ESSAY

Regulatory Approaches to Problems in the Quality of Medical Care: Diagnosis and Prescription

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INTRODUCTION

The quality of medical care has historically been a primary concern of public policy. Medical licensure statutes date from the thirteenth century in Europe and were pervasive in the United States by the end of the nineteenth century. Medical malpractice litigation also has venerable roots, dating from the fourteenth century in England and the eighteenth century in the United States. Recent developments in the health care industry, however, have made the quality of medical care an even more pressing concern. Strategies developed in the mid-1980s for coping with medical cost escalation, such as diagnosis-related-group prospective payment, Health Maintenance Organizations (HMOs),[1] and gate-keeper managed care arrangements,[2] increase the possibility of

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[1] HMOs are "entit[ies] that provide[] comprehensive health care services to an enrolled membership for a fixed, per capita, fee." F. FURROW, S. JOHNSON, T. JOST & R. SCHWARTZ, HEALTH LAW: CASES, MATERIALS AND PROBLEMS 476 (1987) [hereafter HEALTH LAW].

[2] Including Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), or traditional insurance plans with pre-admission certification or other utilization review requirements.

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underserving patients, and of corresponding quality problems. Recognition of these potential problems has led in the late 1980s to a renewed focus on quality assurance.

This concern about medical care quality has resulted in a flurry of legislative and administrative activity to strengthen quality regulation. Evidence of this activity exists at the federal level in legislation altering the primary focus of Medicare Peer Review Organizations (PROs)[3] from utilization to quality control,[4] and subsequent legislation reaffirming and expanding this quality of care mandate.[5] The Federal Health Care Quality Improvement Act of 1986,[6] another manifestation of this concern, attempts to coordinate federal, state, and private quality assurance activities to enhance regulatory effectiveness.[7] At the state level, substantially increased disciplinary activity and licensing reform are underway.[8] The private sector also has shown a renewed concern for quality. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO)[9] is developing new accreditation requirements and techniques using an outcome assessment approach to quality assurance. In addition, managed care arrangements have begun to consider the quality and cost of care.

At cross-currents with this renewed emphasis on quality assurance,

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[3] Medicare Quality and Utilization Peer Review Organizations are entities established in each state that contract with the United States Department of Health and Human Services (DHHS) to assure that medical services rendered by physicians and institutions to Medicare beneficiaries are medically necessary, appropriate, and of acceptable quality. *See* 42 U.S.C.A. § 1320c-1 to -12 (1983 & Supp. 1988).

[4] *See* peer review provisions of the Consolidated Omnibus Reconciliation Act of 1985, Pub. L. No. 99-272, §§ 9401-9406, 100 Stat. 82, 196-201 (1985).

[5] *See* peer review provisions of the Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, §§ 9351-9353, 100 Stat. 1874, 2043-49 (1986).

[6] Pub. L. No. 99-660, §§ 401-432, 100 Stat. 3743, 3784-94 (1986) (codified as amended in scattered sections of 42 U.S.C.).

[7] *See id.*

[8] *See Physicians Disciplined in Record Numbers*, Med. World News, Dec. 8, 1986, at 8. For additional information on licensure reform, see FEDERATION OF STATE MEDICAL BOARDS, A GUIDE TO THE ESSENTIALS OF A MODERN MEDICAL PRACTICE ACT, *reprinted in Medical Malpractice: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong., 2d Sess. 393 (1986) [hereafter *Medical Malpractice Hearings*].

[9] The JCAHO is a private agency governed by the American Medical Association, American Hospital Association, American College of Surgeons, American College of Physicians, and American Dental Association, which inspects and accredits health care institutions, including hospitals. *See generally* Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest*, 24 B.C.L. REV. 835 (1983) (describing the JCAHO).

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however, is a contemporaneous retreat from the means through which our legal system has traditionally overseen health care quality: medical malpractice litigation. Faced with high-power lobbying and advertising campaigns sponsored by medical providers, insurers, and other business groups, and increasing pressure from the federal government, many states have recently adopted tort "reforms" limiting the rights of people injured through medical error. Proposals for limitation of tort remedies often go hand in hand with demands for enhanced regulatory oversight of medical practice, in the belief that tort litigation and regulation are fungible approaches to quality assurance.[10]

Despite all of this activity, surprisingly little attention has been paid in the public policy arena to diagnosing the causes of quality deficiencies and medical failures specifically to prescribe the regulatory strategies that will most effectively deal with specific quality deficiencies or errors. Of course, a substantial and growing literature on quality assurance methodology exists, focusing particularly on the difficult problem of identifying quality deficiencies.[11] However, the implications of this information for regulatory or judicial approaches to quality control have not been sufficiently explored. This Essay examines this problem.

I. Medical Care Deficiencies

Discussions of health care quality problems commonly begin with Donabedian's definition of health care quality. As Donabedian defines quality, health care of optimal quality utilizes technology to maximize benefits to patients and to minimize harm.[12] Optimal quality health care also conforms to appropriate social values and norms governing the interaction of patients and practitioners.[13] Donabedian also notes that a full consideration of health care quality should take into account deficiencies in the amenities that accompany health care delivery, the social cost of health care, and the wishes and desires of the individual

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[10] *See* U.S. Dep't of Health and Human Services, Report of the Task Force on Medical Liability and Malpractice 8-11 (1987); U.S. General Accounting Office, Medical Malpractice: A Framework for Action 12-16 (1987).

[11] Two major recent symposia on the issue of health care quality discuss these deficiencies. *See* Health Aff., Spring 1988, at 5-113; Health Care Financing Rev. 1-85 (1987 Annual Supplement); *see also* Mattson, *Quality Assurance: A Literature Review of a Changing Field*, 35 Hosp. & Community Psychiatry 605 (1984).

[12] *See* 1 A. Donabedian, Explorations in Quality Assessment and Monitoring: The Definition of Quality and Approaches to Its Assessment 4-6 (1980).

[13] *See id.*

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patient.[14] Another recent definition of health care quality, formulated by Caper, also considers the efficacy and appropriateness of technical care offered, the adequacy of the caring, and the interpersonal aspects of the patient-professional relationship.[15]

Deviations from these norms, for purposes of designing regulatory responses, fit into five categories. First, and most obviously, errors take place in professional intervention in the disease process. The patient comes to a health care provider with an illness or injury, the provider acts to address the underlying medical problem. At some stage in the intervention process, however, the professional makes a mistake, thus failing to correct the problem, or even, perhaps, making it worse. The professional may misdiagnose the patient's illness or injury. She may diagnose properly, but prescribe the wrong drug or procedure. She may prescribe the most appropriate treatment, but commit an error of judgment or technique in the treatment process. The medical malpractice system focuses primarily on this first class of deficiencies. Indeed, malpractice most commonly involves one type of medical error: errors involving treatment procedures.[16] Most of the literature on quality assurance also focuses on the identification of errors falling in this first category.

Second, health care professionals and institutions also harm patients by acts or omissions independent of, or tangential to, the treatment of a disease or injury. For example, one of the most common grounds for medical discipline in this country is the abusive prescribing of controlled substances, resulting in addiction and overdoses.[17] Other examples of this type of problem include preventable nosocomial infections or injuries suffered by patients who fall in health care institutions. While these injuries might not have occurred had the patient avoided medical care for the underlying illness, they are not the direct result of treatment of that illness. Injuries resulting from medical procedures not necessitated by disease or injury also fall in this category. Examples of such procedures include unnecessary surgery prescribed largely for financial gain (the notorious case of Dr. Nork in California provides an example of this).[18] While this type of conduct probably is rare in medi-

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[14] *See id.* at 7-16.

[15] *See* Caper, *Defining Quality in Medical Care*, HEALTH AFF., Spring 1988, at 49, 54-57.

[16] *See* P. DANZON, MEDICAL MALPRACTICE 26-28 (1985).

[17] Derbyshire, *Offenders and Offenses*, HOSP. PRAC., Mar. 1984, at 98A, 98M (stating that 44% of disciplinary actions in 1980 were based on violation of controlled substances laws).

[18] *See* S. LAW & S. POLAN, PAIN AND PROFIT: THE POLITICS OF MALPRACTICE

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cal practice, it accounts for a significant share of the disciplinary actions of state medical boards.[19] It may also prove a significant cause of the kinds of serious injuries that result in malpractice litigation.

Third, patients suffer a variety of affronts to dignity from health care professionals. A patient may receive a medical procedure that is technically appropriate but to which the patient did not consent. The patient may also consent to a technically appropriate medical procedure without receiving adequate information concerning the procedure's potential risks and alternatives. A professional may reveal confidential information to a patient's employer without authorization, resulting in job termination. A nursing home may physically or chemically restrain a resident for the convenience of the facility, or subject the resident to verbal abuse. A doctor may be unnecessarily rude or abrupt with a patient, or show contempt for the value of a patient's time by subjecting the patient to a long wait for an examination. Donabedian and Caper refer to these violations of social values and norms in their definition of quality.[20] They seldom result in litigation or regulatory action, but frequently result in patient dissatisfaction.

The quality problems identified in the first three categories primarily result from the conduct of health care professionals. Much health care, however, is received in institutions which may provide deficient care even though the professionals practicing within them are on the whole competent. These institutional problems form a fourth category of quality deficiencies. A health care facility may, for example, afflict patients with unappetizing food, uncomfortable beds, or dismal surroundings. Poor management or lack of staff may delay a patient's access to medication or services. A hospital may neglect proper discharge planning, resulting in an uncomfortable transition from the hospital to the community. A nursing home may lack adequate social, recreational, or rehabilitative services, thus contributing to the deterioration of the condition of its residents even though the residents' medical care is technically correct. Institutional inadequacies may also, of course, result in failures in the technical care process. For example, the institution may have defective equipment that results in patients' receiving faulty diag-

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215-45 (1978) (citing excerpts from Judge Goldberg's opinion in Gonzales v. Nork, No. 228566 (Sacramento Co. Super. Ct. Nov. 19, 1973), *rev'd*, 60 Cal. App. 3d 835, 131 Cal. Rptr. 717 (1976), *rev'd and remanded*, 20 Cal. 3d 500, 573 P.2d 458, 143 Cal. Rptr. 240 (1978)).

[19] *See* Derbyshire, *supra* note 17, at 98I-98M, 98U (stating that of 549 disciplinary actions in 1980, 59 involved conviction of a felony, 24 of sex offenses).

[20] *See* A. DONABEDIAN, *supra* note 12, at 4-6, 7-16; Caper, *supra* note 15, at 54-57.

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noses or treatment.

Finally, broader social failings in the health care delivery system exist. Necessary medical care may be unavailable to the poor and uninsured. Unnecessary medical care, or care of little marginal benefit, or excessive charges for necessary care, may waste resources that could serve more beneficial purposes. Inadequate funding of preventive care may result in avoidable diseases.

Obviously, these categories are not neatly exclusive. Many deficiencies, such as injuries caused by unnecessary care, may fall into several categories. However, this approach to categorization allows us to move to examination of the causes of medical deficiencies, and ultimately, to the design of corrective regulatory strategies.

II. Causes of Medical Deficiencies

Deficiencies in medical care provided by professionals — the first three categories of health care deficiencies identified above — may result from several different causes. They may arise from a general inadequacy in the professional who delivers the care. Such inadequacies can in turn be catalogued. First, there is professional impairment. Impairment often takes the form of substance abuse. Substance abuse may cause a doctor to make errors of judgment or technique, to deliver unnecessary care to support a habit, or to relate inappropriately to patients. Mental illness or deterioration may also impair a physician's judgment or skills. Less commonly, physical impairments, such as deterioration of vision or coordination, may result in medical errors if not attended to. It is estimated that from five to twelve percent of physicians are impaired.[21] Impairment is responsible for a significant proportion of disciplinary actions, and may be the cause of a disproportionate amount of malpractice litigation.

Professional incompetence is a second category of general inadequacy. Some physicians who lack the basic knowledge essential to practice safe and effective medicine inevitably slip through the licensure system and into practice. This possibility would seem likely in those states that have no limit on the number of times a doctor can retake the licensure exam, attempting to squeeze out a barely passing score. More doctors allow their skills to deteriorate, or fail to keep up with medical advances. Still other doctors have adequate knowledge to practice effectively, but simply fail to give their practices the diligence and attention

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[21] Morrow, *Doctors Helping Doctors*, Hastings Center Rep., Dec. 1984, at 32, 32.

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necessary to assure patient care.

Finally, professionals may have character faults that result in injury to their patients. Professional drug pushers, doctors who sexually abuse their patients, or physicians whose insatiable drive for money leads them to perform unnecessary surgery or to carry a much larger patient load than they can competently handle fall into this category. Obviously, whether certain conduct (such as sexual misconduct or substance abuse) is viewed as wrongdoing or as the product of impairment depends on one's viewpoint. Thus, this category overlaps with the impaired behavior discussed above.

The extent to which medical injury results from faulty professionals is difficult to gauge. However, growing evidence indicates that a significant proportion of medical malpractice actions are filed against a relatively small number of professionals.[22] While several reasons for this trend may exist, one plausible explanation is that a small number of deficient professionals cause many patient injuries.

Undoubtedly, a substantial proportion of medical injury occurs from the occasional failure of otherwise competent professionals. Some affronts to patient dignity probably occur because physicians otherwise beyond reproach in their dealings with patients are temporarily overwhelmed by the demands of their practice. Similarly, injury often results from momentary technical oversights or slips. All people make mistakes in their work from time to time. When a professor makes a mistake in the course of a lecture, it is generally missed and invariably forgotten. When a surgeon makes a mistake in the course of a delicate operation, the consequences are often disastrous. It would seem reasonable that mistakes occur more often when a physician is under unusual stress, such as coping with a divorce, the death of a loved-one, a business failure, or just a succession of sleepless nights. Such mistakes do not necessarily evidence more fundamental deficiencies, and a disciplinary board should handle these problems differently than the problems caused by impaired or incompetent physicians.

Medical failures also result from competent physicians who take on medical problems that exceed their competence. Sixty-four percent of PROs' sanctions have been imposed on rural doctors, who represent

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[22] *See* STATE OF NEW JERSEY COMM'N OF INVESTIGATION, REPORT AND RECOMMENDATIONS ON IMPAIRED AND INCOMPETENT PHYSICIANS 32-33 (1987); U.S. GENERAL ACCOUNTING OFFICE, MEDICAL MALPRACTICE: CHARACTERISTICS OF CLAIMS CLOSED IN 1984, at 26 (1987); Marcotte, *Few Physicians, Many Claims*, A.B.A. J., Aug. 1, 1987, at 47, 47.

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eleven percent of the nation's physicians.[23] A recent study by the Inspector General of the Department of Health and Human Services (DHHS) found that the rate of cases involving poor quality care was two-and-a-half times as great in rural as in urban hospitals.[24] One plausible explanation for this greater rate is that physicians practicing in isolated rural environments are more likely than their counterparts in large urban teaching hospitals to get in over their heads, thus causing medical errors and sometimes injury. As medical knowledge continues to expand exponentially, and as medical practice becomes more specialized, it is reasonable to expect this type of error to become more common.

Finally, it is obvious, but still important to note, that many medical failures are not caused by the error of any particular practitioner. Medical knowledge is still very much an art and not a science; much is still not known about how the human body and many disease processes work. As scholars such as Wennberg and Eddy repeatedly remind us, much of today's medical practice has still not been scientifically validated.[25] Indeed, the human organism is so infinite in its complexity that we will probably never fully understand it. Therefore, physicians cannot, despite continual exercise of their best judgment in light of the fullest knowledge available, avoid occasionally injuring patients. To the extent, however, that a medical failure results from a correctable error of the entire profession, remedial efforts may still prove necessary.

Institutional, as distinguished from professional, quality deficiencies generally result from poor management or inadequate resources. Management problems in some cases arise from the poor performance of a particular administrator. Management problems are often more deeply engrained in an institution, however. Thus, receivership has sometimes proved a necessary remedy to turn around a poor quality nursing home. Problems resulting from insufficient resources can sometimes be cured by redeploying resources within an institution. For example, a for-profit nursing home may need to cut profit margins and put more money into patient care.

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[23] INSPECTOR GENERAL, U.S. DEPT. OF HEALTH AND HUMAN SERVICES, THE UTILIZATION AND QUALITY CONTROL PEER REVIEW ORGANIZATION PROGRAM: SANCTION ACTIVITIES, app. XI, table D (1988) (draft subject to revision).

[24] INSPECTOR GENERAL, U.S. DEPT. OF HEALTH AND HUMAN SERVICES, NATIONAL DRG VALIDATION STUDY: QUALITY OF PATIENT CARE IN HOSPITALS 7 (1988).

[25] Eddy & Billings, *The Quality of Medical Evidence: Implications for Quality of Care*, HEALTH AFF., Spring 1988, at 19, 19-32; Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, HEALTH AFF., Summer 1984, at 6.

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Often, however, institutional problems reflect broader political decisions reflecting the allocation of economic resources. Some state Medicaid programs simply do not provide sufficient resources to fund quality institutional care. Other defects in the health care system also result from political resource allocation decisions or from economic incentives created by our health care financing system. As long as our national health insurance programs (Medicare and Medicaid) leave many people without access to health insurance coverage, these people will not receive preventive care, or even care for acute or chronic conditions. As long as the nation continues to rely on fee-for-service payment for health care practitioners, unnecessary care will occasionally be provided.

III. Regulatory Approaches to Quality Assessment

Once one identifies the causes of health care deficiencies, one can turn to strategies for disclosing deficiencies and identifying their causes. Historically, most public regulatory programs addressing health care quality have relied on two approaches to quality assessment: investigation of complaints and examinations or inspections. State professional and institutional licensure and disciplinary programs have relied on licensure examinations and facility inspections to identify qualified care deliverers. Licensure exams screen out candidates for medical practice who lack basic knowledge or cognitive skills, but the exams do little to address the interpersonal element of care, or even to assure ongoing technical competence. Periodic institutional inspections also identify some quality problems, though in the past prearranged inspections have often been little more than Potemkin tours.[26]

Disciplinary agencies until recently have relied heavily on complaints to identify problem providers. Consumers often initiate these complaints, since professionals are generally reluctant to criticize their peers, preferring instead to deal with quality problems "in-house." While consumer complaints may uncover some serious affronts to patient dignity, these complaints are less useful in identifying quality problems, since patients generally lack the knowledge necessary for this task. Reliance on complaints has other shortcomings as well. Professionals who are substance abusers or who engage in criminal conduct have substantial incentives to conceal their problems. Patients who have been sexually assaulted are often reluctant to publicize this information.

Regulatory efforts to identify deficient practitioners and institutions

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[26] B. Vladeck, Unloving Care 159 (1980).

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have made three major advances in recent years. First, the federal government and many states have adopted mandatory reporting statutes. These statutes may apply to several different classes of potential informants. Many states now require professionals to report observed impairment, incompetence, or unethical activity in their peers. These requirements might marginally increase the likelihood that professionals will report this conduct, though substantial disincentives against professionals' informing on their peers remain, and failure to report is seldom punished.[27] More important, some statutes require health care institutions to report staff disciplinary actions and insurers to report malpractice settlements. Both of these requirements are found in the Health Care Quality Improvement Act of 1986.[28] Discipline of a provider by a hospital usually evidences serious impairment, incompetence, or unethical activity, and should in most instances result in swift action by public regulatory bodies. A more difficult question arises in determining how to handle malpractice data. To the extent that malpractice settlements result from the aberrant mistakes of otherwise careful physicians, they should not normally result in discipline. However, regulatory bodies should be alert for patterns that develop in judgments or settlements, which often indicate impaired or incompetent practitioners.

Reporting quality deficiencies of institutions is not yet required by law, but should be. For example, doctors should be required to report deficient practices in nursing homes or hospitals to relevant state licensure agencies. Mandatory reporting should also be used more widely to link up licensure agencies with other behavior control systems. For example, law enforcement agencies should routinely report convictions of medical professionals for driving under the influence of alcohol or for sexual misconduct.

The second quality assessment innovation is screening. PROs now routinely screen vast numbers of medical charts. Some are screened on a random sample basis. Others are examined as the result of intensified reviews when problem situations or institutions are identified. Technology for screening the process or outcome of medical care to identify quality problems has been the focus of much recent research. Computer technology makes screening a tool of great potential use in evaluating health care problems. States could, for example, maintain central data banks containing information on all prescriptions of controlled substances, which could be routinely screened to reveal improper prescrib-

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[27] *Medical Malpractice Hearings*, *supra* note 8, at 236-37 (testimony of Richard Kusserow, Inspector General, Department of Health and Human Services).

[28] *See supra* note 6, §§ 421, 423, at 3788-94.

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ing practices.[29] The vast federal data bank to be created by the electronic point-of-sale drug claims processing system of the Medicare Catastrophic Coverage Act of 1988[30] could also be used for this purpose. Insurers could use computer screens to identify doctors who excessively order unnecessary diagnostic tests. Nonelectronic forms of professional oversight should also be expanded. Hospitals, HMOs, and Preferred Provider Organizations (PPOs),[31] for example, could routinely review a random sample of the records of their medical staff to identify quality problems or take patient satisfaction surveys to identify problems in the interpersonal aspect of medical care.

Third, institutional survey methodology has dramatically improved in the recent past. Traditionally, institutional licensure and accreditation inspections have focused almost exclusively on the structural characteristics of institutions: their physical plant, administrative protocols, and staff qualifications. They have largely ignored the processes through which care is delivered in the institution or the quality of the outcomes with that care. This is beginning to change. The JCAHO, for example, has announced its intention to implement an inspection system that would be much more attentive to defects in the quality of the care delivery process and to patient outcomes.[32] The DHHS has recently instituted a nursing home survey system that involves resident interviews and direct observation of resident care, administration of medications, and feeding of residents.[33]

IV. Quality Regulation: Approaches and Methods

Once quality problems are identified, a variety of regulatory approaches and methods are available to address them. At one end of the spectrum, programs could focus on auditing performance and providing feedback. To the extent that practitioners or institutions are unaware of problems in their care delivery process, merely noting those problems may suffice to bring improvement.[34] Computer screens of drug pre-

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[29] *See* Whalen v. Roe, 429 U.S. 589 (1977) (upholding New York system of this nature).

[30] Pub. L. No. 100-360, § 202(c)(4), 102 Stat. 683, 715 (1988).

[31] PPOs "sell[] the health care services of independent providers to third party payors at a discounted rate in exchange for expedited payment and preferential access to insured consumers." Health Law, *supra* note 1, at 476.

[32] *See* Joint Commission on Accreditation of Hospitals, Overview of the Joint Commission's "Agenda for Change" (1987).

[33] *See* Long-Term Care Survey, Final Regulations, 53 Fed. Reg. 22,850 (June 17, 1988) (to be codified at 42 C.F.R. pt. 488).

[34] *See* J. Eisenberg, Doctors' Decisions and the Cost of Medical Care 99-

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scriptions and diagnostic test orders may identify problems, which could be called to the attention of offending physicians. Medical chart audits conducted by PROs often result in this kind of informal feedback to physicians.

Education programs go beyond simple feedback, addressing situations in which a doctor not only has an inability to perceive the problem, but also lacks understanding of how to deal with it. A doctor who persistently engages in questionable prescribing practices may simply have failed to keep up with developments in pharmaceuticals, and may benefit from a continuing education program. Many state medical boards can compel a professional to submit to additional education either as part of a consent agreement or by a direct order. PROs also increasingly engage in educational activities.[35]

The physician impaired by a mental, physical, or substance abuse problem may benefit from a treatment or rehabilitation program. State medical boards and societies have in recent years made a substantial commitment to impaired physician programs. When these programs work properly, they achieve commendable results — restoring physicians to a competent and productive practice while at the same time protecting the public from the errors that can result from impairment. There is always a tension in these programs, however, between protecting the confidentiality of the professional and protecting the public. As long as the program stays "in house," there is the danger of erring on the side of protecting the professional.[36]

At the other end of the spectrum, a variety of sanctions exist to restrain professionals who exhibit severe problems. The traditional medical licensure board sanctions of suspension or revocation temporarily or permanently remove the physician from practice. They are certainly appropriate for professionals whose impairment or incompetence interferes with their practice and for those engaged in criminal or unethical conduct. More recent sanctions, such as probation contingent on supervised or restricted practice, can provide a solution to more particularly identifiable problems. For example, a doctor engaging in medical practice beyond her competence can be restricted to practice in areas for which she is trained. A recovering substance abuser can be prohibited

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124 (1986) (discussing feedback and education as approaches to improvement of physician performance).

[35] Recent amendments to the PRO law require an even greater emphasis on educative activities. *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4094(d), 101 Stat. 1330, 1330-37 (1987).

[36] Morrow, *supra* note 21.

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from prescribing controlled substances and limited to practice in a supervised environment. Restraint can also be program specific. The most serious sanction available to the PRO program is exclusion from the Medicare program, which, while it does not necessarily protect the general public, at least protects the beneficiaries of Medicare. Analogous restraining sanctions also exist for dealing with problems in institutions. For example, authorities can close or place a seriously deficient nursing home under receivership.[37]

Sanctions can also serve a deterrent function. The single most important assurance of quality medicine is the professional's desire to provide good medical care based on an indeterminate mix of professional ethics, personal self-esteem, concern for reputation, and fear of sanctions that may result from a medical error. The more marginal the professional and the greater that person's temptation to engage in unethical or illegal behavior, the more we must rely on deterrence for our protection. Fear of license revocation might suffice to keep the physician inclined to defraud or to sexually abuse his patients from acting. This fear may even force the substance abuser into treatment. Obviously, however, some physicians have such serious impairments that they will not respond to deterrence, and the incompetent physician may not know how to respond.

Deterrence is also one of the primary purposes of the medical malpractice system. Most agree that medical malpractice litigation is not a terribly effective system of compensation. It undercompensates many victims of medical error, overcompensates others, and imposes wholly unreasonable administrative costs.[38] On the other hand, it does have a deterrent effect of undetermined extent.[39] Moreover, it is arguable that the medical malpractice system's deterrent effect is greatest in dealing with the problem that is most intractable to other regulatory approaches — the occasional mistake.

Because medical malpractice liability insurance is by and large not experience-rated, the threat of litigation probably has little deterrent effect on the truly incompetent or seriously impaired physician (though such a physician may have reason to fear the disciplinary system). A competent doctor, on the other hand, realistically has little fear of license revocation but is not immune from malpractice litigation if a momentary inadvertence has disastrous consequences. Therefore, to the

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[37] *See supra* note 35, § 4213(a)(2)(A)(iii), at 1330-214 to -215.

[38] Bovbjerg, *Medical Malpractice on Trial: Quality of Care is the Important Standard*, LAW & CONTEMP. PROBS., Spring 1986, at 321, 326-28.

[39] *Id.* at 335.

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extent that such errors can be prevented, the potential for malpractice liability is the primary legal stimulus for prevention.

While this result is the greatest benefit of the medical malpractice system, it is also its greatest weakness. Much of the criticism of the malpractice system comes from the fact that competent physicians face malpractice suits for aberrational errors. Thus, the Damoclean threat of malpractice litigation results in an undetermined but substantial amount of unnecessary medical treatment. Further examination of whether these costs outweigh the benefits of the system is necessary.

The potential of malpractice liability is also important for another reason: it provides the stimulus necessary to assure cooperation by professionals and institutions with the regulatory system. For example, without potential malpractice liability, hospitals would probably take a less aggressive stance in disciplining their medical staff, and professionals would lack the necessary incentive to cooperate with disciplinary bodies in identifying and sanctioning their deficient peers.

The threat of civil fines or criminal sanctions can also provide deterrence. Civil fines are increasingly used to respond to problems in nursing homes, in which fines can presumably encourage redeployment of resources or stimulate improved management to address quality problems.[40] PROs also can impose monetary penalties on physicians who commit gross errors or who repeat substantial errors.[41] The threat of jail sentences or criminal fines might also deter extreme misconduct, such as drug pushing or sexual assault on patients.

Finally, the market also provides a substantial incentive for good performance, and conversely, a deterrent against poor performance. The manifold failures of the market for medical care have been fully explored elsewhere.[42] One of the most significant of these failures is the difficulty consumers face in obtaining and effectively using information on health care quality. To the extent, however, that regulatory agencies can provide consumers with useful information, they may be able to direct market forces to play a useful role in quality assurance. HCFA's release of hospital outcome assessment data might be a first step in this effort, as might be PRO notification to Medicare beneficiaries of denial of payment for substandard care.[43]

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[40] *See* INSTITUTE OF MEDICINE, IMPROVING THE QUALITY OF CARE IN NURSING HOMES 166 (1986) (discussing civil fines).

[41] 42 U.S.C. § 1320c-5(b)(1) (1982).

[42] *See* Jost, *The Necessary and Proper Role of Regulation to Assure Quality of Health Care*, 25 HOUS. L. REV. 525, 558-72 (1988).

[43] 42 U.S.C. §§ 1320c-3(a)(1) & (2) (1982 & Supp. IV 1986).

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CONCLUSION

To this point, this Essay has largely been descriptive. This kind of description is essential for formulating an effective and coordinated program for quality regulation. Once different forms of quality deficiencies are described, identifying their causes is easier. Once one identifies these causes, and can determine their relative prevalence, one can design effective tools for diagnosing problems and prescribing their solutions.

If, for example, the most important effect of malpractice litigation is to deter occasional mistakes and to encourage cooperation with regulatory programs, proposals to abolish malpractice liability and to leave the job of regulation to state licensure boards are misguided. Licensure programs have little ability to deal with occasional errors and increasingly depend on reporting from professionals and institutions to operate effectively. Instead, an alternative tool could be created that will serve some of these purposes equally well. An alternative compensation system, for example, could be financed in part through a heavily experience-rated system of assessments on physicians. This system could sanction occasional errors even more effectively than the present system. The AMA's recent proposal that would combine the medical disciplinary system with a system that awards compensation to those injured through medical negligence[44] deserves further study.

If a substantial portion of patient injuries occur as the result of criminal conduct on physicians' part (and this certainly seems to be the focus of much of the activity of professional disciplinary bodies), perhaps we should shift some of the responsibility for protecting the public to the criminal justice system. Perhaps, as Andrew Dolan has suggested,[45] the criminal courts ought to have power to revoke or to suspend the privilege to deliver medical care, thus streamlining the restraining system and increasing deterrence.

If a substantial portion of medical error is the result of impairment, strategies that focus on rehabilitating impaired professionals or removing them from practice should take high priority. Strategies aimed at deterring those who can rationally calculate the results of their actions

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[44] *See* AMA SPECIALTY SOCIETY MEDICAL LIABILITY PROJECT, A PROPOSED ALTERNATIVE TO THE CIVIL JUSTICE SYSTEM FOR RESOLVING MEDICAL LIABILITY DISPUTES 19-66 (1988).

[45] *See* A. DOLAN, AN EVALUATION OF THE PERFORMANCE OF THE MEDICAL DISCIPLINARY BOARDS OF STATE GOVERNMENTS: STRUCTURE, PROCESS AND OUTCOME 322-25 (unpublished doctoral dissertation, on file with Columbia University School for Public Health).

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will be less successful if impairment interferes with rational functioning. On the other hand, if medical error is the result of incompetence, educational strategies may be more effective. Problems that result from poor management and resource allocation in facilities may respond to civil fine assessments, or, in severe cases, to receivership. If, as some suspect, medical errors primarily result from the generally unscientific nature of much of medicine, regulatory efforts should be focused on validating medical procedures as well as on improving the work of professionals and institutions.[46]

Further, as one better understands the causes and cures of medical error, one can better articulate and coordinate systems of data collection and quality assurance. Medical licensure boards should certainly have access to PRO screening data. Licensure boards should also relay validated complaints to the PROs. As medical boards and PROs process an increasing volume of data, it will become easier to identify patterns that will lead to earlier identification of truly impaired and incompetent physicians.

Recent state and federal quality assurance initiatives — the Health Care Quality Improvement Act, the PRO program, state licensure reform — have made important strides towards addressing quality problems that exist in health care delivery. However, continued research and analysis as suggested in this Essay are needed to identify the causes of quality deficiencies, to create new tools for quality assurance, and to deploy and coordinate properly the tools now available.

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[46] *See* Roper, Winkenwerder, Hackbarth & Krakauer, *Effectiveness in Medical Care: An Initiative to Evaluate and Improve Medical Practice*, 319 New. Eng. J. Med. 1197 (1988).

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