active at the informal level than is commonly supposed. Indeed, given the resource constraints generally faced by licensure boards, and the substantial commitment of resources required when formal action is taken, it may be that informal action is not just an alternative to formal disciplinary action, but a more rational strategy for boards to pursue in some cases." See Timothy S. Jost, et al., Consumers, Complaints, and Professional Discipline: A Look At Medical Licensure Boards, 3 HEALTH MATRIX, 309, 335-36 (1993). See also the related article, Timothy S. Jost, Oversight of the Quality of Medical Care: Regulation, Management, or the Market?, 37 ARIZ. L. REV. 825 (1995).

thesis of this article is developed in two parts: (1) a detailed review of the police power and the court's construction of it in relation to medical practice; and (2) an analysis of the role of physicians in MCOs and how this role can be controlled by state police power regulation.

I. THE POLICE POWER AND THE REGULATION OF MEDICAL PRACTICE

A. The Colonial and Early Constitutional Period

Since colonial times, the regulation of professions has been seen as a state activity in the United States. Medicine is a particular creature of state regulation because it is the nexus of three traditional areas of police power regulation. First, it is a profession like law, and as such, was subject to state regulation. Second, medical practitioners posed peculiar risks to the public health and safety that other professions such as law did not pose. Third, and most important historically, physicians have been closely involved in the state public health regulations as they applied to epidemic disease and sanitation. In this role, physicians acted both as private volunteers and as public health officers, this generally being a part-time and unpaid office but one that allowed the physician to exercise the state's police powers to abate local threats to the public health, including imposing quarantine.

1. Epidemic Disease and the Police Power

Disease control and nuisance abatement were a primary focus in the colonial governments. The authority for these actions was described in Blackstone³ and was assumed to have belonged to the state

³ AThe fourth species of offenses, more especially affecting the commonwealth, are such as are against the public health of the nation; a concern of the highest importance, and for the preservation of which there are in many countries special magistrates or curators appointed. . . . The first of these offenses is a felony, but by the blessing of Providence for more than a century past, incapable of being committed in this nation. For by statute I Jac. I c. 31 . . . it is enacted, that if any person infected with the plague, or dwelling in any infected house, be commanded by the mayor or constable or other head officer of his town or vill to keep his house, and shall venture to disobey it he may be enforced . . . to obey such necessary command and, if any hurt ensue by such enforcement, the watchmen are thereby indemnified. And further, if such person so commanded to confine himself goes abroad, and converses in company, if he has no plague sore upon him, he shall be punished as a vagabond by whipping, and be bound to his good behavior; but if he has any infectious sore upon him uncured, he then shall be guilty of felony. By the statute 26 George. II, c. 6 . . . the method of performing quarantine, or forty days probation, by ships coming from infected countries, is put in a much more regular and effectual order than formerly, and masters of ships, coming from infected places and disobeying the directions there given, or having the plague on board and concealing it, are guilty of felony without benefit of clergy. The same penalty also attends persons escaping from the lazarets, or places

from time immemorial. While it is little noted in constitutional theory, the natural history of disease in the colonies did much to shape the ultimate distribution of powers between the states and the federal government.⁴ Most of the population centers in the colonies were near or on rivers or bays because water was the prime way to move goods within the colonies and between the colonies and England. This meant that they were subject to mosquito depredations for all of the year in the southern colonies and in the summer in the northern colonies. Malaria, caused by a protozoa spread by mosquitoes, was endemic in the colonies. Malaria is a chronic illness that causes great morbidity and substantial mortality, but kills slowly and does not manifest as fast-moving epidemics. As it still does in much of the developing world, malaria provides a constant background of illness.

The colonies were also subject to yellow fever, a viral disease also spread by mosquitos. Yellow fever is a rapidly progressive disease that makes the victim extremely sick within a week or so after exposure to an infected mosquito. Yellow fever in urban areas is carried from infected persons to the uninfected by mosquito bites. As more people become infected, there is a greater chance that a mosquito will be carrying the disease. This means that yellow fever tended to develop from a few cases into massive epidemics very rapidly. Patients who survive the first week of the infection usually have a prolonged convalescence but recover fully. Many victims die from the primary effect of the disease. Even those who might have otherwise recovered, died during epidemics in the colonies because there was no one to nurse them due to the number of people who were ill at one time. The impact on the colonies of the 1798 epidemic was described in counsel's argument before the United States Supreme Court in one of the key police power cases:

For ten years prior, the yellow-fever had raged almost annually in the city, and annual laws were passed to resist it. The wit of man was exhausted, but in vain. Never did the pestilence rage more violently than in the summer of

wherein quarantine is to be performed, and officers and watchmen neglecting their duty, and persons conveying goods or letters from ships performing quarantine. @ See 4 WILLIAM. BLACKSTONE, COMMENTARIES 161.

⁴ This is ironic given that it was largely the effects of communicable diseases that allowed the Europeans to quickly subdue the indigenous populations and colonize the Americas. *See* WILLIAM. H. MCNEILL, PLAGUES AND PEOPLES 160-65 (1976).

⁵ Ten percent of the population of Philadelphia died of yellow fever between September and November, 1793. J. H. POWELL, BRING OUT YOUR DEAD at page xiv (1949).

1798. The State was in despair. The rising hopes of the metropolis began to fade. The opinion was gaining ground, that the cause of this annual disease was indigenous, and that all precautions against its importation were useless. But the leading spirits of that day were unwilling to give up the city without a final desperate effort. The havoc in the summer of 1798 is represented as terrific. The whole country was roused. A cordon sanitaire was thrown around the city. Governor Mifflin of Pennsylvania proclaimed a non-intercourse between New York and Philadelphia.⁶

Yellow fever had raged through the colonies since the earliest period, always in the late summer and fall when the mosquito populations were highest. The epidemic decimated Philadelphia in the summer and fall of 1793, killing in excess of 5,000 out of a population of about 55,000. The combined effect of yellow fever, malaria, typhus, water-borne diseases such as typhoid, and other communicable diseases, was a life expectancy in the cities of about twenty-five years. Fear of communicable disease permeated society, affecting legislators, judges, and the drafters of the Constitution. The result was twofold: first, it was recognized that the government, under the old doctrine of societal self-defense, had plenary power to impose restrictions on property and persons to prevent to spread of disease; and second, that this power belonged to the states, subject to concurrent congressional regulation for

⁶ Smith v. Turner, 48 U.S. 283, 340-41, 7 How. 283 (1849). (This is an important case in the evolution of the distinction between permissible police power regulations and impermissible state regulation of commerce. Smith is actually a pair of cases argued and decided together as the ALicense Cases. Boston and New York had established state public health hospitals whose duties included determining if ship passengers landing in their ports were infected with communicable diseases. To fund this, the states imposed a head tax on persons landing at their ports. These were attacked as impermissible restrictions on interstate commerce and foreign trade. In their defense, the states argued that this was analogous to the closing of state borders that had been allowed during the epidemics. The court rejected this, finding that border closing was a direct public health measure related to the threat of disease, while the tax was only a way of funding this protection. Such tax acted as an unconstitutional restraint on trade because it interfered with interstate commerce and invaded the federal government's exclusive right to regulate foreign commerce.). See also Compagnie Francaise de Navigation a Vapeur v. Louisiana State Bd. of Health, 186 U.S. 380 (1902).

⁷ The colonists saw it as cyclic, increasing in severity in some years and falling off in others. What they did not know was the reason for the cycles, that the disease would have followed both weather, because of the mosquitos, and also the number of cases imported into the region from trading partners such as the West Indies, where the disease was endemic and which were close enough to allow infected persons to reach the colonies before they either died or recovered and were no longer infectious.

⁸ HANS, ZINSSER, RATS, LICE AND HISTORY 129 (1963).

⁹ LEMUEL, SHATTUCK REPORT OF THE SANITARY COMMISSION OF MASSACHUSETTS 1850. (Cambridge: Harvard University Press, 1948). (Facsimile Edition).

¹⁰ Edward P. Richards, *The Jurisprudence of Prevention: The Right of Societal Self-Defense Against Dangerous Individuals*, 16 HASTINGS CONST. L.Q. 329, 391 (1989).

[&]quot;The acts of Congress, passed in 1796 and 1799, empowering and directing the officers of the general government to conform to, and assist in the execution of the quarantine and health laws of a State, proceed, it is said, upon the idea that these laws are constitutional. It is undoubtedly true, that they do proceed upon that idea; and the

national purposes.¹² Despite the enormous expansion of individual rights jurisprudence since the early constitutional period, the United States Supreme Court has not substantially limited the police power as it relates to public health disease control. It most recently affirmed the validity of these cases in the 1997 decision in *Kansas v. Hendricks*, ¹³ which explicitly relied on *Jacobson v. Massachusetts*, ¹⁴ a 1905 smallpox immunization case.

2. Regulation of Physicians in the Colonial Period

During the colonial and early constitutional period, there was very limited regulation of the professions. With some limited exceptions, ¹⁵ formal regulation of the professions is a post-Civil War phenomenon. Those regulations that had been passed by state legislatures were repealed in the period from the early 1800s to the Civil War because of Jacksonian democratic notions of "every man his own doctor" (and lawyer), combined with the poor organization of the professions. Most studies of professional licensing do not attempt to differentiate between medicine and law during this period, assuming that similar treatment by state legislatures implied similar reasons for the treatment. While it is difficult to sort out cause and effect for events that occurred two hundred years ago, medicine was very different in 1790 than it is today, or than it was in 1910.

Medicine in 1790 did not work. There were a few effective drugs, mostly known from medieval times, but these could be applied as usefully by herbalists or other non-physician healers. Mainstream medical treatment consisted of purges, bleeding, and other regimes whose overall effect was to weaken the patient and increase the probability of death. More dangerously, since the germ theory and antisepsis

constitutionality of such laws has never, so far as we are informed, been denied. But they do not imply an acknowledgment that a State may rightfully regulate commerce with foreign nations, or among the States; for they do not imply that such laws are an exercise of that power, or enacted with a view to it. On the contrary, they are treated as quarantine and health laws, are so denominated in the acts of Congress, and are considered as flowing from the acknowledged power of a State, to provide for the health of its citizens. © See Gibbons v. Ogden, 22 U.S. 1, 205 (1824).

<sup>205 (1824).

12 &</sup>quot;No direct general power over these objects is granted to Congress; and, consequently, they remain subject to State legislation. If the legislative power of the Union can reach them, it must be for national purposes; it must be where the power is expressly given for a special purpose, or is clearly incidental to some power which is expressly given." See Gibbons v. Ogden, 22 U.S. 1, 203-4 (1824). Id. at 203-204.

¹³ Kansas v. Hendricks, 521 U.S. 346 (1997).

¹⁴ Jacobson v. Mass., 197 U.S. 11, 26, 25 S.Ct. 358, 361, 49 L.Ed. 643 (1905).

¹⁵ See Paul Starr, The Social Transformation of American Medicine 44 (Basic Books).

had not been discovered, physicians did not practice good sanitation. When a physician made his rounds of patients, he became a very effective vector for communicable diseases, assuring that his entire practice had the benefit of whatever diseases were current at the moment. From a 1790s frame of reference, medicine worked as it was supposed to work - it might do some good, but it was unlikely to prevent death. It might work in minor cases, but people tended to get well in minor cases anyway. There was no shortage of physicians, mostly untrained and self-proclaimed. In the minds of the populace and the legislatures, there was no justification for setting some physicians up with a state-enforced monopoly through licensing them, and excluding other physicians. Had medicine worked, having a good physician as opposed to a quack would have made a significant difference in survival that could have influenced the marketplace to support regulation and licensing. It is tempting to speculate on whether this would have encouraged state regulation of physicians to begin during the colonial period. ¹⁶

The low esteem of medicine as a profession did not mean that individual physicians were not respected and influential. Dr. Benjamin Rush is a useful archetype for understanding the societal role of the physician in this pre-regulation period. Dr. Rush was a noted patriot and a signer of the Declaration of Independence. He treated many wealthy and prominent citizens. His reputation and respect was based on his personal behavior rather than his status as a physician.¹⁷ This was most evident during the yellow fever epidemic in Philadelphia in 1793. At the height of the epidemic, the city was near chaos because of fear of the disease itself and because of the epidemic's interference with basic civic services and commerce.¹⁸ Dr. Rush was instrumental in controlling the hysteria and preserving public order.¹⁹ In

¹⁶ This may not have been enough, however. *See generally id.* for a discussion of whether modern medical science, transported to early 1800s America would have been significantly affected by the political response to the profession.

¹⁷ As argued by Milton Friedman, this is the ideal position because status and credibility is determined by personal actions and not by state fiat through the licensing process. *See* Michael H. LeRoy, et al., *The Law And Economics Of Collective Bargaining For Hospitals: An Empirical Public Policy Analysis Of Bargaining Unit Determinations*, 9 YALE J. ON REG. 1 (1992) (citing MILTON FRIEDMAN, CAPITALISM AND FREEDOM 149-60 (paperback ed. 1962). This is a very thoughtful article arguing that the courts have been much too willing to enforce restrictions on professional licenses.

Community infrastructure is critical to preventing deaths in epidemics. For example, when measles was introduced into the indigenous populations in the Americas, all members of the tribe would become ill at the same time because none of them had resistance from previous infection. Measles in individual cases that are properly nursed does not have a high fatality rate. However, when everyone is sick, no one can gather food or go for water,

retrospect, and even in the eyes of some of his contemporaries, the treatments provided by Dr. Rush clearly hastened many to the grave, some of whom might have survived without his ministrations. Yet his courage in the face of the epidemic, his willingness to go to the homes of the sick of all social classes, and his unshakable belief that the epidemic would pass, helped preserve public order and thus the provision of basic services, which clearly did save many lives and improve the lot of the afflicted and the healthy alike.20

Physicians such as Dr. Rush, who had great personal credibility, were deeply involved in colonial affairs and were relied upon to help guide the state's exercise of its police powers with regard to public health and safety. The state itself valued medical knowledge, as was evident in the Draconian measures that were taken to stem epidemics. For example, one of Paul Revere's children was infected during the smallpox epidemic of 1764. Under the public health ordinances, she would have had to be moved to the pesthouse, or the entire family would be quarantined. Out of concern for her well-being, he refused to allow her to be taken to the pesthouse.²¹ He and his family were confined in their house for the duration of the infection. During this period (over a month), a quarantine flag was hung in front of the house and a guard was posted to keep the Reveres in and others away from the house.²² That prominent citizens would submit to these restrictions is proof of their respect for medical opinion. These two factors respect for individual physicians, and respect for "proven" medical knowledge - prepared the state for later licensing efforts.

or provide for warmth if it is in the winter. Dehydration, starvation, and cold will dramatically increase the lethality of any serious illness. Colonial cities, even ones large for the time, were subject to the same forces. They did not have extensive food stores, water had to be carried in most homes and waste disposed of by hand. All commerce was very labor intensive. If the labor force became frightened by either disease or social disorder and fled, the remaining townspeople would be isolated and unable to care for themselves.

See Powell, supra note 5.

Doctor Rush was certainly not the only hero of the epidemic. The selflessness of Stephen Girard, the mayor at the time, was captured in case involving the disposition of this estate: "During his life he exhibited his philanthropy at a perilous moment. When the yellow fever burst upon Philadelphia in 1794, almost every one fled, regardless of his property. Girard walked the wards of hospitals, not subdued by the groans of the dying or deterred by the fear of death to himself. All that he had was freely given to alleviate the wretched sufferers. More charitable even than the good Samaritan, he had not only poured oil upon their wounds, but stood by them to the last." Vidal v. Girard's Ex'rs, 43 U.S. 127 (1844).

²¹ See Kirk v. Wyman, 83 S.C. 372, 65 S.E. 387, 388 (1909) (pesthouse described as "coarse and comfortless . . . adjoin[ing] the city dumping grounds").

B. The Shift to Regulation

In the post-Civil War period the states began to license physicians and institute regulations on the practice of medicine. While a detailed discussion of the politics behind this shift from *caveat emptor* to state regulation is beyond the scope of this article, ²³ there were several interrelated factors behind the change in legislative attitudes to physician licensing.

1. Advances in Medical Science

In hindsight, the most important development during this period was the triumph of medical science. Medicine in 1800 was not significantly different from medicine in Hippocrates' time. The theories had shifted and some of the remedies were different, but the underlying philosophy was still not scientific. By 1880, the foundation had been laid for modern medical science. More importantly, medical science had advanced to the point where medical treatments started to work and physicians became less dangerous to their patients. Jenner's discovery of the relationship of immunity to cowpox and smallpox prevention had been known at the beginning of the nineteenth century, but it was nearly fifty years later before the next significant discoveries. The first was anesthesia, discovered by Morton in 1846. This was a critical development because surgeries without anesthesia had to be brief and brutal, lest the patient die of shock from the pain and blood loss. This limited the types of procedures that could be carried out, and made it difficult to prevent complications such as internal bleeding from inadequately closed arteries and veins.

The second was the discovery that keeping wounds, surgical instruments, and physicians clean would dramatically reduce deaths due to infection. This was crucial to effective surgery. Although anesthesia improved surgical technique, most patients still died from post-operative infection. The pioneering work was done by Ignaz Semmelweis on childbed fever. He published his first findings in 1849, but was ridiculed as a fraud for attacking established medical practices. He published a book on antisepsis in 1861, then lapsed into madness and lived out his remaining few years in an asylum. His

 $^{^{\}rm 22}~$ Esther Forbes, Paul Revere and the World He Lived In 76-77 (1942).

²³ See Starr, supra note 15.

findings were taken up by Joseph Lister and formed the basis for a revolution in surgical practice starting in the late 1860s. Work by Pasteur during this time, and, later by Koch, elaborated the modern germ theory. Anesthesia and antisepsis, combined with the realization that germs formed the general mechanism of spread for infections diseases, shifted medicine from an enterprise that generally reduced the patient's chance of survival to one that could offer dramatically effective cures.

2. Public Policy and Professionalism

The modern debate on the regulation of the professions has tended to focus on the benefits to the profession of being regulated, and the dynamic of the regulators being captured by the regulated industry. This is a valid issue in medical licensing: physicians have benefited greatly from licensing; and they have certainly captured the licensing process, to the detriment of the public and, as will be discussed, themselves. These issues arise as licensing systems mature and become entrenched. Different factors operate in the initial development of a licensing system. This is especially true of medicine. Medicine is such a large and powerful industry today that it is very difficult to step back to the 1860s, when there were no powerful medical organizations and little public support for medical professionalism. During this period, legislators were concerned with improving the quality of medical care, assuring fair pricing for medical services, and achieving other societal goals, such as effective control of communicable diseases.²⁴

Once medical science began to offer effective treatments, it was in the interest of the public for physicians to be educated in these treatments and the underlying medical science. Such training would be time consuming and expensive, both for the physician and for the state, if it was done in public facilities. Economically, it only made sense for the physician to undertake such training if it would improve the physician's income to a point where educational debts could be paid and the lost revenue while in training amortized. If the entry cost into the profession were too low, and there were not effective ways to

²⁴ Ironically, this is a fair statement of current legislative interests, although the legislatures are only beginning to appreciate the resurgence of communicable diseases.

differentiate the trained physician from the quack, then medical training was not economically viable.²⁵ Even if an occasional individual of independent means was willing to pay for the training, this was not enough to made rigorous medical schools viable. Licensing based on education added this economic value to the education, making the development of medical schools possible.

Fair pricing and quality of care are inseparable because fair pricing deals both with the valuation of proper services and the prevention of fraud by charging for improper or ineffective services. While states did attempt to regulate physician's fees, most of the regulatory effects were directed at limiting the ability of unorthodox practitioners to charge for ineffective and dangerous treatments. This was done through direct prohibition of specific practices and through a circular process of defining the scope of licensure. State medical licensing laws avoid defining allowable medical practice in terms of specific procedures or methods of practice. Instead, the practice of medicine is defined in terms of the diagnosis and treatment of illness in the manner used by physicians who meet the training requirements for licensure. This effectively delegates the definition of appropriate medical practice to medical schools, residency programs, and their private accreditation agencies. Things that physicians do to diagnose and treat illness are limited to licensed physicians, unless they are permitted by state law to other licensed personnel such as chiropractors. As will be discussed later, the state has plenary power to define medical care and to determine the licensing requirements for providing that care.

Medical licensing serves other governmental interests that are more tangentially related to quality of individual patient care. While neglected by medical licensing boards because of their domination by physicians, an important function of licensing should be to assure that physicians fulfill their role in the public health system. Individual physicians see most of the cases of communicable diseases treated in the community. These physicians must comply with disease control reporting laws and must assist in the investigation of disease outbreaks. They should also be the primary vehicle for assuring universal

²⁵ Timing complicated the market differentiation problem. Forty years later, when the public generally accepted the importance of educated physicians, the economic investment in training would have been worthwhile even without licensing restrictions on entry into the profession. The problem was that this depended on the development of credible medical education, which was dependent on the indirect subsidy of license restrictions.

immunizations for immunization-preventable diseases. Unfortunately, state licensing boards have not used their power to assure that these functions are adequately carried out. A more complicated issue is the use of medical licensing to enforce political, as opposed to scientific, decisions about what constitutes proper medical care. The classic examples are abortion laws and narcotics laws.²⁶ These are discussed separately because they illustrate the only important restrictions on the police power to regulate medical practice.

3. Constitutionality of Initial Licensing Laws

When states began to pass licensing laws they had to decide what to do about the physicians who were already in practice. This issue is common to all new regulations. When the group being regulated is large, important to society, and powerful, it is politically impossible to use new regulatory law to disqualify any substantial fraction of the existing industry.²⁷ Each state reached its own mix of prospective licensure requirements and retroactive qualifications that persons already practicing medicine had to meet. Disqualified practitioners attacked these laws as being unconstitutional *ex post facto* laws, as taking their property without due process and compensation, and as denying them equal protection.

a. Ex Post Facto Laws

²⁶ The federal and state laws grossly misuse the term narcotic to refer to almost any pharmaceutical that is regulated because of its neuropharmacologic effect. The traditional scientific usage was limited to compounds that were derived from the opium poppy, most commonly morphine, heroin, and codeine. This was then extended to synthetic compounds based on the morphine structure or affecting the same receptors, such as fentanyl.

²⁷ In a more modern medical context, Congress passed the Medical Device Amendments of 1976 to give the FDA the power to assure the safety and effectiveness of medical devices. Despite the legislative history showing grave safety problems in the medical devices industry, the law both grandfathered in most existing devices, and allowed new devices to enter the market with little FDA review if they were equivalent to devices on the market in 1976. *See* Medtronic, Inc. v. Lohr, 518 U.S. 470, 476, 116 S.Ct. 2240, 2245-56, (1996).

The first issue raised when a state passes a new law prohibiting conduct that had previously been unregulated is whether it is an ex post facto law. The Constitution provides, "No Bill of Attainder or ex post facto Law shall be passed."²⁸ The reach of this provision was quickly challenged after the adoption of the Constitution and was reviewed by the United States Supreme Court in the 1798 case of Calder v. *Bull.*²⁹ Justice Chase found that:

> The prohibition, in the letter, is not to pass any law concerning, and after the fact: but the plain and obvious meaning and intention of the prohibition is this; that the Legislatures of the several states, shall not pass laws, after a fact done by a subject, or citizen, which shall have relation to such fact, and shall punish him for having done it. The prohibition considered in this light, is an additional bulwark in favour of the personal security of the subject, to protect his person from punishment by legislative acts, having a retrospective operation. I do not think it was inserted to secure the citizen in his private rights, of either property, or contracts.³⁰

Licensing laws do contain provisions to punish the unauthorized practice of medicine. These are not retrospective, however, but only punish practices that occur after the effective date of the licensing law. Thus, they would not seem to implicate the Constitutional prohibition on ex post facto laws as construed by Justice Chase. The issue did not reach the United States Supreme Court with regard to medical licensing until 1898, when the Court decided Hawker v. People of New York.³¹ In 1878, Hawker was convicted of performing an abortion and sentenced to ten years in the penitentiary. After completing his sentence, he resumed the practice of medicine in New York. In 1893, New York passed a law making it a crime to practice medicine after being convicted of a felony.³² Hawker continued to practice medicine and was indicted and convicted and ordered to pay a fine. Since this was clearly a criminal statute, it met the first prong of Justice Chase's test for an ex post facto law. Defendant argued that it met the second prong as well by increasing the punishment for a crime after he had committed the crime and been

²⁸ U.S. CONST. art. I, § 9, cl. 3. (emphasis added).

²⁹ Calder v. Bull, 3 U.S. 386 (1798).

³⁰ *Id.* at 390.

³¹ Hawker v. N.Y., 170 U.S. 189, 18 S.Ct. 573, (1898).

³² "Section 153. Any person who... after conviction of a felony, shall attempt to practice medicine, or shall so practice... shall be guilty of a misdemeanor, and on conviction thereof shall be punished by a fine of not more than two hundred and fifty dollars, or imprisonment for six months for the first offense, and on conviction of any

punished for it. The United States Supreme Court disagreed, finding that assuring the good character of physicians was within the state's police power:

No precise limits have been placed upon the police power of a state, and yet it is clear that legislation which simply defines the qualifications of one who attempts to practice medicine is a proper exercise of that power. Care for the public health is something confessedly belonging to the domain of that power. The physician is one whose relations to life and health are of the most intimate character. It is fitting, not merely that he should possess a knowledge of diseases and their remedies, but also that he should be one who may safely be trusted to apply those remedies. Character is as important a qualification as knowledge, and if the legislature may properly require a definite course of instruction, or a certain examination as to learning, it may with equal propriety prescribe what evidence of good character shall be furnished.³³

The Court found that physicians, perhaps more than any other state regulated profession, are directly involved with matters of both personal and public health, thus justifying very intrusive regulation. Thus the Court found that defendant was denied the right to continue to practice medicine to protect the public, not as an additional punishment. The defendant's conviction and sentence were based on his failing to obey the new public health law, a new violation that would justify punishment under the criminal laws. He was not being additionally punished for his original crime of performing an abortion.³⁴ Key to the Court's opinion is the special status of medical practice and physicians. This reiterates the theme from earlier cases contesting licensing actions as depriving physicians of a property right without due process or compensation.

b. Is There a Property Right to Practice Medicine? - The Dent Case

Most of the challenges to medical licensing laws and disciplinary actions taken under them are predicated on the assumption that the right to practice a profession is a quasi-property right, and as such

subsequent offense, by a fine of not more than five hundred dollars, or imprisonment for not less than one year, or by both fine and imprisonment." *Id.* at 190.

³³ *Id.* at 192-94.

This same public safety analysis was used by the court to uphold a law that provided for indefinite detention of sexually dangerous persons after they had served their sentence and were about to be released from prison. *See* Kansas v. Hendricks, 521 U.S. 346, 117 S.Ct. 2072 (1997).

cannot be infringed without due process and compensation.³⁵ The Slaughter-House Cases³⁶ are the first important post-Fourteenth Amendment review of occupational licensing under the police power. Louisiana passed a law creating a corporation with the exclusive franchise to run slaughter-houses in New Orleans and surrounding areas, covering an area of 1,154 square miles. The butchers and others with affected businesses in the franchise area, more than 1,000 persons, brought suit, claiming that they had been deprived of property - their right to conduct their businesses - without due process and compensation. While recognizing the validity of the complaint that their businesses would be rendered worthless by this act, the United States Supreme Court found that it was within the state's police power, and that this police power function had not been modified by the Fourteenth Amendment.³⁷ This was affirmed and expanded in subsequent cases, 38 subject to the caveat that the regulations be proper measures to protect the public health, and not shams that used public health rhetoric to justify improper discriminatory regulations.³⁹

The United States Supreme Court addressed medical licensing directly in Dent v. State of West Virginia. 40 The West Virginia law provided three ways to become licensed: (1) graduate from a "a reputable medical college in the school of medicine to which the person desiring to practice belongs;"41 (2) practice "medicine in this state continuously for the period of ten years prior to the 8th day of March,

³⁵ Interestingly, because the states did not begin serious licensing efforts until after the Civil War, we have no relevant cases before the Thirteenth and Fourteenth Amendments. Given the courts' broad deference to the states on licensing physicians in the face of these amendments, their passage clearly had little impact on the police power. See Barbier v. Connolly, 113 U.S. 27 (1885).

³⁶ See Slaughter-House Cases, 83 U.S. 36 (1872).
37 "The argument has not been much pressed in these cases that the defendant's charter deprives the plaintiffs of their property without due process of law, or that it denies to them the equal protection of the law. The first of these paragraphs has been in the Constitution since the adoption of the Fifth Amendment, as a restraint upon the Federal power. It is also to be found in some form of expression in the constitutions of nearly all the States, as a restraint upon the power of the States. This law then, has practically been the same as it now is during the existence of the government, except so far as the present amendment may place the restraining power over the States in this matter in the hands of the federal government. "We are not without judicial interpretation, therefore, both State and National, of the meaning of this clause. And it is sufficient to say that under no construction of that provision that we have ever seen, or any that we deem admissible, can the restraint imposed by the State of Louisiana upon the exercise of their trade by the butchers of New Orleans be held to be a deprivation of property within the meaning of that provision." Id. at 80-81.

 ³⁸ See generally Mugler v. Kansas, 123 U.S. 623, 8 S.Ct. 273 (1887).
 39 See Yick Wo v. Hopkins, 118 U.S. 356, 6 S.Ct. 1064 (1886).

⁴⁰ Dent v. West Va., 129 U.S. 114, 9 S.Ct. 231 (1889).

one thousand eight hundred and eighty-one;" or (3) pass an examination by members of the state board of health. Persons who continued to practice medicine without fulfilling one of these requirements "Yshall be guilty of a misdemeanor, and fined for every such offense not less than fifty nor more than five hundred dollars, or imprisoned in the county jail not less than one month nor more than twelve months, or be punished by both such fine and imprisonment, at the discretion of the court." Defendant Dent had been practicing since 1876 and had a diploma from the American Medical Eclectic College of Cincinnati, Ohio. After reviewing this diploma, the members of the board of health found that it was not from a "reputable" medical college as intended by the statute. Defendant was indicted and convicted under the statute, ordered to pay fifty dollars, plus court costs, and, it is assumed, enjoined from continuing to practice medicine. Defendant appealed to the United States Supreme Court from an adverse judgment in the state supreme court, claiming that he had been denied his property right in his profession without due process of law and due compensation.

The balancing between the property right claim of the defendant and the state's right to regulate under the police powers is best seen in the United States Supreme Court's own words in *Dent*. This statement of the constitutional limits on state licensing of physicians has not been modified by subsequent decisions.⁴⁵ The court begins its analysis with a statement of the traditional view of the right to practice a profession or a trade as a property interest:

It is undoubtedly the right of every citizen of the United States to follow any lawful calling, business, or profession he may choose, subject only to such restrictions as are imposed upon all persons of like age, sex, and condition. This right may in many respects be considered as a distinguishing feature of our republican institutions. Here all vocations are

⁴¹ Id. at 231.

⁴² *Id.* at 232.

⁴³ See id.

⁴⁴ *Id*.

⁴⁵ "In a line of earlier cases, this Court has indicated that the liberty component of the Fourteenth Amendment's Due Process Clause includes some generalized due process right to choose one's field of private employment, but a right which is nevertheless subject to reasonable government regulation. *See, e.g.*, Dent v. West Va., 129 U.S. 114, 9 S.Ct. 231, (1889) (upholding a requirement of licensing before a person can practice medicine); Truax v. Raich, 239 U.S. 33, 41, 36 S.Ct. 7, (1915) (invalidating on equal protection grounds a state law requiring companies to employ 80 percent United States citizens). These cases all deal with a complete prohibition of the right to engage in a calling, and not the sort of brief interruption which occurred here." Conn v. Gabbert ____U.S. ___, 119 S.Ct. 1292, 1295 (1999).

open to every one on like conditions. All may be pursued as sources of livelihood, some requiring years of study and great learning for their successful prosecution. The interest, or, as it is sometimes termed, the 'estate,' acquired in them--that is, the right to continue their prosecution--is often of great value to the possessors, and cannot be arbitrarily taken from them, any more than their real or personal property can be thus taken.

But there is no arbitrary deprivation of such right where its exercise is not permitted because of a failure to comply with conditions imposed by the state for the protection of society. The power of the state to provide for the general welfare of its people authorizes it to prescribe all such regulations as in its judgment will secure or tend to secure them against the consequences of ignorance and incapacity, as well as of deception and fraud. As one means to this end it has been the practice of different states, from time immemorial, 46 to exact in many pursuits a certain degree of skill and learning upon which the community may confidently rely; their possession being generally ascertained upon an examination of parties by competent persons, or inferred from a certificate to them in the form of a diploma or license from an institution established for instruction on the subjects, scientific and otherwise, with which such pursuits have to deal. The nature and extent of the qualifications required must depend primarily upon the judgment of the state as to their necessity. If they are appropriate to the calling or profession, and attainable by reasonable study or application, no objection to their validity can be raised because of their stringency or difficulty. It is only when they have no relation to such calling or profession, or are unattainable by such reasonable study and application, that they can operate to deprive one of his right to pursue a lawful vocation.

Few professions require more careful preparation by one who seeks to enter it than that of medicine. It has to deal with all those subtle and mysterious influences upon which health and life depend, and requires not only a knowledge of the properties of vegetable and mineral substances, but of the human body in all its complicated parts, and their relation to each other, as well as their influence upon the mind. The physician must be able to detect readily the presence of disease, and prescribe appropriate remedies for its removal. Every one may have occasion to consult him, but comparatively few can judge of the qualifications of learning and skill which he possesses. Reliance must be placed upon the assurance given by his license, issued by an authority competent to judge in that respect, that he possesses the requisite qualifications. Due consideration, therefore, for the protection of society may well induce the state to exclude from practice those who have not such a license, or who are found upon examination not to be fully qualified. The same reasons which control in imposing conditions, upon compliance with which the physician is allowed to practice in the first instance, may call for further conditions as new modes of treating disease are discovered, or a more thorough acquaintance is obtained of the

⁴⁶ It is interesting that the court uses the "time immemorial" language in the context of medical licensing, which was only newly adopted by the states.

remedial properties of vegetable and mineral substances, or a more accurate knowledge is acquired of the human system and of the agencies by which it is affected. It would not be deemed a matter for serious discussion that a knowledge of the new acquisitions of the profession, as it from time to time advances in its attainments for the relief of the sick and suffering, should be required for continuance in its practice, but for the earnestness with which the plaintiff in error insists that by being compelled to obtain the certificate required, and prevented from continuing in his practice without it, he is deprived of his right and estate in his profession without due process of law. We perceive nothing in the statute which indicates an intention of the legislature to deprive one of any of his rights.⁴⁷

Dent is emblematic of the deference the United States Supreme Court accords state medical licensing laws. 48 As reviewed below, state court decisions accord with this, finding few real impediments to state regulatory action. Dent and its progeny left the states wide discretion in the content and enforcement of medical licensing laws, subject to state constitutional law protections and the political power of the regulated groups. Cases like Dent, which dealt with initial access to the profession, raised only limited due process issues because they involved just comparing the candidate's credentials to the state standards. Even when, as in *Dent*, there was an element of judgment about whether the practitioner's medical school was credible, that was seen to be totally within the board's discretion and provided no grounds for review. 49 A licensed physician is entitled to more extensive due process protections if the licensing board decides to suspend, revoke, or not renew the physician's license. 50 The extent of this process is determined by state administrative procedure acts, subject, of course, to the constitutional limitations on a state actor.⁵¹ A physician who is improperly sanctioned by a state licensing board may be

47 See Dent, 129 U.S. 121-23.

⁴⁸ See Missouri ex rel. Hurwitz v. North, 271 U.S. 40 (1926); Graves v. Minnesota, 272 U.S. 425 (1926);

Barsky v. Board of Regents of Univ. of N.Y., 347 U.S. 442 (1954).

State *ex rel.* Powell v. State Med. Examining Bd., 32 Minn. 324, 20 N.W. 238, 50 Am. Rep. 575 (Minn., 1884); State ex rel. Chapman v. State Bd. of Med. Exam'rs, 34 Minn. 387, 26 N.W. 123 (Minn., 1885).

⁵⁰ These rights may be very limited if the revocation is based on a clear violation of a condition of licensure, such as being convicted of a felony. See Cooper v. State Bd. of Med. Exam'rs, 489 S.W. 2d 129 (Tex. Civ. App. El Paso, 1972).

For example, the board may not condition licensure on providing information that is otherwise constitutionally protected from disclosure by the Fifth Amendment: See Hirsch v. State Bd. of Med. Exam'rs, 252 N.J. Super. 596, 600 A.2d 493 (N.J. Super. A.D., 1991). The board must also not engage in entrapment: See Patty v. Bd. of Med. Exam'rs, 9 Cal. 3d 356, 508 P.2d 1121, 107 Cal. Rptr. 473, 61 A.L.R.3d 342 (Cal., 1973). See generally Lind v. Med. Licensing Bd., 427 N.E.2d 671 (Ind. Ct. App., 1981).

entitled to injunctive relief, but there is little chance of recovering damages from either the state or the members of the board.⁵²

c. Defining and Limiting the Practice of Medicine

Implicit in the state's power to require an individual to obtain a license to practice medicine is the power to determine the scope of the license and to establish conduct that may not be performed by licensed physicians. Historically, the most controversial laws restricting the physicians' scope of practice regulated narcotics and abortions. The United States Supreme Court first ruled on state narcotics law restrictions on physicians in Minnesota *ex rel. Whipple v. Martinson*, hick concerned the appeal of a physician convicted under a state law making it illegal to dispense narcotics directly to an addict. The intent of the state law was to force addicts to get their drugs by a written prescription so that there would be a documented record of their drug use. Defendant physician was convicted of supplying an addict directly from the physician's office stock of narcotics. The defendant appealed, arguing that the Fourteenth Amendment prohibited the licensing agency from regulating defendant's business as provided for in the statute, and that the state law was in conflict with the Harrison Anti-Narcotic Drug Act.55 The United States Supreme Court upheld the conviction, finding that:

There can be no question of the authority of the state in the exercise of its police power to regulate the administration, sale, prescription and use of dangerous and habit-forming drugs, such as are named in the statute. The right to exercise this power is so manifest in the interest of the public health and welfare, that it is unnecessary to enter upon a discussion of it beyond saying that it is too firmly established to be successfully called in question. ⁵⁶

⁵² "...[T]he risk of an unconstitutional act by one presiding at an agency hearing is clearly outweighed by the importance of preserving the independent judgment of these men and women. We therefore hold that persons subject to these restraints and performing adjudicatory functions within a federal agency are entitled to absolute immunity from damages liability for their judicial acts." Butz v. Economou, 438 U.S. 478, 514, 98 S.Ct. 2894, 2915 (1978). *See also* Bradley v. Fisher, 80 U.S. 335 (Mem), 13 Wall., (1872); and Watts v. Burkhart, 978 F.2d 269 (6th Cir. 1992), (overruling Manion v. Michigan Bd. of Med., 765 F.2d 590 (6th Cir. 1985)).

⁵³ Minnesota ex rel. Whipple v. Martinson, 256 U.S. 41, 41 S.Ct. 425, (U.S. Minn., 1921).

same, any of the substances enumerated in section 1 of this act: Provided that the provisions of this section shall not be construed to prevent any legally licensed physician from prescribing in good faith, for the use of any patient under his care, for the treatment of a drug habit, such substances as he may deem necessary for such treatment; provided that such prescriptions are given in good faith for the treatment of such habit." *Id.* at 44.

⁵⁵ Insert Cite Here
56 Id. at 45.

This ruling was reaffirmed in *Robinson v. California*, ⁵⁷ a decision that otherwise limited the state's ability to punish a person for the status of being an addict. Given the financial temptations to provide narcotics and other psychoactive drugs to addicts, many physicians have lost their licenses and even been jailed for violating the terms of the controlled substances laws. ⁵⁸ The United States Supreme Court approved the combination of traditional public health reporting duties with the controlled substances laws in *Whalen v. Roe.* ⁵⁹ *Whalen* was a challenge by physicians and patients to a New York law that required the reporting of all prescriptions for Schedule II drugs ⁶⁰ to a central state agency. This agency could then check the prescriptions to detect improper prescribing practices, forged prescriptions, pharmacies that were dispensing unusual amounts of Schedule II drugs, and patients that were filling prescriptions from multiple physicians. The physicians and patients argued that the law invaded the patient's privacy, deterred them from receiving proper medication because of their fears of being reported to the state, and improperly interfered with the physician's right to practice medicine. These claims were predicated largely on the holdings in the contraceptive and abortion cases, the sole area where the courts have found significant constitutional limitations on the state's right to regulate medical practice. The court rejected this comparison, finding that physician reporting was a valid public health function that did

⁵⁷ Robinson v. California, 370 U.S. 660, 82 S.Ct. 1417 (1962).

⁵⁸ See Application of Palmer, 275 A.D. 5, 87 N.Y.S.2d 655 (N.Y.A.D. 3 Dept., 1949); Stolz v. Board of Regents of Univ. of State of N.Y., 4 A.D.2d 361, 165 N.Y.S.2d 179 (N.Y.A.D. 3 Dept., 1957); Ray v. Board of Regents of Univ. of State of N.Y., 9 A.D.2d 560, 189 N.Y.S.2d 299 (N.Y.A.D. 3 Dept., 1959); Leonard v. State, 172 Tex. Crim. 394, 356 S.W.2d 926 (Tex. Crim. App., 1962); Thorpe v. Board of Exam'rs, 104 Cal. App. 3d 111, 163 Cal. Rptr. 382, 8 A.L.R. 4th 216 (Cal. App. 4 Dist., 1980); Arlen v. State, 61 Ohio St.2d 168, 399 N.E.2d 1251, 15 O.O. 3d 190 (Ohio, 1980); Lind v. Med. Licensing Bd., 427 N.E.2d 671 (Ind. Ct. App., 1981).; Horvat v. Commonwealth Dept. of State Professional and Occupational Affairs, 128 Pa. Cmmw., 546, 563 A.2d 1308 (Pa. Cmmw., 1989); and Denier v. State Bd. of Med., Bureau of Professional and Occupational Affairs, 683 A.2d 949 (Pa. Cmmw., 1996).

⁵⁹ Whalen v. Roe, 429 U.S. 589, 97 S.Ct. 869 (1977).

⁶⁰ The New York law used the classification from the federal controlled substances laws, which is based on five schedules. Schedule I covers drugs, such as heroin, that are prohibited for clinical use in the United States because of their high potential for abuse. Schedule II covers drugs that have a high potential for abuse, such as morphine, but that are used clinically in the United States.

not pose an unconstitutional burden on the patient's right to privacy, ⁶¹ and later extending this holding to include reporting of abortion-related information. ⁶²

The abortion and contraception cases, while creating broad rights of privacy for patients, create only very limited rights for physicians. From the perspective of the police power to regulate medical practice, physicians are only bystanders in these cases. Beginning with Griswold v. Connecticut, 63 the courts have first had to wrestle with whether physicians have standing in these cases at all, despite the substantive reality that the physician is being prosecuted for a crime based on the law. Griswold held that the physicians had standing to assert the rights of their patients to challenge the Connecticut law because of the special relationship between them and their patients.⁶⁴ In essence, the court found that the physicians had standing because the state was using them as the mechanism for forbidding the dissemination of the information about contraception. While the court in Griswold did not elaborate on this analysis, it underlies the decisions in the later abortion cases as they apply to physicians. The key to this approach is recognizing the unspoken assumption that physicians are involved because the state has restricted the provision of these particular medical services to physicians. For example, assume that Connecticut had allowed pharmacists to provide contraceptive information and to prescribe and fit contraceptives, while still making it illegal for physicians to do so. In this situation the patient's right to privacy would not have been invaded and thus the physician would have not had any standing to contest his conviction under the law.65

This analysis carries through the subsequent abortion cases, in that physicians are only able to assert standing and the physician-patient relationship is only protected to the extent that the state has decreed that abortions be done or supervised by physicians. Since no state has prohibited physicians from

⁶¹ See Whalen, 429 U.S. at 600.

⁶² See Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 884, 112 S.Ct. 2791 (1992).

⁶³ Griswold v. Connecticut, 381 U.S. 479, 85 S.Ct. 1678 (1965).

 $^{^{64}}$ "The rights of husband and wife, pressed here, are likely to be diluted or adversely affected unless those rights are considered in a suit involving those who have this kind of confidential relation to them." *Id.* at 481.

There are circumstances where physicians have been sanctioned by license revocation for providing medical services that might legally have been provided by a non-physician. *See In re Guess*, 393 S.E. 2d. 833, 327

performing abortions while allowing them to be performed by another group, perhaps nurses, it is impossible to determine if there is any constitutional right to have a physician-performed abortion, as opposed to a right to an abortion.⁶⁶ In Roe v. Wade, the court found that the physician did not have standing at all in the case, even though it was the appeal of a state law providing for criminal prosecution of physicians and others who performed abortions.⁶⁷ Thus the state's right to regulate medical practice is only limited when it uses that right to impermissibly interfere with the constitutional rights of patients. Subject to this limitation, physicians have no constitutionally protected sphere of practice that is not subject to state regulation. Planned Parenthood of Southeastern Pennsylvania v. Casey⁶⁸ emphasized this distinction between patient and physician rights by preserving basic patient's rights established in Roe, but allowing the state to regulate the physicians providing the abortions in the same way that they could have regulated them in providing other medical treatments.⁶⁹ This right to regulate medical practice was strengthened in the recent cases upholding the state police power to regulate medical practice by banning physician-assisted suicide. 70 Interestingly, these cases hinted that there might be a constitutional right to adequate pain relief, which would be the first significant limitation on the state's right to limit access to drugs through controlled substance laws and physician licensing restrictions.⁷¹

N.C. 46 (N.C. 1990), which upheld the revocation of a physician's license for practicing homeopathic medicine, regardless of whether the state could show that homeopathic medicine posed a threat to the patient's health.

⁶⁶ Such a right to a physician-performed abortion might arise if the state could be shown to be trying to interfere with the right of access to abortions by who it designated to perform them. For example, if the state limited abortions to lay abortion providers and there was evidence that such providers substantially increased the risk of complications.

The court found that the physician could assert any constitutional defenses arising from its decision during his pending state criminal law prosecutions. Roe v. Wade, 410 U.S. 113, 127 S.Ct. (1973).

Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833 S.Ct. (1992).

⁶⁹ This is clear from the court's own analogy: "We also see no reason why the State may not require doctors to inform a woman seeking an abortion of the availability of materials relating to the consequences to the fetus, even when those consequences have no direct relation to her health. An example illustrates the point. We would think it constitutional for the State to require that in order for there to be informed consent to a kidney transplant operation the recipient must be supplied with information about risks to the donor as well as risks to himself or herself." Id. at 882-83. See also Rust v. Sullivan, 500 U.S. 173, 111 S.Ct. 1759 (1991).

⁶ See Washington v. Glucksberg, 521 U.S. 702, 117 S.Ct. 2302 (1997) and Vacco v. Quill, 521 U.S. 793, 117 S.Ct. 2293 (1997).

[&]quot;The parties and *amici* agree that in these States a patient who is suffering from a terminal illness and who is experiencing great pain has no legal barriers to obtaining medication, from qualified physicians, to alleviate that suffering, even to the point of causing unconsciousness and hastening death. See WASH. REV. CODE § 70.122.010 (1994); Brief for Petitioners in No. 95-1858, p. 15, n. 9; Brief for Respondents in No. 95-1858, p. 15. In this light, even assuming that we would recognize such an interest, I agree that the State's interests in protecting

II. REGULATING MEDICAL PRACTICE IN MCOS

The central regulatory issue for MCOs is that they are generally exempt from the states' existing system of regulating insurance because of the Employee Retirement Income Security Act ("ERISA").

ERISA was passed to regularize the administration of pension plans and to protect their assets from improper or improvident management. The ERISA provisions dealing with health insurance were passed by Congress to allow large multi-state companies such as automobile manufacturers to sign uniform labor agreements across all state lines. Prior to ERISA, a multi-state employer could not offer the same health insurance plan to all employees because of differences in state laws regulating insurance. Even if the terms of the plan could be worked out, there was a substantial administrative cost in getting the plans approved in fifty different states, and assuring continuing compliance as the state laws changed over time. ERISA provides that health insurance plans that meet certain organizational requirements are exempt from most state regulation. Most private employer health plans meet this standard. Since there is little federal regulation of private health insurance, this means that ERISA plans are essentially unregulated. The insulation from state regulation gives ERISA plans a competitive advantage, so they have displaced non-ERISA plans for most employers.

A. ERISA Preemption and State Regulation

ERISA plans differ from traditional insurance policies because the employer usually retains some or all of the risk of insurance and pays the insurer for administration of the benefits rather than for a guaranteed rate for the year. The care is provided by either an MCO controlled by the plan administrator, an MCO, or individual physicians and clinics contracting directly with the plan administrator. Since the employer is less insulated from the costs than in traditional plans, there is more pressure to keep costs down during the term of the plan. If there are unexpected costs, they are passed on to the employer,

those who are not truly competent or facing imminent death, or those whose decisions to hasten death would not truly be voluntary, are sufficiently weighty to justify a prohibition against physician-assisted suicide." *Glucksberg*, 521 U.S. at 2303 (O'Connor, J. concurring).

⁷² This discussion of ERISA adapted from Edward P. Richards and Katharine C. Rathbun, MEDICAL CARE LAW, (Aspen 1999).

which puts pressure on the employer to limit coverage for expensive procedures and conditions. Under ERISA, employers are free to limit the benefits provided by their health plans, subject to certain Americans with Disabilities Act limitations.⁷⁴ As a result, some plans provide inadequate coverage for medically necessary conditions.

ERISA plans are also insulated from medical malpractice lawsuits in most circumstances. The text of ERISA does not mention medical malpractice lawsuits and there was no discussion of them in the Congressional hearings preceding the adoption of ERISA. Nonetheless, the broad language of ERISA that exempts it from state regulation has been construed by the courts to prevent state tort lawsuits against ERISA plans. In most cases where a denial of benefits is challenged because the plan claimed they were excluded under the contract, courts find the claims to be preempted. The courts have also limited direct actions against the plans for medical malpractice, except for traditional vicarious liability for physician employees. Since most plans do not employ physicians directly, this provides limited relief for plaintiffs. ERISA does not affect the physician=s liability for medical malpractice, so the physician is left as the target defendant when the plaintiff=s case against the plan is dismissed. This encourages ERISA MCOs to use benefits administration systems that create incentives for physicians to breach their fiduciary duty to their patients by denying them medically necessary treatments, even when those treatments are covered by the health plan.

The clearest conflicts between the demands of MCOs and the physician=s fiduciary duty to the patient arise from the "gag" rules, which are MCO contract provisions intended to prevent physicians from telling patients medically significant information, or from indicating that the plan might not be treating the patient fairly. A typical clause reads as follows:

⁷³ ERISA plans account for about fifty percent of insured lives, with most of the rest being covered by governmental employee health insurance or Medicare and Medicaid.

 ⁷⁴ See Ford v. Schering-Plough Corp., 145 F.3d 601, 604-05 (3d Cir.1998), cert. denied, U.S.
 119 S.Ct. 850 (1999); Castellano v. NewYork, 142 F.3d 58, 67 (2d Cir. 1998); Lewis v. Aetna Life Ins. Co., 982 F. Supp. 1158, 1160-61 (E.D. Va. 1996).

⁷⁵ See Metro. Life Ins. Co. v. Taylor, 481 U.S. 58, 107 S.Ct. 1542 (1987).

⁷⁶ See Katz v. Colonial Life Ins. Co. of Am., 951 F. Supp. 36 (S.D.N.Y. 1997).

Physician shall agree not to take any action or make any communication which undermines or could undermine the confidence of enrollees, potential enrollees, their employers, their unions, or the public in U.S. Healthcare or the quality of U.S. Healthcare coverage. Physician shall keep the Proprietary Information payment rates, utilization-review procedures, etc. and this Agreement strictly confidential.⁷⁷

Even when the plans do not have formal "gag" rules, the physicians are discouraged from discussing financial incentives with the patients. This is enforced by sanctions for not being a team player, or other criteria that are based on furthering the plan's interests. More fundamentally, the physicians have an economic stake in not making the patients aware of necessary treatments because the physicians are evaluated on the cost of care for their patients. If physicians help patients get all the care they are entitled to under the plan, the physicians will be penalized by the plan and eventually deselected, or – fired, by the plan.⁷⁸ The results of such policies are demonstrated by some of the cases that have been brought by plaintiffs attempting to defeat ERISA preemption so they can get compensation from the plans.

In the *Lancaster v. Kaiser Foundation* case, ⁷⁹ the court reviewed the legality of hidden MCO provisions in a Kaiser health plan that provided financial incentives for physicians to deny patients care. In 1991, an eleven-year-old child was taken to the physician complaining of nausea and severe daily headaches on the right side of her head. She was examined, but no diagnostic tests were performed. The physician prescribed adult strength narcotic painkillers. Her condition did not resolve and she continued to see the physician through 1995. During this time, the prescriptions were continued but the primary care physician never consulted with a neurologist. In 1996, the school psychologist, alarmed at the child=s "intense, localized headaches, vomiting, and blood-shot eyes," persuaded the parents to demand that the child receive a proper neurologic workup and diagnostic testing. The child was found to have a

⁷⁷ Seffie Woolhandler & David U. Himmelstein, *Extreme RiskCThe New Corporate Proposition for Physicians*, 333 New Eng. J. Med. 1706, 1706 (Dec. 21, 1995).

⁷⁸ Brian A. Liang, Deselection Under Harper v. Healthsource: A Blow for Maintaining Patient-Physician Relationships in the Era of Managed Care, 72 N.D. L. REV. 799 (1997).

⁷⁹ See Lancaster v. Kaiser Found. Health Plan, 958 F. Supp. 1137 (E.D. Va. 1997).

brain tumor that had displaced forty percent of her brain. After extensive surgeries, she still had substantial impairment and the prospect of more surgery in the future.

It appeared, under the facts of this case, that this systematic malpractice was financially motivated because there was evidence that throughout the nearly five-year period the defendant physicians treated the patient, Kaiser and the Medical Group had in place a financial incentive program that paid physicians bonuses for avoiding excessive treatments and tests. This same type of incentive was present in *Shea v*. *Esensten*. ⁸⁰ The court's summary of Mr. Shea's medical care is poignant:

After being hospitalized for severe chest pains during an overseas business trip, Patrick Shea made several visits to his long-time family doctor. During these visits, Mr. Shea discussed his extensive family history of heart disease, and indicated he was suffering from chest pains, shortness of breath, muscle tingling, and dizziness. Despite all the warning signs, Mr. Shea's doctor said a referral to a cardiologist was unnecessary. When Mr. Shea's symptoms did not improve, he offered to pay for the cardiologist himself. At that point, Mr. Shea's doctor persuaded Mr. Shea, who was then forty years old, that he was too young and did not have enough symptoms to justify a visit to a cardiologist. A few months later, Mr. Shea died of a heart attack.

These claims are typical of the cases brought against MCOs. They are, at their core, medical malpractice cases because the physicians delivered substandard care. Irrespective of ERISA preemption, the plaintiffs can prevail in traditional medical malpractice litigation against the physicians. They are also not fundamentally different from some cases that occurred under traditional fee-for-service medicine, in that there have always been physicians who put their own financial interests above the well-being of their patients. The result was usually over-treatment, rather than under-treatment, but that can be just as deadly to the patient. Most critically, the physicians are the same; MCOs either bought existing practices or recruited their physicians from these practices. The vast majority of MCO physicians were fee-for-service physicians ten years ago. Yet, while fee-for-service certainly had problems, it did not generate the public concern, and calls for state regulation, that MCOs have engendered. While some of the concern

⁸⁰ See Shea v. Esensten, 107 F.3d 625 (8th Cir. 1997).

⁸¹ *Id.* at 626.

about MCOs is displaced from general anxiety about rising health care costs, MCOs do pose unique problems that demand new regulatory responses.

B. Checks and Balances in MCOs

Traditional fee-for-service medicine, paid for with indemnity insurance plans that paid for all care that the patient's physician deemed medically necessary, had several checks and balances that operated to protect the quality of patient care. These have been eliminated by MCOs.

1. Physician Independence –

Physicians were traditionally independent decision makers, operating for their own self-interest, either as sole proprietors or in small partnerships. This style of business organization was driven by state bars on the corporate practice of medicine. Arising in cases decided in the 1920s and 1930s, they were based on conflict of interest doctrines developed for legal practice. Corporate practice of medicine bars prevented physicians from working for non-physicians who would then profit from the physician's work. While this did prevent some abuses, it did not protect patients from individual greedy physicians who

⁸² See Mars, The Corporate Practice Of Medicine: A Call For Action; 7 HEALTH MATRIX 241 (1997); Chase-Lubitz, The Corporate Practice of Medicine Doctrine: An Anachronism in the Modern Health Care Industry, 40 VAND, L. REV. 445 (1987); St. Francis Reg'l Med. Ctr. v. Weiss, 869 P.2d 606, 254 Kan. 728 (Kan. 1994); Sampson v. Baptist Mem. Hosp. Sys., 940 S.W. 2d 128 (Tex. App. 1996).

⁸³ See People v. Merchants' Protective Corp., 209 P. 363, 189 Cal. 531 (Cal. 1922); Dr. Allison, Dentist, Inc. v. Allison, 196 N.E. 799, 360 Ill. 638 (Ill. 1935); Parker v. Board of Dental Exam'rs, 14 P. 2d 67, 216 Cal. 285 (Cal. 1932); People v. United Med. Serv., Inc., 200 N.E. 157, 362 Ill. 442 (Ill. 1936).

[&]quot;The relation of attorney and client is that of master and servant in a limited and dignified sense, and it involves the highest trust and confidence. It cannot be delegated without consent and it cannot exist between an attorney employed by a corporation to practice law for it, and a client of the corporation, for he would be subject to the directions of the corporation and not to the directions of the client. There would be neither contract nor privity between him and the client, and he would not owe even the duty of counsel to the actual litigant. The corporation would control the litigation, the money earned would belong to the corporation and the attorney would be responsible to the corporation only. His master would not be the client but the corporation, conducted it may be wholly by laymen, organized simply to make money and not to aid in the administration of justice which is the highest function of an attorney and counselor at law. The corporation might not have a lawyer among its stockholders, directors or officers. Its members might be without character, learning or standing. There would be no remedy by attachment or disbarment to protect the public from imposition or fraud, no stimulus to good conduct from the traditions of an ancient and honorable profession, and no guide except the sordid purpose to earn money for stockholders. The bar, which is an institution of the highest usefulness and standing, would be degraded if even its humblest member became subject to the orders of a money-making corporation engaged not in conducting litigation for itself, but in the business of conducting litigation for others. The degradation of the bar is an injury to the state." In re Co-operative Law Co., 92 N.E. 15, 16, 198 N.Y. 179 (N.Y. 1910). This was adopted by the California Supreme Court in its decisions barring the corporate practice of medicine. See People ex rel. Bd. of Med. Exam'rs v. Pacific Health Corp. Inc., 82 P.2d 429, 430, 12 Cal.2d 156 (Cal. 1938); People v. Merchant's Protective Corp., 189 Cal. 531, 209 P. 363 (Cal. 1922).

were willing to subvert patient care to the physician's own financial gain. It did mean that if the patient saw another physician, that physician would probably not be profiting by the first's physician greed and would independently evaluate the patient. While such independent evaluation is usually thought of in terms of formal second opinions for surgery and other procedures, its most important manifestation is in routine care by different specialists. Few patients sought out formal second opinions, but most patients would discuss their care with all of their physicians, giving their internist a chance to raise questions about proposed surgery, for example.

MCOs undermine this independence in two ways. First, as discussed below, they eliminate patient self-referral. Second, they give physicians powerful financial incentives to provide less care to patients. These can be "hold-backs," or money withheld from the physician's pay and only returned if the physician meets cost-cutting goals; partial or complete capitation, where the physician is paid a flat rate for caring for the patients and has to pay for extra care out of this payment; or economic deselection, where the physician is no longer allowed to participate in the plan, if the physician does not meet the MCO's economic goals. In most communities deselection by a couple of plans will put the physician out of business. For physicians employed by the MCOs, deselection is accompanied by anti-compete agreements in their contracts with the MCO, which will keep them from practicing medicine in their community if they are deselected. Deselection poses the economic death penalty for both independent contractor and employed physicians. Deselection is also immediate, making the linkage between the cost of care given patients and the physician's own economic well-being very clear. Conversely, possible medical malpractice litigation, the only sanction for dangerous under-treatment, is a vague future threat. Lawsuits are only filed months to years after the care is rendered and they take years more to resolve. The discounted present value of a potential lawsuit over improper medical care is very low compared to immediate threat of deselection. The MCO itself is immune to medical malpractice litigation as long as it does not employ physicians. As long as there are excess physicians in the community, the MCO has an incentive to push its physicians to the edge of malpractice to save money.

2. Patient Self-Referral

Patients traditionally could choose their own physicians, decide when they wanted to chance physicians, and could see specialists when they wanted and for whatever condition they wanted. Again, this did not always work to the patient's benefit because patients usually did not have enough information to make choices based on quality of care, and it encouraged hypochondria. However, it did increase the chance that one physician's errors would be seen and corrected by a second physician.

MCOs limit or eliminate patient self-referral by forcing patients to see physicians from an approved list of specialists and by requiring that the patient's primary care physician, commonly called the gatekeeper physician, approve all referrals. This prevents the patient from getting an independent second opinion. It also assures that the patient will see as few physicians as possible, limiting the chance that errors in diagnosis or treatment will be identified and corrected. The most extreme limit on patient self-referral is to prevent the patient from seeing a physician at all, which some plans have implemented by using nurses for primary care.

3. Hospital Staff Credentialing

In a post-*Darling*⁸⁵ world, hospitals had an incentive to assure that physicians provided good quality patient care. Ref. Hospitals also had an incentive to encourage physicians to provide more medical care, because reimbursement was based on services provided. As MCOs gain market share, they negotiate bulk purchase agreements with hospitals for bed and care rates. Implicit in these agreements is that the plan's physicians will be allowed to treat patients in the hospital, putting irresistible pressure on hospitals to limit their own credentialing process. In some cases, the medical staff credentialing is delegated to the MCO.

⁸⁵ See Darling v. Charleston Community Mem'l. Hosp., 211 N.E.2d 253, 33 Ill. 2d 326 (Ill. 1965). (This is the lead case establishing hospital liability for independent contractor physicians.).

⁸⁶ Credentialing was not a perfect mechanism because it was controlled by physicians whose personal interests were sometimes at odds with the hospital's interests. *See* Weiss v. York Hosp., 745 F.2d 786, 824 (3d Cir. 1984); Quinn v. Kent Gen. Hosp., Inc., 617 F. Supp. 1226 (Dist. Ct. Del. 1986); Patrick v. Burget 486 U.S. 94, 108 S.Ct. 1658 (1988); Bryan v. James E. Holmes Reg'l. Med. Ctr., 33 F.3d 1318, (11th Cir. 1994).

4. Benefits of Over-treatment

Over-treatment is a danger to patients, whether it is done by a dangerous incompetent such as the infamous Dr. Nork, ⁸⁸ or a well meaning physician who loses sight of the potential risks of what seems like harmless extra care. ⁸⁹ On balance, however, over-treatment is less dangerous than under-treatment, especially when dealing with diagnostic tests. MCOs are correct when they argue that physicians in fee-for-service systems order unnecessary diagnostic tests. What is unsaid is why these tests were ordered. If the physicians knew they were unnecessary and only ordered them to make the laboratories rich, then it is logical to believe that limiting the tests physicians order will cause them to only order the right tests. Contrary to this assumption, most physicians were honest prior to MCOs and ordered too many tests because they did not know which ones were important. Putting these same physicians in an environment where they are not allowed to order many tests does not make them more skillful in ordering tests. If they are forced to order fewer tests, they are more likely to miss necessary tests.

C. Controlling MCOs Through Medical Licensing

MCOs depend on physicians for three key functions: (1) providing direct medical services; (2) supervising non-physician personnel ("NPPs"); and (3) medical director services reviewing the care provided by other physicians and NPPs, determining whether care recommended by treating physicians is medically necessary, ⁹⁰ and setting medical standards for the organization. The first two functions are clearly the practice of medicine and subject to state regulation through the licensing board. The third function combines activities that are administrative with others that are subject to regulation as practice of

⁸⁷ Hospital credentialing began to erode as a safeguard when DRGs were introduced, giving the hospital an incentive to do economic credentialing and remove physicians who did not discharge the patient quickly enough from the hospital.

⁸⁸ See Gonzalez v. Nork, 131 Cal. Rptr. 717 (Cal. Ct. App. 1976) reprinted in Liability and Quality Issues in Health Care 25 (Barry R. Furrow et al. eds., 1991); rev'd on other grounds.).,

⁸⁹ Perhaps the most common example is antibiotic overuse. *See* Howard S. Gold and Robert C. Moellering, *Drug Therapy: Antimicrobial-Drug Resistance*, 335 New Eng. J. Med. 1445 (Nov. 7, 1996).

Denial of benefits cases involve three questions: (1) whether the requested benefit is covered for anyone at any time, i.e., whether it is excluded by the insurance contract; (2) if the benefit is covered, whether it is medically necessary for this patient; and (3) if the benefit is covered and medically necessary, who is going to do it and at what facility.

medicine. This issue was litigated in *Murphy v. Board of Medical Examiners of State of Arizona*⁹¹ and found to be within the state's police power to define and regulate the practice of medicine.

1. The Murphy Case

At this point in time, *Murphy* is the only case to directly address whether a medical director in an MCO is practicing medicine when the medical director is prospectively reviewing a recommended treatment to determine if it is medically necessary and thus whether the patient will be able to have the treatment. Dr. Murphy was the medical director of Blue Cross Blue Shield of Arizona ("Blue Cross"). He filed this lawsuit to contest the authority of the Arizona Board of Medical Examiners ("BOMEX") to review and criticize his medical necessity decisions for Blue Cross. The case arose when Dr. Murphy refused to "pre-certify" a patient for laparoscopic cholecystectomy, despite the recommendations of the patient's surgeon. The patient filed a complaint with the Arizona Department of Insurance, alleging that Blue Cross refused to honor the terms of its insurance contract. The Department of Insurance reviewed the claim, but determined that there was no violation of the Arizona insurance code. The surgeon filed a complaint with the BOMEX alleging unprofessional conduct on the part of Dr. Murphy.

⁹¹ Murphy v. Board of Med. Exam'rs, 190 Ariz. 441, 949 P.2d 530 (Ariz. App. Div. 1, 1997).

This article does not address the related issue of whether patients injured by a decision to deny care should be entitled to sue medical directors and insurance plans. These two issues are not legally linked since the state's police power is much more extensive than a plaintiff's right to compensation for an activity that is also subject to police power regulation. For a discussion of liability for utilization review decisions; see also J. Scott Andresen, Is Utilization Review The Practice Of Medicine? Implications For Managed Care Administrators, 19 J. LEGAL MED. 431 (1998); Jeffrey E. Shuren, Legal Accountability For Utilization Review In ERISA Health Plans, 77 N.C. L. REV. 731 (1999).

 $^{^{93}}$ If the plan refuses to pre-certify the surgery, it is telling the patient that it will not pay for the surgery and that the patient will have to find other means of payment. In this case, the surgeon did the surgery anyway, believing it was critical to the patient's health. The plan ultimately paid for the surgery because the pathology report on the removed tissue indicated that the surgery was necessary. *Murphy*, 949 P.2d at 532.

⁹⁴ See id. at 533. This ruling is not surprising, given that most state insurance laws are concerned only with the procedure for filing and resolving claims, not the accuracy of medical determinations. "Moreover, before patients can obtain relief from ADI, they must first show that failure to pay for reasonable and necessary medical services occurs with such a frequency to indicate ... a general business practice.' A.R.S. § 20-461(A)(16). This statutory limitation hinders patients such as S.B. who are complaining of single occurrences from obtaining any relief from ADI." *Id.* at 536.

^{95 &}quot;Dr. Johnson chose a different course; he sent BOMEX a letter complaining of Dr. Murphy's 'unprofessional conduct' and 'medical incompetence' associated with the rejection of S.B.'s pre-certification request. Dr. Johnson alleged that Dr. Murphy's decision caused S.B. to question Dr. Johnson's professional judgment and to waver in her decision to proceed with surgery that was not covered by insurance. Dr. Johnson also maintained that the physician-patient relationship he established with S.B. suffered 'to a dangerous degree." *Id.* at 533.

The BOMEX wrote Dr. Murphy a letter expressing its concern that his decision might have endangered the patient.⁹⁶ Dr. Murphy filed two lawsuits contesting the BOMEX's authority to review his actions as medical director, the procedure used to issue the letter, and the substantive basis for criticism, and he requested a temporary restraining order to prevent the issuance of the letter. While the BOMEX also prevailed on the procedural claims, the key issue was whether the BOMEX had jurisdiction to review his actions.⁹⁷ The plaintiff contested jurisdiction on the grounds that he was not practicing medicine as defined in the enabling legislation for the BOMEX, and that medical necessity decisions are insurance determinations and thus subject to Arizona Department of Insurance regulation only. 98 Consistent with state's medical licensing laws, the court found that the BOMEX's " . . primary duty is 'to protect the public from unlawful, incompetent, unqualified, impaired or unprofessional practitioners' of medicine in the state."99 The court then reviewed the defendant's actions in light of the Arizona statutory definition of medical practice:100

> Although Dr. Murphy is not engaged in the traditional practice of medicine, to the extent that he renders medical decisions his conduct is reviewable by BOMEX. Here, Dr. Murphy evaluated information provided by both the patient's primary physician and her surgeon. He disagreed with their decision that gallbladder surgery would alleviate her ongoing symptoms. S.B.'s doctors diagnosed a medical condition and proposed a nonexperimental course of treatment. Dr. Murphy substituted his medical judgment for theirs and determined that the surgery was 'not medically necessary.' There is no other way to characterize Dr. Murphy's decision: it was a 'medical' decision. 101

⁹⁶ "The Board voted to resolve the case by issuing Dr. Murphy an advisory letter of concern regarding 'an inappropriate medical decision which could have caused harm to a patient." Id. at 534.

In fact, the BOMEX's procedure of issuing the letter without giving Dr. Murphy a chance to respond in person, coupled with certain other irregularities, might not have been acceptable under some other state codes of administrative procedure. See Thebaut v. Georgia Bd. of Dentistry, 235 Ga. App. 194, 509 S.E.2d 125 (Ga. App., 1998). It should be assumed that had the Arizona APA given Dr. Murphy more extensive procedural rights, the BOMEX would have modified its procedures accordingly.

⁸ The plaintiff did not raise ERISA directly at the trial court. While it was raised by *amici* at the appellate level, the court declined to consider it. Id. at 533, n.4.

⁹⁹ *Id.* at 535-36.

100 "Arizona Revised Statutes Annotated ('A.R.S.') §32-1401(21) (formerly (17)) defines the practice of medicine as 'the diagnosis, the treatment or the correction of or the attempt or the holding of oneself out as being able to diagnose, treat or correct any and all human diseases." Id. at 532, n.1.

The court found that there was nothing in the state insurance regulations to prevent the BOMEX from exercising this jurisdiction because Dr. Murphy was not providing insurance coverage but was employed to make medical decisions. This is consistent with the ERISA cases that find that there is no ERISA preemption of medical malpractice lawsuits against physicians employed by ERISA plans to provide medical care. There is some division on the issue of whether medical necessity decisions are covered by ERISA, the courts that have considered this issue have not had the benefit of state licensing board determinations. Because the federal government leaves the definition of medical practice and the extent of licensing to the states, the courts should defer to a clear policy statement by state licensing boards that medical decision making about the care specific individual patients receive is always the practice of medicine.

D. A Strategy for Medical Licensing Boards

Medical licensing boards must be more active in setting acceptable parameters for medical practice in MCOs. This should be done on two levels: regulation of physicians providing direct patient care; and regulation of physicians providing medical director services. The guiding principles behind this regulation should be to assure that all physicians respect their fiduciary duty to their patients, and that all physicians adhere to appropriate standards for medical care. For physicians providing direct patient care, this means establishing clear professional standards that limit compensation agreements that put

[&]quot;Counts I and II allege that Campbell and Pauls breached the applicable standard of care for medical providers in Virginia by failing to diagnose Lancaster's brain tumor. More specifically, these claims assert that Campbell and Pauls violated the standard of care by failing: (i) to order an MRI, EEG, or other diagnostic test, which would have disclosed Lancaster's tumor; (ii) to refer Lancaster to a neurologist; and (iii) to medicate Lancaster properly. These allegations, distilled to their essence, attack medical decisions concerning treatment, not administrative decisions concerning benefits; they focus on a physician's medical determination concerning appropriate treatment and medication, not on an administrator's decision to deny benefits as a matter of coverage or discretion; they attack the quality of treatment afforded Lancaster as a patient, not the quantity of benefits provided Lancaster as a plan beneficiary. So viewed and understood, Counts I and II are entirely state malpractice claims that do not trigger or implicate [sec.] 502(a)(1)(B) and hence provide no basis for the operation of the complete preemption doctrine." Lancaster v. Kaiser Found. Health Plan of Mid-Atlantic States, Inc., 958 F. Supp. 1137, 1145-46 (E.D. Va. 1997); see also Nealy v. US Healthcare HMO, 93 N.Y. 2d 209, 1999 WL 161389 (N.Y., 1999).
See Scalamandre v. Oxford Health Plans (N.Y.), Inc., 83 F. Supp. 1050, 17 Employee Benefits Cas.

See Scalamandre v. Oxford Health Plans (N.Y.), Inc., 83 F. Supp. 1050, 17 Employee Benefits Cas. 1030 (E.D.N.Y., 1993); Damare v. Occidental Petroleum Corp. Med. Care Plan, 1993 WL 92503, 16 Employee Benefits Cas. 2789 (E.D. La., 1993).

physicians in conflict with their patients' best interest. While MCOs complain that they cannot manage medical care without these devices, there are other methods of establishing appropriate standards for managing medical practice. The best alternative is to use evidence-based clinical guidelines. These have the advantage of improving the clinical information available to the physicians, rather than just demanding that they reduce utilization without regard to how reduction is accomplished. Formal guidelines are also easier for physicians to contest when there is a good clinical reason that the patient does not fit, and they provide excellent evidence of standard of care in court and in administrative proceedings.

Medical licensing boards should also assure that physicians are in charge of patient care in the MCO. Legally, there is a profound difference between physician-directed care and nursing care. For example, there is no "corporate practice of nursing" doctrine because the courts have always assumed that nurses will be under the direction of physicians, and that physicians are subject to corporate practice bans. Another example is the learned intermediary doctrine for prescription drugs. The courts do not accept

With only a few exceptions, the federal pay programs such as Medicare will pay whatever provider the state allows to perform a service. Thus in some states Medicare will pay nurses to deliver services that are not reimbursable in other states.

the extent that physicians in health plans are privy to confidential business information - which is rarely the case for treating physicians - it can be protected under existing state trade secret laws. In Missouri, which will enforce Draconian restrictions against physicians, restrictive covenants and non-compete agreements are banned as unethical for lawyers: Missouri recognizes the importance of the professional relationship for lawyers. "Supreme Court Rules for Professional Conduct, Rule 5.6: A lawyer shall not participate in offering or making: (a) a partnership or employment agreement that restricts the rights of a lawyer to practice after termination of the relationship, except an agreement concerning benefits upon retirement; or (b) an agreement in which a restriction on the lawyer's right to practice is part of the settlement of a controversy between private parties. [Official] Comment: An agreement restricting the right of partners or associates to practice after leaving a firm not only limits their professional autonomy but also limits the freedom of clients to choose a lawyer." Edward P. Richards and Katharine C. Rathbun, *Covenants to not Compete: A Trap for Missouri Physicians*, 94 Mo. Med. 224 (May 1997).

patients and consumer organizations to evaluate the care the MCO is providing.

107 See Wyeth Lab., Inc. v. Fortenberry, 530 So.2d 688 (Miss. 1988); Swayze v. McNeil Lab., Inc., 807
F.2d 464 (5th Cir. 1987); Timm v. Upjohn Co., 624 F.2d 536, 638 (5th Cir. 1980), cert. denied, 449 U.S. 1112, 101
S.Ct. 921, 66 L.Ed.2d 840 (1981); and Mauldin v. Upjohn Co., 697 F.2d 644, 647 (5th Cir.), cert. denied, 464 U.S.
848, 104 S.Ct. 155, 78 L.Ed.2d 143 (1983).

that NPPs are learned intermediaries.¹⁰⁸ Allowing nurses without physician supervision to deliver medical care as employees of MCOs threatens the quality of care and allows medical care to be delivered outside of the traditional regulatory system. While nurses, nurse practitioners, and physician assistants provide invaluable medical care services, if they are allowed to practice outside of physician supervision they may not resist pressures by their employers to compromise patient care to protect the assets of the MCOs. This does not mean direct supervision in most cases, but it does mean that the NPPs work from agreed upon practice guidelines, that physicians are always available for consultation, that each nurse is supervised by a specific physician who is limited to supervising a set number of nurses, and that there is a systematic quality assurance program in place to assure the quality of the care rendered by NPPs. It also means that the medical licensing boards must assure that physicians do carry out the supervision properly.¹⁰⁹ Otherwise supervision requirements will just be a sham that NPPs can rightfully claim only assures job security for physicians without improving patient care.

Regulating the activities of medical directors requires separating their non-medical from their medical duties. Physicians work in many jobs that do not involve the practice of medicine as it is regulated by licensing laws. A physician who works as an executive in a health insurance company, but who does not provide medical services personally, who does not make or direct decisions that influence the care of individual patients and who does not supervise NPPs, should not be subject to license related sanctions¹¹⁰ and should not even have to hold a medical license.¹¹¹ Medical licensing boards should not attempt to become consumer protection agencies for insurance issues. Whether the health insurance policy is fair or properly administered is an insurance issue, and trying to use medical licensing to regulate it will only invite preemption by state insurance laws and by ERISA. Regulation should be

¹⁰⁸ See Mazur v. Merck & Co., 964 F.2d 1348 (3rd Cir. 1992).

This is usually done through prosecutions for aiding in the unauthorized practice of medicine. *See* Sermchief v. Gonzales, 660 S.W. 2d 683 (Mo. Banc 1983); People v. Varas, 110 A.D. 2d 646, 487 N.Y.S. 2d 577 (N.Y.A.D. 2 Dept. 1985); State *ex rel*. Mo. State Bd. of Registration for the Healing Arts v. Hartenbach, 768 S.W. 2d 657 (Mo. App. E.D., 1989); People v. Gandotra, 11 Cal. App. 4th 1355, 14 Cal. Rptr. 2d 896 (Cal. App. 2 Dist., 1992)

based on whether the medical director is practicing medicine as defined by the state law, and, if so, whether the medical director is acting in a professional manner. In the *Murphy* case, the BOMEX found that Dr. Murphy's decision was inappropriate and could have harmed the patient. This would have been true whether Dr. Murphy was the medical director denying pre-certification or a treating physician making an incompetent decision not to operate in the face of substantial medical evidence that the surgery was necessary. If the medical director is practicing medicine, then he/she should be licensed in the state where the patient who is being treated resides. This means that nurses cannot be substituted for physicians if the medical director job requires decisions to be made about individual patient care, and that out-of-state medical directors must have a local license, or the insurer must reserve medical care decisions for local medical directors.

CONCLUSION

The police power to regulate matters that affect the health of the citizenry was well established in the colonies. This was not a dormant power, but one that was constantly exercised because of the epidemics that swept through the colonies. When the Constitution was written, this power was reserved to the states, and within a few years it was challenged by the yellow fever epidemic of 1793. As the state began to regulate medical practice and to license physicians, the courts uniformly found that this was an expression of the police power and granted the states the same broad authority to regulate medical practice that they already exercised in their control of other threats to the public health.

In modern society, the health of the citizenry is threatened by a regulatory vacuum surrounding ERISA health plans. State medical licensing boards must step in and assure that medical care is delivered by properly licensed physicians, and that these physicians practice in an ethical manner. The police

Physicians who commit crimes in this non-medical care role can have their licenses revoked, however. *See* State Bd. of Med. Exam'rs v. Boyle, 924 P. 2d 1113 (Colo. App. 1996) and Erickson v. State *ex rel.* Bd. of Med. Exam'rs, 282 Mont. 367, 938 P. 2d 625 (Mont., 1997).

See Morris v. District of Columbia Bd. of Med., 701 A.2d 364 (D.C., 1997).

¹¹² See Murphy, 949 P. 2d at 534.

This is not to say that BOMEX does not have the authority to regulate non-medical practices such as over-billing, only that it is best to focus narrowly on medical practice when ERISA is involved. *See* Maun v. Department of Prof. Regulation, 701 N.E.2d 791, 299 Ill. App. 3d 388 (Ill. App. 4 Dist. 1998).

power gives the states great flexibility in addressing this problem through administrative rules, license limitations and revocations, and informal sanctions. This regulation will not conflict with ERISA or state insurance laws as long as it is directed at the practice of medicine, rather than trying to substitute medical licensing boards for state insurance regulators. The goal of such state regulation of medical practice in MCOs is to reestablish the checks and balances of traditional medical practice to assure that physicians respect their fiduciary duty to their patients. Good quality medical care and respect for patient autonomy are not incompatible with effective managed care, but they demand that care be managed ethically and not by simplistic economic incentives.