Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities

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INTRODUCTION

The 1980s have witnessed sharp and dramatic increases in the size and frequency of medical malpractice claims and in the cost of malpractice insurance for health care providers.[1] Some evidence suggests

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[1] *See* U.S. GENERAL ACCOUNTING OFFICE (GAO), MEDICAL MALPRACTICE: NO AGREEMENT ON THE PROBLEMS OR SOLUTIONS (1986) [hereafter GAO, NO AGREEMENT]. *See generally* GAO, MEDICAL MALPRACTICE CHARACTERISTICS OF CLAIMS CLOSED IN 1984 (1987) [hereafter GAO, 1984 CLAIMS]; DEPARTMENT OF HEALTH & HUMAN SERVS. (DHHS), REPORT OF THE TASK FORCE ON MEDICAL LIABILITY AND MALPRACTICE 3-6 (1987) [hereafter DHHS TASK FORCE REPORT].

that physicians have responded by practicing "defensive" medicine and adopting many inefficient practice patterns.[2] These practices have contributed to overutilization of medical services in the American health care system.[3]

The 1980s have also witnessed continued inflation in the cost of health care services at rates exceeding inflation in other sectors of the economy.[4] In response, federal and state governments, and private health insurers have put significant pressure on physicians to cut costs. Many payment reforms, which public and private health insurers have adopted, transfer the financial risk of providing costly services from the health insurer to the health care provider.[5] Concerned that health care providers cut corners in delivering care, or "game" utilization of health care services to maximize payment, health insurers and others who pay for care have developed methods to ensure that health care services are utilized appropriately and are of high quality. For example, Congress created Peer Review Organizations (PROs), to monitor the utilization

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[2] *See* Harris, *Defensive Medicine: It Costs, But Does it Work?*, 257 J. A.M.A. 2801 (1987).

[3] *See* Zuckerman, *Medical Malpractice: Claims, Legal Costs, and the Practice of Defensive Medicine*, HEALTH AFF., Fall 1984, at 128.; AMERICAN MEDICAL ASS'N (AMA), PROFESSIONAL LIABILITY IN THE 1980S 3 (1985) [hereafter AMA, 1980s LIABILITY].

[4] *See* Arnett, Freeland, McKusick & Waldo, *National Health Expenditures, 1986-2000*, HEALTH CARE FINANCING REV., Summer 1987, at 1.

[5] Payment reforms in recent years are of three types. *See* Kinney, *Making Hard Choices Under the Medicare Prospective Payment System: One Administrative Model for Allocating Medical Resources Under a Government Health Insurance Program*, 19 IND. L. REV. 1151, 1151 nn.1, 2 & 4 (1986). The first is rate regulation by a public authority or private insurer which, directed chiefly at institutional providers, regulates the amount paid for a unit of services, *i.e.*, the price per case as under the Medicare prospective payment system, or even the entire amount the program will annually pay an institution under revenue caps or budget review strategies. *See id.* at 1151 n.1. In many but not all of these rate regulation schemes, the provider is put at risk for services provided patients in excess of preset norms upon which payment is based. *Id.* The second type of payment reform is the preferred provider organization (PPO), which is an arrangement between selected providers and at least one group purchaser whereby the services of the providers are purchased for a specified group of individuals at a negotiated rate. *See id.* at 1151 n.2. The third type of payment reforms are those characterized by prepaid health plans, in which the consumer or someone on her behalf pays a fixed amount to the provider, and in return, the provider furnishes any volume of covered health care services regardless of cost. *See id.* at 1151 n.4. A Health Maintenance Organization (HMO) is an example of a prepaid health plan. A prepaid health plan is distinguished from conventional health insurance in that the provider rather than the health insurance company is at risk for the cost of services to beneficiaries over and above the premiums. *Id.* at 1151 n.2.

and quality of inpatient hospital services for Medicare beneficiaries.[6] State Medicaid programs and private insurance plans have instituted similar utilization and quality review programs.[7] These developments have precipitated a greater interest among payers in ways to measure the "outcome" of medical treatment to be sure that payees are purchasing high quality services in the wake of cost containment efforts.[8] Further, these developments have spawned scholarly speculation as to how these payment reforms and accompanying standard setting activities will influence the standard of care in malpractice cases.[9]

Traditionally physicians resisted attempts to quantify or even define what constitutes quality in the performance of specific procedures or treatment of specific diseases. However, this situation has changed markedly in recent years. The leadership of American medicine is actively attempting to define quality medical care with respect to specific diseases and procedures as well as delineate when health care services are appropriately provided. In 1987, the Council of Medical Specialty Societies convened a conference on "Standards of Quality in Patient Care: The Importance and Risks of Standard Setting."[10] A consensus emerged from the conference that the medical profession and specialty societies need to set standards to define quality medical care. The leading professional organizations for physicians, the American Medical Association (AMA) and the American College of Physicians (ACP), have adopted formal policies endorsing the development of standards for clinical practice.[11]

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[6] *See* Peer Review Improvement Act of 1982, Pub. L. No. 97-248, § 141-150, 96 Stat. 381, 385 (1982) (enacted as part of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, §§ 141-150, 96 Stat. 324 (amending 42 U.S.C. §§ 1320c-1 to 1320c-12 (1982 & Supp. III 1985); 42 C.F.R. pts. 461-478 (1988))).

[7] *See* 42 U.S.C. § 1396a (1982); 42 C.F.R. pt. 456 (1988); *see also* Jost, *The Necessary and Proper Role of Regulation to Assure the Quality of Health Care*, 25 HOUS. L. REV. 525, 565-68 (1988).

[8] *See* Ellwood, *Shattuck Lecture — Outcomes Management: A Technology of Patient Experience*, 318 NEW ENG. J. MED. 1549 (1988).

[9] *See, e.g.*, Eddy, *Costs: Impact on the Standard of Care*, in MEDICAL MALPRACTICE (D. Yaggy & P. Hodgson eds. 1986); Morreim, *Cost Containment and the Standard of Medical Care*, 75 CALIF. L. REV. 1719 (1987); Note, *Rethinking Medical Malpractice Law in Light of Medicare Cost-Cutting*, 98 HARV. L. REV. 1004 (1985).

[10] COUNCIL OF MEDICAL SPECIALTY SOCIETIES, STANDARDS OF QUALITY IN PATIENT CARE: THE IMPORTANCE AND RISKS OF STANDARD SETTING (Sept. 25-26, 1987).

[11] *See* DEPARTMENT OF PUB. POLICY, AMERICAN COLLEGE OF PHYSICIANS, QUALITY ASSURANCE AND UTILIZATION REVIEW (1984); AMA, DIAGNOSTIC AND THERAPEUTIC TECHNOLOGY ASSESSMENT, DATTA: THE FACTS (1987).

These developments have resulted in an increase in the number and type of standards regarding the appropriate utilization and quality of health care services. These standards may have an important impact on day-to-day clinical practice and on the medical malpractice climate because, as explained below, negligence law requires that a defendant physician's conduct be measured against a standard of care established by the medical profession before liability can be imposed.

The purpose of this Article is to analyze how medical standards may be used in medical malpractice litigation. Part I describes the types of medical standards in effect today. Part II explains how the standard of care is now established in medical malpractice lawsuits and how medical standards may be used in establishing the applicable standard of care. This Article concludes that medical standards will and should play a prominent role in setting the standard of care in malpractice cases.

I. Typology of Medical Standards

Basically, two major types of medical standards[12] have evolved: (1) clinical practice protocols and (2) utilization review protocols. These two categories can be distinguished further according to the purpose for which the standard is to be used and the author or sponsorship of the standard.

A. Clinical Practice Protocols

Clinical practice protocols are disease or procedure specific protocols that describe or recommend specific steps in the diagnosis or treatment of particular diseases or conditions or the performance of medical procedures. Most clinical practice protocols are written by physicians for physicians in the medical management of their patients and are intended to be recommendations only.

However, payers are increasingly using clinical practice protocols and other medical standards as a basis for making payment decisions. For example, in the early 1980s, the Blue Cross and Blue Shield Association was concerned that admission testing of hospital patients was excessive. In response, the American College of Physicians developed standards in its Medical Necessity Program describing appropriate tests

[12] The Authors are aware that the term "standards" is controversial in the medical community and has numerous meanings. The term is used in a very general sense in this Article.

to provide patients upon admission to the hospital.[13] These standards are now used by Blue Cross plans around the country to determine what tests administered to hospital patients should be reimbursed.[14] Similarly, in recent years, the Medicare program has based policies and decisions on coverage of medical procedures and technologies on clinical practice protocols, technology assessments, and other standards developed by medical organizations.[15]

An important factor in the development of clinical practice protocols and their role in malpractice litigation is the sophistication of health services research conducted in the last decade by physicians on the efficacy and cost effectiveness of specific medical treatments. These researchers have described sharp differences in clinical practices among different geographic areas.[16] John E. Wennberg, M.D., has conducted extensive research on geographic variations in medical practice[17] and

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[13] *See* TECHNOLOGY MANAGEMENT DEP'T, HEALTH BENEFITS MANAGEMENT DIV., BLUE CROSS & BLUE SHIELD ASS'N, MEDICAL NECESSITY PROGRAM DIAGNOSTIC TESTING GUIDELINES (1987).

[14] *See* Freudenheim, *New Guidelines on Giving Tests in Medical Care*, N.Y. Times, Apr. 2, 1987, at A12, col. 1.

[15] *See* MEDICARE PROGRAM, HEALTH CARE FIN. ADMIN., PROCEDURES FOR MEDICAL SERVICES COVERAGE DECISIONS; Request for Comments, 52 Fed. Reg. 15560 (1987). *See generally* Kinney, *National Coverage Policy Under the Medicare Program: Problems and Proposals for Change*, 32 ST. LOUIS U.L.J. 869 (1988); Ruby, Banta & Burns, *Medicare Coverage, Medicare Costs, and Medical Technology*, 10 J. HEALTH POL., POL'Y & L. 141 (1985). On January 30, 1989, HCFA issued a proposed rule outlining criteria and procedures for making medical services coverage decisions that relate to health care technology. "Medicare Program; Criteria and Procedures for Making Medical Services Coverage Decisions That Relate to Health Care Technology," 54 Fed. Reg. 4302 (1989) (to be codified at 42 C.F.R. pts. 400, 405).

[16] *See* Brook, Lohr, Chassin, Kosecoff, Fink & Solomon, *Geographic Variations in the Use of Services: Do They Have Any Clinical Significance*, HEALTH AFF., Summer 1984, at 63; Caper, *Variations in Medical Practice: Implications for Health Policy*, HEALTH AFF., Summer 1984, at 110, 113-18; Eddy, *Variations in Physician Practice: The Role of Uncertainty*, HEALTH AFF., Summer 1984, at 74 *passim*; Wennberg, *Dealing with Medical Practice Variations: A Proposal for Action*, HEALTH AFF., Summer 1984, at 6 *passim*; *cf.* Schwartz, *The Role of Professional Medical Societies in Reducing Practice Variations*, HEALTH AFF., Summer 1984, at 91.

[17] *See, e.g.*, Fowler, Wennberg, Timothy, Barry, Mulley & Hanley, *Symptom Status and Quality of Life Following Prostatectomy*, 259 J. A.M.A. 3018 (1988); Wennberg, Freeman & Culp, *Are Hospital Services Rationed in New Haven or Over-Utilized in Boston?*, I The Lancet 1185 (1987); Wennberg, Mulley, Hanley, Timothy, Fowler, Rous, Barry, McPherson, Greenberg, Soule, Bubolz, Fisher & Malenka, *An Assessment of Prostatectomy for Benign Urinary Tract Obstruction: Geographic Variations and the Evaluation of Medical Care Outcomes*, 259 J. A.M.A. 3027 (1988); *cf.* Wennberg, McPherson & Caper, *Will Payment Based On Diagnosis-Related Groups*

has exhorted the medical profession to apply the same scientific analysis in determining the efficacy of clinical procedures as is now required for new drugs.[18] Robert Brook, M.D., and his researchers at the Rand Corporation have convened medical experts to assess the appropriate application of certain medical procedures. Brook and his team have then conducted studies to determine the extent of the inappropriate use of certain medical procedures in practice.[19] David Eddy, M.D., Ph.D., of Duke University, has employed quantitative methodologies to predict the likely medical outcomes of certain clinical procedures.[20] Further, several prestigious physician researchers have called for an expansion of research to develop clinical prediction rules to guide physicians in the treatment of disease.[21] Finally, the Robert Wood Johnson Foundation is now funding research that develops clinical practice protocols specifically designed to prevent malpractice claims.[22]

Control Hospital Costs?, 311 N. ENG. J. MED. 295 (1984).

[18] *See* Wennberg, *supra* note 16, at 6; Wennberg, *Improving the Medical Decision-Making Process*, HEALTH AFF., Spring 1988, at 99; *see also* Wennberg, *Commentary: On Patient Need, Equity, Supplier-Induced Demand, and the Need to Assess the Outcome of Common Medical Practices*, 23 MED. CARE 512 (1985).

[19] *See* Brook & Lohr, *Efficacy, Effectiveness, Variations, and Quality: Boundary-Crossing Research*, 23 MED. CARE 710 (1985); *see also* Kosecoff, Brook, Fink, Kamberg, Roth, Goldberg, Linn, Clark, Newhouse & Delbanco, *Providing Primary General Medical Care in University Hospitals: Efficiency and Cost*, 107 ANNALS OF INTERNAL MED. 399 (1987); Merrick, Fink, Park, Brook, Kosecoff, Chassin & Solomon, *Derivation of Clinical Indication for Carotid Endarterectomy by an Expert Panel*, 77 AM. J. PUB. HEALTH 187 (1987); Park, Fink, Brook, Chassin, Kahn, Merrick, Kosecoff & Solomon, *Physician Ratings of Appropriate Indications for Six Medical and Surgical Procedures*, 76 AM. J. PUB. HEALTH 766 (1986); Winslow, Solomon, Chassin, Kosecoff, Merrick & Brook, *The Appropriateness of Carotid Endarterectomy*, 318 NEW ENG. J. MED. 721 (1988); *cf.* Chassin, Kosecoff, Winslow, Kahn, Merrick, Keesey, Fink, Solomon & Brook, *Does Inappropriate Use Explain Geographic Variations in the Use of Health Care Services?*, 258 J. A.M.A. 2533 (1987); Chassin, Brook, Park, Keesey, Fink, Kosecoff, Kahn, Merrick & Solomon, *Variations in the Use of Medical and Surgical Services by the Medicare Population*, 314 NEW ENG. J. MED. 285 (1986); Fink, Siu, Brook, Park & Solomon, *Assuring the Quality of Health Care for Older Persons: An Expert Panel's Priorities*, 258 J. A.M.A. 1905 (1987).

[20] *See, e.g.*, Eddy, *supra* note 9, at 30; Eddy, Neugent, Eddy, Coller, Gilbertsen, Gottlieb, Rice, Sherlock & Winawer, *Screening for Colorectal Cancer in a High-Risk Population: Results of a Mathematical Model*, 92 GASTROENTEROLOGY 682 (1987); Eddy, Hasselblad, McGivney & Hendee, *The Value of Mammography Screening in Women Under Age 50 Years*, 259 J. A.M.A. 1512 (1988).

[21] *See* Wasson, Sox, Neff & Goldman, *Clinical Prediction Rules: Applications and Methodological Standards*, 313 NEW ENG. J. MED. 793 (1985).

[22] *See* Tomich, *AFIP Unit to Study Liability Issues, Develop Protocol for "Preven-*

For the most part, clinical practice protocols are developed in three ways: (1) by individual physicians for use in a local context such as a hospital; (2) by commercial enterprises with physician input; and (3) by national medical specialty societies, voluntary health organizations or government agencies. The authorship and sponsorship of clinical practice protocols have important implications for their roles in medical malpractice litigation. Thus, the subsequent discussion of clinical practice protocols will distinguish between professionally sponsored and individually sponsored protocols.

1. Professionally Sponsored Clinical Practice Protocols

Perhaps the most important clinical practice protocols from a malpractice perspective are those developed by physicians under the auspices of national medical specialty societies, voluntary health organizations, or the Public Health Service (PHS). As noted above, the development of clinical practice protocols by these organizations has been a relatively recent phenomenon, recognizing from health services research that standards by which to measure and assess quality of medical care can be developed more rigorously than in the past.

The medical professional organizations have played a prominent role in this development of clinical practice protocols. The American Medical Association (AMA) has been quite active in developing recommendations regarding the proper provision of medical care in a variety of contexts. The AMA's Council on Scientific Affairs, using panels of experts, conducts studies and publishes reports that outline proper procedures for the treatment of many diseases and conditions and include informal standards and recommendations.[23] The AMA's Diagnostic And Therapeutic Technology Assessment (DATTA) program conducts assessments of medical technologies. Specifically, through a formal process of synthesizing expert opinion and literature reviews, DATTA develops and publicizes conclusions about the safety and effectiveness of medical technologies.[24] The AMA publishes the DATTA reports and the reports of its Council on Scientific Affairs in its journal, the *Journal of the American Medical Association* (JAMA).

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tion," U.S. MED., Dec. 1987, at 3.

[23] *See, e.g.*, COUNCIL ON SCI. AFF., AMA, DEMENTIA (1985); COUNCIL ON SCI. AFF., AMA, TOXIC SHOCK (1985); COUNCIL ON SCI. AFF., AMA, STATEMENT ON LIVER TRANSPLANTATION (1986).

[24] *See* AMA, DATTA: AN AMA PROGRAM IN MEDICAL TECHNOLOGY ASSESSMENT (1987); Jones, *The American Medical Association's Diagnostic and Therapeutic Technology Assessment Program*, 250 J. A.M.A. 387 (1983).

The activities of medical specialty societies in developing standards is diverse, but almost all are engaged in some way. The ACP has been extremely active, indeed innovative, in the development of medical standards. Through its Clinical Efficacy Assessment Project, ACP has published a wide range of standards and guidelines for the use of medical technologies and the management of medical conditions.[25] The standards and guidelines developed in the Clinical Efficacy Assessment Project are disseminated through its Clinical Efficacy Reports and published in the *Annals of Internal Medicine*.[26] In addition, as noted above, ACP, working with the Blue Cross and Blue Shield Association, developed the Blue Cross' Medical Necessity Program to assess costly, but commonly used, medical tests and procedures for determining coverage of services under Blue Cross health insurance programs.[27] Finally, ACP has recently published a manual specially addressed to primary care physicians on the use and interpretation of common diagnostic tests.[28]

Other specialty societies in the field of internal medicine are also active in developing clinical practice protocols. The American Society of Internal Medicine has developed some guidelines for the treatment of disease in outpatient settings.[29] The American College of Cardiology, through its Cardiovascular Norms Committee, has developed guidelines for the use of medical technologies (*e.g.*, cardiac pacemakers) in the treatment of heart disease.[30] Other medical specialty societies in the internal medicine field have few clinical practice protocols or other medi-

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[25] *See, e.g.*, CLINICAL EFFICACY ASSESSMENT PROGRAM, AM. COLLEGE OF PHYSICIANS, PROCEDURE MANUAL (1986); CLINICAL EFFICACY ASSESSMENT PROJECT, AM. COLLEGE OF PHYSICIANS, RECOMMENDATIONS 1981-86 (1987).

[26] *See, e.g.*, Centor, Meier & Dalton, *Throat Cultures and Rapid Tests for Diagnosis of Group A Streptococcal Pharyngitis*, 105 ANNALS INTERNAL MED. 892 (1986); Goldberger & O'Konski, *Utility of the Routine Electrocardiogram Before Surgery and on General Hospital Admission*, 105 ANNALS INTERNAL MED. 552 (1986); Raffin, *Indications for Arterial Blood Gas Analysis*, 105 ANNALS INTERNAL MED. 390 (1986); Sox, *Probability Theory in the Use of Diagnostic Tests*, 104 ANNALS INTERNAL MED. 60 (1986); Tape & Mushlin, *The Utility of Routine Chest Radiographs*, 104 ANNALS INTERNAL MED. 663 (1986).

[27] *See* LEWIN & ASSOCS., INC., A FORWARD PLAN FOR MEDICARE COVERAGE AND TECHNOLOGY ASSESSMENT, at B.23-B.25 (1987).

[28] *See* AMERICAN COLLEGE OF PHYSICIANS, COMMON DIAGNOSTIC TESTS: USE AND INTERPRETATION (1987).

[29] *See supra* note 20.

[30] *See* JOINT AM. COLLEGE OF CARDIOLOGY/AM. HEART ASS'N TASK FORCE ON ASSESSMENT OF CARDIOVASCULAR PROCEDURES, GUIDELINES FOR PERMANENT CARDIAC PACEMAKER IMPLANTATION (1984).

cal standards, but are engaged in some standard setting activity. For example, the American Academy of Neurology has a formal process for responding to inquiries from insurers and others about appropriate uses of medical procedures.[31]

The American Academy of Pediatrics (AAP) has also been extensively engaged in the development of medical standards for many years. For example, the *Report of the Committee on Infectious Disease*, colloquially called the "Red Book," provides current information and consensus on the effective control of pediatric infectious disease.[32] Pediatricians use the AAP's "Red Book" extensively in the management of infectious disease. The AAP now publishes guidelines and manuals for a wide variety of subjects and will soon publish guidelines for perinatal care and supervising the health of children.[33]

The American College of Surgeons (ACS) has published a statement of principles, some of which address appropriate management of surgical patients.[34] In addition, ACS publishes manuals on the practice of surgery in specific settings[35] and other publications containing recommendations for good surgical practice in the treatment of cancer, trauma and other conditions.[36] The American Society of Anesthesiologists has also become especially prolific in publishing standards and recommendations for the organization of anesthesia practice[37] and for proper management of anesthesia in various clinical settings.[38]

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[31] *See* Letter from H.D. Garretson, M.D., Ph.D., President of the American Ass'n of Neurological Surgeons, to Mr. Francis Ohnsorg, Blue Cross & Blue Shield of Minnesota, Medical Policy Comm. (Oct. 26, 1987) (discussing reimbursement criteria for extracranial/intracranial by-pass (EC-IC) procedures); *see also* AMERICAN COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS, TECHNICAL BULLETINS (1988); AMERICAN COLLEGE OF PHYSICIANS, POSITION STATEMENTS (1986).

[32] *See* AMERICAN ACADEMY OF PEDIATRICS, REPORT OF THE COMMITTEE ON INFECTIOUS DISEASE (1988).

[33] *See* AMERICAN ACADEMY OF PEDIATRICS, PUBLICATIONS AND SERVICES FOR PEDIATRIC HEALTH CARE PROFESSIONALS (1988).

[34] *See* AMERICAN COLLEGE OF SURGEONS, STATEMENTS ON PRINCIPLES (1985).

[35] *See, e.g.*, PRE- AND POSTOPERATIVE CARE COMM., AMERICAN COLLEGE OF SURGEONS (ACS), MANUAL ON PREOPERATIVE AND POSTOPERATIVE CARE (3d ed. 1983); PRE- AND POSTOPERATIVE CARE COMM., ACS, MANUAL OF SURGICAL INTENSIVE CARE (1977); SUBCOMM. ON CONTROL OF SURGICAL INFECTION, PRE- AND POSTOPERATIVE CARE COMM., ACS, MANUAL ON CONTROL OF INFECTION IN SURGICAL PATIENTS (2d ed. 1984).

[36] *See* ACS, PUBLICATIONS AND SERVICES 1988 (1988).

[37] *See, e.g.*, AMERICAN SOC'Y OF ANESTHESIOLOGISTS, THE ORGANIZATION OF AN ANESTHESIA DEPARTMENT (1987).

[38] *See, e.g.*, AMERICAN SOC'Y OF ANESTHESIOLOGISTS, AMBULATORY SURGICAL FACILITIES (1983); AMERICAN SOC'Y OF ANESTHESIOLOGISTS, GUIDELINES FOR

The American College of Obstetrics and Gynecology (ACOG) is in a state of transition with respect to the publication of standards and recommendations for the practice of obstetrics and gynecology. ACOG is presently revising its clinical practice protocols and other medical standards and recommendations.[39] ACOG also publishes technical bulletins, written by practitioners under ACOG's direction, designed to provide practitioners with information on the latest proven medical procedures.[40]

The American Academy of Family Physicians does not publish clinical practice protocols or other medical standards because the academy maintains that there is wide variation throughout the country in the practice of family medicine and medical standards are best developed at the local level.[41] However, the Academy convened a task force in August of 1988 to consider whether to develop clinical practice protocols that are national in scope. This task force will convene in early 1989 to identify several specific disease areas for which protocols would be useful and begin developing such protocols.[42]

Voluntary health organizations have also gotten involved in the development of clinical practice protocols. The three major voluntary health organizations — the American Heart Association (AHA), the American Cancer Society, and the American Diabetes Association (ADA) — are excellent examples of this effort. The AHA has developed standards and recommendations for the management of cardiac patients in a variety of settings, for example, in recommending appropriate diets for the prevention of Coronary Artery Disease and appropriate exercise for patients with heart disease or at risk of heart disease.[43] The AHA has also published an extensive guide, *The Exercise*

CRITICAL CARE IN ANESTHESIOLOGY (1986).

[39] *See* COUNCIL ON MEDICAL SPECIALTY SOCIETIES, *supra* note 10, at 55-57.

[40] *See* AMERICAN COLLEGE OF OBSTETRICS AND GYNECOLOGY, TECHNICAL BULLETINS (1988).

[41] Telephone interview with Karen Carter, Manager, Information Services Department, American Academy of Family Physicians (Jan. 8, 1989).

[42] *Id.*

[43] *See, e.g.*, AMERICAN HEART ASS'N (AHA), DIET AND CORONARY HEART DISEASE (1978); AHA, DIET MODIFICATION TO CONTROL HYPERLIPEDMIA (1978); AHA, RISK FACTORS AND CORONARY DISEASE: A STATEMENT FOR PHYSICIANS (1980); COMMITTEE ON ELECTROCARDIOGRAPHY AND CARDIAC ELECTROPHYSIOLOGY, COUNCIL ON CLINICAL CARDIOLOGY, AHA, TASK FORCE RECOMMENDATIONS FOR STANDARDS OF INSTRUMENTATION AND PRACTICE IN THE USE OF AMBULATORY ELECTROCARDIOLOGY (1985); COMMITTEE ON EXERCISE, AHA, EXERCISE TESTING AND TRAINING OF INDIVIDUALS WITH HEART DISEASE OR AT HIGH RISK FOR ITS DEVELOPMENT: A HANDBOOK FOR PHYSICIANS (1975); COMMITTEE ON

Standards Book, for use in conducting exercise tests on heart patients.[44] The ADA, in direct consultation with other medical specialty societies, has prepared guides with protocols for the diagnosis and treatment of both juvenile and adult diabetics.[45] The ADA's *Long-Range Plan* calls for the adoption and development of standards for the treatment of diabetes.[46] The American Cancer Society has also been active in setting medical standards. For example, the American Cancer Society has adopted protocols for the use of pap smears in diagnosing cervical cancer, the use of hemocult and other techniques in diagnosing colorectal cancer, and the use of mammography in diagnosing breast cancer.[47]

2. Government-Sponsored Clinical Practice Protocols and Other Medical Standards

The federal government, in its capacities as chief financier of biomedical research and major health insurer, has played an important role in the development of medical standards. The PHS within the Department of Health and Human Services (DHHS)[48] and the Health Care Financing Administration (HCFA), also within DHHS and

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RHEUMATIC FEVER AND INFECTIVE ENDOCARDITIS, COUNCIL OF CARDIOVASCULAR DISEASE IN THE YOUNG, AHA, PREVENTION OF RHEUMATIC FEVER (1985); NUTRITION COMM., AHA, DIETARY GUIDELINES FOR HEALTHY AMERICAN ADULTS (1986); SUBCOMMITTEE ON EXERCISE/CARDIAC REHABILITATION, AHA, STATEMENT ON EXERCISE (1981); WORKING GROUP TO THE SUBCOMM. ON SMOKING, AHA, PUBLIC POLICY ON SMOKING AND HEALTH: TOWARD A SMOKE-FREE GENERATION BY THE YEAR 2000 (1988).

[44] SUBCOMMITTEE ON REHABILITATION TARGET ACTIVITY GROUP, AHA, THE EXERCISE STANDARDS BOOK (1979).

[45] *See, e.g.*, AMERICAN DIABETES ASS'N (ADA), GUIDES; ADA, PHYSICIAN'S GUIDE TO INSULIN-DEPENDENT (TYPE I) DIABETES: DIAGNOSIS AND TREATMENT (1988); ADA, PHYSICIAN'S GUIDE TO NON-INSULIN-DEPENDENT (TYPE I) DIABETES: DIAGNOSIS AND TREATMENT (2d ed. 1988).

[46] *See* ADA, LONG-RANGE PLAN (1988).

[47] *See* AMERICAN CANCER SOC'Y, COLORECTAL POLYPS: PATHOLOGIC DIAGNOSIS AND CLINICAL SIGNIFICANCE (1985); AMERICAN CANCER SOC'Y, DETECTING COLON AND RECTUM CANCER (1984); AMERICAN CANCER SOC'Y, DYSPLASIA, CARCINOMA IN SITU, AND EARLY INVASIVE CERVICAL CARCINOMA (1984); AMERICAN CANCER SOC'Y, MAMMOGRAPHY: TWO STATEMENTS OF THE AMERICAN CANCER SOC'Y (1984); *see also* AMERICAN CANCER SOC'Y, MAMMOGRAPHY GUIDELINES 1983: BACKGROUND STATEMENT AND UPDATE OF CANCER-RELATED CHECKUP GUIDELINES FOR BREAST CANCER DETECTION IN ASYMPTOMATIC WOMEN AGE 40-49 (1983); AMERICAN CANCER SOC'Y, SUMMARY OF CURRENT GUIDELINES FOR THE CANCER-RELATED CHECKUP: RECOMMENDATIONS (1988).

[48] *See infra* notes 49-61 and accompanying text.

which administers the Medicare and Medicaid programs,[49] have been the most prominent government agencies involved in the development of medical standards. The Department of Defense health care programs have also been particularly active.[50]

The National Institutes of Health (NIH), within PHS, has played a critical role in developing medical standards. Periodically, the Office of Medical Applications of Research (OMAR), with the NIH, convenes Consensus Development Conferences to evaluate new and established medical technologies and associated treatment modalities.[51] In these conferences, the NIH gathers the leading experts in the field to develop conclusions about the appropriate uses and efficacy of the modality or technology used in the treatment of disease or injury.[52]Using the information from some of these Consensus Development Conferences, the NIH has published a guide for the prevention of venous thrombosis and pulmonary embolism and the role of diet and exercise in Noninsulin-Dependent Diabetes Mellitus.[53] Other organizations within the NIH have also been actively involved in the development of standards and guidelines. For example, the National Diabetes Advisory Board has published a guide for the treatment of diabetes for primary care physicians.[54]

PHS also engages in some technology assessment to advise federal health insurance programs on coverage of new technologies.[55] The PHS

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[49] *See infra* notes 56-63 and accompanying text.

[50] *See* LEWIN & ASSOCS., INC., *supra* note 27, at 3.32.

[51] *See* OFFICE OF MEDICAL APPLICATIONS OF RESEARCH, DHHS, NIH, GUIDELINES FOR THE SELECTION AND MANAGEMENT OF CONSENSUS DEVELOPMENT CONFERENCES (1986); *see also* Greenberg, *Health Care Technology: A Small Office vs. a Big Problem*, 302 NEW ENG. J. MED. 243 (1980); Kosecoff, Kanouse, Rogers, McCloskey, Winslow & Brook, *Effects of the National Institutes of Health Consensus Development Program on Physician Practice*, 258 J. A.M.A. 2708 (1987); Perry & Kalberer, *The NIH Consensus-Development Program and the Assessment of Health Care Technologies: The First Two Years*, 303 NEW ENG. J. MED. 169 (1980).

[52] *See* Bernstein, *National Institutes of Health Consensus Development Program*, 48 CONN. MED. 513 (1984); Mullan & Jacoby, *The Town Meeting For Technology: The Maturation of Consensus Conferences*, 254 J. A.M.A. 1068 (1985).

[53] *See* OFFICE OF MEDICAL APPLICATIONS AND RESEARCH, NIH, PREVENTION OF VENUS THROMBOSIS AND PULMONARY EMBOLISM (1986); OFFICE OF MEDICAL APPLICATIONS AND RESEARCH, NIH, DIET AND EXERCISE IN NONINSULIN-DEPENDENT DIABETES MELLITUS (1986).

[54] DHHS, PHS, THE PREVENTION AND TREATMENT OF FIVE COMPLICATIONS OF DIABETES: A GUIDE FOR PRIMARY CARE PRACTITIONERS (1983).

[55] *See* Health Promotion and Disease Prevention Amendments of 1984, Pub. L. No. 98-551, § 5, 98 Stat. 2815 (codified as amended at Public Health Service Act § 305(e), 42 U.S.C. § 242c(e) (1982 & Supp. IV 1986)).

Office of Health Technology Assessment (OHTA), in the National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA), coordinates the statutorily mandated assistance of PHS in making recommendations on whether federal health insurance programs should pay for specific technologies.[56] OHTA often evaluates the uses of a technology using data, studies and opinions of other federal agencies as well as the medical community and other interested parties.[57] In particular, OHTA considers actions of the Food and Drug Administration (FDA) in its reviews of new medical devices under the Medical Device Amendments of 1976.[58] Under these amendments, the FDA must approve all medical devices that are marketed in the United States and in so doing, determines whether a device is safe and effective for the purposes stated on the manufacturer's label.[59]

Most recently, NCHSR/HCTA has initiated the National Program for the Assessment of Patient Outcomes.[60] The purpose of this research program is to evaluate patient outcomes to determine the appropriateness of these treatments and procedures, to create data bases and improve research methods used to evaluate patient outcomes, and to disseminate study results to modify clinical practice.[61]

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[56] *See* 42 U.S.C. § 242c(e)(1) (Supp. IV 1986).

[57] *See, e.g.*, NATIONAL ADVISORY COUNCIL ON HEALTH CARE TECHNOLOGY ASSESSMENT, OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH AND HUMAN SERVS., THE MEDICARE COVERAGE PROCESS (1988); NATIONAL CENTER FOR HEALTH SERVICES RES., PHS, DHHS, ANGLECHILK ANTI-REFLUX PROSTHESIS (1986); NATIONAL CENTER FOR HEALTH SERVICES RES., PHS, DHHS, CONTINUOUS POSITIVE AIRWAY PRESSURE FOR THE TREATMENT OF OBSTETRICAL SLEEP APNEA IN ADULTS (1986); NATIONAL CENTER FOR HEALTH SERVICES RES., PHS, DHHS, FULL AUTOMATED AMBULATORY BLOOD PRESSURE MONITORING OF HYPERTENSION (1986); NATIONAL CENTER FOR HEALTH SERVICES RES., PHS, DHHS, LIVER TRANSPLANTATION (1983); NATIONAL CENTER FOR HEALTH SERVICES RES., PHS, DHHS, PUBLIC HEALTH SERVICE PROCEDURES FOR EVALUATING HEALTH CARE TECHNOLOGIES FOR PURPOSES OF MEDICARE COVERAGE (1983); NATIONAL CENTER FOR HEALTH SERVICES RES., PHS, DHHS, SINGLE PHOTON ABSORPTIOMETRY FOR MEASURING BONE MINERAL DENSITY (1986).

[58] Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at Federal Food, Drug, and Cosmetic Act §§ 513-521, 21 U.S.C. §§ 301, 360(c)-(k) (1982 & Supp. III 1985)).

[59] *See id.*; Cahill, *Technology Assessment: One View from American Medicine*, 3 INT'L J. TECH. ASSESSMENT IN HEALTH CARE 693 (1985).

[60] Nat'l Center for Health Services Res. and Health Care Tech. Assessment, Program Note/Patient Outcome Assessment Research Program Extramural Assessment Teams (Nov. 1988).

[61] *See id.*; *see also* Roper, Winkenwerder, Hackbarth & Krakauer, *Effectiveness in Health Care: An Initiative to Evaluate and Improve Medical Practice*, 319 NEW ENG. J. MED. 1197, 1200 (1988).

HCFA, in developing coverage policy for the Medicare program, has become increasingly involved in the development of medical practice standards. Since the inception of the Medicare program, HCFA and its predecessors have made approximately 200 national coverage policies regarding medical technologies and procedures and continue to make about ten to twenty coverage policies each year.[62] Most of these national coverage policies have been developed in consultation with the PHS technology assessment activity described above.

In recent years, HCFA has demonstrated considerable and increasing interest in medical standard setting.[63] Just recently, HCFA announced that, in conjunction with PHS, it would become directly involved in the effort to develop standards for clinical practice with its "Health Care Effectiveness Initiative."[64] One key activity of this initiative is the funding of clinical research to examine "the appropriateness and effectiveness of various procedures and interventions."[65] HCFA has already funded some studies of procedures and interventions based on PRO data, conducted by the Rand Corporation.[66] One objective of these HCFA efforts and the NCHSR/HCTA initiative referred to above, according to HCFA's Administrator, is to improve guidelines for clinical practice and thus provide more protection from malpractice liability for physicians complying with guidelines.[67]

Finally, the activities of the Institute of Medicine (IOM) in the development of medical standards are noteworthy. In 1984, Congress authorized federal support to the IOM to support creation of the Council on Health Technology.[68] The Council's purpose is to promote the development and application of appropriate health care technology assess-

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[62] *See* LEWIN & ASSOCS., INC., *supra* note 27, at 3.6 & 3.18; *see also* Kinney, *supra* note 5, at 873-83.

[63] *See* Roper & Hackbarth, *HCFA's Agenda for Promoting High-Quality Care*, HEALTH AFF., Spring 1988, at 91.

[64] *See* Roper, Winkenwerder, Hackbarth & Krakauer, *supra* note 61, at 1198.

[65] *Id.* at 1198.

[66] Brook & Lohr, *Monitoring Quality of Care in the Medicare Program*, 258 J. A.M.A. 3138 (1987); Chassin, Kosecoff, Park, Winslow, Kahn, Merrick, Keesey, Fink, Solomon & Brook, *Does Inappropriate Use Explain Geographic Variations in the Use of Health Care Services*, 258 J. A.M.A. 2533 (1987); Wenslow, Solomon, Chassin, Kosecoff, Merrick & Brook, *The Appropriateness of Carotid Endarterectomy*, 318 NEW. ENG. J. MED. 721 (1988).

[67] *See* Roper, Winkenwerder, Hackbarth & Krakauer, *supra* note 61, at 1202; *see also* DHHS TASK FORCE REPORT, *supra* note 1.

[68] *See* Health Promotion and Disease Prevention Amendments of 1984, Pub. L. No. 98-551, § 8, 98 Stat. 2815 (codified at Public Health Service Act § 309(2), 42 U.S.C. § 242n (1982 & Supp. 1985)).

ments, to review existing health care technologies and identify those which were obsolete and inappropriately used, and to fund private sector initiatives in this area.[69] In 1985, the IOM conducted a seminal study of technology assessment which renewed existing technology assessment activities and methodologies.[70] The IOM and its Council on Health Technology are now developing an initiative to coordinate technology assessment activities in the public and private sectors, and to assess medical technologies for clinical use.[71]

3. Individually Sponsored Clinical Practice Protocols

Many clinical practice protocols are developed by individual physicians — often for use in a local context, such as the physician's hospital. These protocols are of varying degrees of sophistication and most are not published or widely disseminated. Some individually sponsored protocols, however, have been developed by nationally known physicians for prestigious hospitals and are published in national medical journals. Examples of such protocols are the standard for minimal patient monitoring during anesthesia that the Department of Anesthesia at Harvard Medical School developed for use in its teaching hospitals[72] and the standards for arterial blood gas analysis developed at Stanford University School of Medicine.[73]

One type of individually sponsored protocol that is proliferating in recent years is the commercially prepared consultation guides for treatment or diagnosis of specific diseases. Such consultation guides are now available for a number of diseases including diagnosis and treatment of glaucoma[74] and diagnosis of particularly challenging cases in internal medicine.[75] Some of these services are intended to operate like an elec-

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[69] *See id.*

[70] *See* INSTITUTE OF MEDICINE (IOM), ASSESSING MEDICAL TECHNOLOGIES (1985).

[71] *See* COMMITTEE FOR EVALUATING MEDICAL TECHNOLOGIES IN CLINICAL USE, IOM, ASSESSING MEDICAL TECHNOLOGY 39 (1985); COUNCIL ON HEALTH CARE TECHNOLOGY, IOM, INTERIM REPORT (1987).

[72] *See* Eichorn, Cooper, Cullen, Ward, Maier, Philip & Seeman, *Standards for Patient Monitoring During Anesthesia at Harvard Medical School*, 256 J. A.M.A. 1017 (1986) [hereafter Eichorn, *Harvard Anesthesia Standards*].

[73] *See* Raffin, *supra* note 26, at 390.

[74] *See* Weiss, Kulikowski & Safir, *Glaucoma Consultation by Computer*, 8 COMPUTER BIOLOGY MED. 25 (1978).

[75] *See* First, Weimer, McLinden & Miller, *Localize: Computer-Assisted Localization of Peripherial Nervous System Lesions,* 15 COMPUTERS & BIOMED. RES. 525 (1982); Masarie, Miller & Myers, *Internist-I Properties: Representing Common Sense*

tronic textbook of medicine.[76] Subscription services are also available for selection of drugs to treat specific conditions.[77] While technically not clinical practice protocols, these consultation aids suggest normative approaches to making diagnosis or treatment decisions and have generated concern within the medical profession about their proper use from a legal and ethical perspective.[78]

B. Utilization Review Protocols

Utilization review is an established quality assurance and cost containment strategy. Its goal is to assess whether the health care services in a given case are medically necessary and appropriate. Basically, the utilization review process involves comparing the use of health care services for a particular patient against some established norm for the utilization of similar services for comparable patients.

A wide variety of utilization review protocols are in use today. Like clinical practice protocols, many are developed by or for individual payers either commercially or, in limited cases, with HCFA funding. Predominantly, payers use the protocols to control the utilization of hospital inpatient and ancillary services. Utilization review protocols are chiefly used in two different contexts: (1) before or during the course of an admission to determine whether continued stay or a particular treatment is medically appropriate; and (2) after discharge, to determine for payment purposes whether the stay or services rendered were medically appropriate. The protocols have an impact on clinical

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and Good Medical Practice in a Computerized Medical Knowledge BAse, 18 COMPUTERS & BIOMED. RES. 458 (1985); Miller, *Internist-I/Cadusceus: Problems Facing Expert Consulatant Programs, 23* METHOD INFO. MED. 9, 14 (1984); Miller, Poole & Myers, *Internist-I, An Experimental Computer-Based Diagnostic Consultant for General Internal Medicine*, 307 NEW ENG. J. MED. 468 (1982); Van Mlle, *Mycin: A Knowledge-Based Consultation Program for Infectious Disease Diagnosis*, 10 INT'S J. MAN-MACHINE STUD. 313 (1978).

[76] *See* First, Soffer & Miller, *QUICK (QUICK) Index to Caduceus Knowledge): Using the Internist-1/Caduceus Knowledge Base as an Electronic Textbook of Medicine*, 18 COMPUTERS & BIOMED. RES. 137 (1985).

[77] *See, e.g.*, Shortlife, Axline, Buchanan, Davis & Cohen, *A Computer-based Approach to the Promotion of Rational Clinical Use of Antimicrobials*, CLINICAL PHARMACY & CLINICAL PHARMACOLOGY 259 (1976); Shortlife, Davis, Axline, Buchanan, Green & Cohen, *Computer-Based Consultations in Clinical Therapeutics: Explanation and Rule Acquisition Capabilities of the MYCIN System*, 8 COMPUTERS & BIOMED. RES. 303 (1975).

[78] *See* Miller, Schnaffner & Meisel, *Ethical and Legal Issues Related to the Use of Computer Programs in Clinical Medicine*, 102 ANNALS OF INTERNAL MED. 529 (1985).

practice because physicians often feel pressure to conform their treatment of patients to the utilization review protocol.

HCFA has served as a strong catalyst for the development and use of utilization review protocols. By law, Peer Review Organizations (PROs) must develop standards for the utilization of inpatient hospital services in their areas and for quality of care services.[79] PRO regulations and program instructions require PROs to specify norms, criteria and standards for review and prescribe the manner in which they must be established.[80] Also, other Medicare contractors, with HCFA's encouragement, and in the case of home health benefits by statute,[81] often use "screens" to identify claims for more conventional services in which the items or services provided exceed preset norms as to durations, frequency or intensity of the utilization of such services.[82] These screens are used for a wide variety of Medicare benefits including physician, home health, and skilled nursing home services.

Recent years have witnessed the development and widespread dissemination of several utilization review protocols. One of the most widely used standards is the Appropriateness Evaluation Protocol (AEP), developed by Gertman and Restuccia at Boston University with HCFA funding.[83] The AEP measures whether a particular admission or day of stay is appropriate given the patient's treatment and use of services. The AEP is generally used by Blue Cross plans and other insurers, particularly those using cost-based reimbursement payment methodologies, for pre-admission or concurrent review of hospitalization as well as post-discharge review for payment purposes.

Several utilization review protocols also measure severity of illness and account for more variables regarding the patient's condition in order to identify more accurately the appropriateness of hospitalization

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[79] *See* 42 U.S.C. §§ 1153(c)(7), 1154(a)(6) (1982 & Supp. IV 1986).

[80] *See* 42 C.F.R. § 466.100 (1988); *see also* 2 Medicare & Medicaid Guide (CCH) ¶ 12,870 (1987).

[81] 42 U.S.C. § 1395y(f).

[82] *See* GAO, IMPROVING MEDICARE AND MEDICAID SYSTEMS TO CONTROL PAYMENTS FOR UNNECESSARY PHYSICIANS' SERVICES (1983). *See generally Issues Related to Medicare Contracting: Hearings Before the Subcomm. on Health of the House Comm. on Ways and Means*, 99th Cong., 2d Sess. (1986).

[83] *See* Gertman & Restuccia, *The Appropriateness Evaluation, Protocol: A Technique for Assessing Unnecessary Days of Hospital Care*, 19 MED. CARE 855, 868-69 (1981); AEP REVIEW MANAGER'S MANUAL (1984). Another utilization review protocol which refines and combines the approaches of ISD and AEP is the Standardized Medreview Instrument (SMI) developed by SysteMetrics, Inc. *See* SYSTEMETRICS, INC., STANDARDIZED MEDREVIEW INSTRUMENT (SMI) REVIEWERS' TRAINING MANUAL 5 (1983).

and the use of services for particular patients. For example, the ISD Review System[84] developed by Lamprey at InterQual for use by hospital utilization review committees, not only measures whether services are medically necessary and whether services provided are rendered in an appropriate setting, but also whether quality of services meet professionally recognized standards of care.[85] The ISD Review System expressly takes into account the patient's diagnosis as well as the intensity of service needed.[86] The AS-SCORE severity of illness classification, developed by Roveti, Horn, and Kreitzer,[87] uses five factors — patient age, organ system involved with the patient's disease, disease state, complications, and response to therapy — to measure the severity of illness for purposes of utilization review.

II. Medical Standards and the Legal Standard of Care

The increasing number and use of clinical practice and utilization review protocols raises critical questions about their potential role in medical malpractice litigation, including whether and how they may be used to establish the standard of care for a defendant physician in a medical malpractice lawsuit. This Part of the Article explains how the standard of care is now established in medical malpractice lawsuits and analyzes how the various types of medical standards described above could be used in establishing the applicable standard of care.

A. Establishing the Legal Standard of Care in Medical Malpractice Litigation

Medical malpractice is the tort of negligence committed by physicians and other health care professionals. The *Second Restatement of Torts* defines negligence as "conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm."[88] In order to recover damages in negligence, three elements must be present: the plaintiff must be damaged, the defendant must be

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[84] J. Lamprey, The ISD Review System (1982).

[85] *See id.*

[86] *See id.*

[87] Roveti, Horn & Kreitzer, *AS-SCORE: A Multi-Attribute Clinical Index of Illness Severity*, 1984 QRB 472, 476; *see also* Conklin, Lieberman, Barnes & Louis, *Disease Staging: Implications for Hospital Reimbursement and Management*, Health Care Financing Rev., Nov. 1984, at 13; Louis & Gonnella, *Disease Staging: Applications for Utilization Review and Quality Assurance*, Quality Assurance & Utilization Rev., Feb. 1986, at 13.

[88] Restatement (Second) of Torts § 282 (1977).

at fault, and the defendant's fault must be the legal cause of the plaintiff's damage.[89] To show fault, a plaintiff must prove that a defendant breached the legal duty not to expose the plaintiff to a reasonably foreseeable risk of injury.[90]

1. The Standard of Care in Conventional Negligence

In conventional negligence actions, breach of a defendant's duty not to expose the plaintiff to a reasonably foreseeable risk of injury is demonstrated by establishing that the defendant did not meet the applicable standard of care. There are several ways to establish the standard of care in conventional negligence cases including statute, regulation, or prior judicial decision.[91]

The most prevalent standard of care by which the defendant's conduct is measured is that of the "reasonable person" under like or similar circumstances.[92] The trier of fact, generally the jury, has the responsibility of determining compliance with the reasonable person standard. The jury decides whether the defendant should have recognized the potential risk of his conduct[93] and whether his judgment in assessing the potential risk was reasonable.[94] In making this determination, the jury assesses whether a reasonable person would have determined that the utility of the conduct giving rise to the accident outweighed the magnitude of the risk posed by the conduct[95] and whether the probability of the risk was significant enough to modify his conduct.[96]

Industry customs and standards of industrial organizations have long been used as evidence to assist a jury and court to establish the standard of care.[97] The theory for this approach was aptly stated by Justice Oliver Wendell Holmes: "What usually is done may be evidence of what ought to be done."[98] However, courts need not find that custom is

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[89] G. CHRISTIE, CASES AND MATERIALS ON THE LAW OF TORTS 109 (1983).

[90] *Id.*

[91] RESTATEMENT (SECOND) OF TORTS § 285 (1977).

[92] *Id.* § 283.

[93] *Id.* §§ 289-290.

[94] *Id.* § 291.

[95] *Id.* §§ 291-293.

[96] *See, e.g.*, United States v. Carroll Towing Co., 159 F.2d 169 (2d Cir. 1947); Helling v. Carey, 83 Wash. 2d 514, 519 P.2d 981 (1974).

[97] *See, e.g.*, Shafer v. H.B. Thomas Co., 53 N.J. Super. 19, 146 A.2d 483, 485 (1958); Pan Am. Petroleum Corp. v. Like, 381 P.2d 70, 76 (Wyo. 1963); *see also* W. PROSSER & J. KEETON, HANDBOOK OF THE LAW OF TORTS § 33, at 193-96 (5th ed. 1985) [hereafter PROSSER & KEETON].

[98] Texas & Pac. Ry. v. Behymer, 189 U.S. 468, 470 (1903).

conclusive evidence of the standard of care, for as Justice Holmes continued: "[W]hat ought to be done is fixed by a standard of reasonable prudence, whether it is usually complied with or not."[99] Indeed, courts tend to view industry custom with circumspection and many courts have found that a custom may itself be found to be negligent.[100]

2. The Standard of Care in Medical Malpractice Cases

The standard of care, as well as its proof and application, in a medical malpractice case is markedly different than in the conventional negligence case. Negligence law leaves the definition of the standard of care and the determination of breach of the standard to members of the medical profession. As one commentator observed: "The open-ended task of planning reasonable medical care is not attempted in court, but is delegated to the collective managerial authority of the medical profession."[101]

The reason for this approach is that the practice of medicine involves a body of knowledge outside the scope of knowledge of the average lay person. Thus, only a physician, as an expert witness, may testify as to the applicable standard of care and give an opinion as to whether or not the defendant breached that standard. The plaintiff must have a medical expert witness testify at trial to establish a prima facie case of negligence against the physician defendant. The defense is then generally under considerable pressure as a practical matter to put on contrary expert testimony. The judge and jury have no role in evaluating the defendant physician's conduct directly but rather only evaluate the persuasiveness of the expert testimony in light of all other evidence.[102]

In general, the standard of care for a physician in a medical malpractice case is that degree of care exercised by physicians of good standing and of the same "school" as the defendant physician.[103] But most states impose specific limitations as to whom the defendant physician will be compared based on either the defendant physician's geo-

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[99] *Id.*

[100] *See, e.g.*, The T.J. Hooper, 60 F.2d 737 (2d Cir.), *cert. denied sub nom.* Eastern Trans. Co. v. Northern Barge Corp., 287 U.S. 662 (1932); Dempsey v. Addison Crane Co., 247 F. Supp. 584 (D.D.C. 1965); *see* Keeton, *Medical Negligence — The Standard of Care*, 10 TEX. TECH L. REV. 351, 351-54 (1979); Morris, *Custom and Negligence*, 42 COLUM. L. REV. 1147, 1149, 1158 (1942); *see also infra* notes 112-14 and accompanying text.

[101] Henderson, *Expanding the Negligence Concept: Retreat from the Rule of Law*, 51 IND. L.J. 467, 480 (1976).

[102] Keeton, *supra* note 100, at 364.

[103] PROSSER & KEETON, *supra* note 97, § 32, at 187.

graphic location or, more recently, the defendant physician's field of specialization.[104]

Until the middle of this century, most states established the standard of care by comparing the defendant physician to other physicians in the same locality.[105] This "strict locality rule" sometimes proved unworkable because local physicians would often refuse to testify against their colleagues, making it impossible for plaintiffs to establish the local standard of care and its breach. Moreover, a small group of practitioners in an isolated community could establish a standard of practice in that community that was lower than that required in other communities — an unattractive possibility given the development of transportation and communication that should enable physicians in remote communities to learn about and adopt mainstream medical advances.

Most states have now modified the strict locality rule. They hold physicians to the standard of physicians practicing in the same or a similar locality.[106] It has been suggested that, because of modern communication and transportation, all physicians should be held to national standards of care.[107] Although no state has moved wholly to such national standards for all physicians, almost all states have adopted a national standard of care for specialists.[108]

The standard of care in malpractice cases is actually based much more on "industry" custom than it is in conventional negligence cases.[109] In present times, this situation is perhaps inevitable since physician testimony is necessary to establish the standard of care. Many

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[104] *See* Annotation, *Modern Status of "Locality Rule" in Malpractice Actions Against Physician Who Is Not Specialist*, 99 A.L.R.3d 1133 (1980).

[105] *See* PROSSER & KEETON, *supra* note 97, § 32, at 188; Waltz, *The Rise and Gradual Fall of the Locality Rule in Medical Malpractice Litigation*, 18 DE PAUL L. REV. 408 (1969).

[106] *See* Annotation, *supra* note 104, at 1133; Annotation, *Malpractice Testimony: Competency of Physician or Surgeon from One Locality to Testify, in Malpractice Case, as to Standard of Care of Defendant Practicing in Another Locality*, 37 A.L.R.3d 420 (1971); Annotation, *Standard of Care Owed to Patient by Medical Specialist as Determined by Local, "Like Community," State, National, or Other Standards*, 18 A.L.R.4th 603 (1982).

[107] *See* Shilkret v. Annapolis Emergency Hosp. Ass'n, 276 Md. 187, 192-99, 349 A.2d 245, 248-52 (1975).

[108] Annotation, *Standard of Care Owed to Patient by Medical Specialist as Determined by Local, "Like Community," State, National, or Other Standards*, 18 A.L.R.4th 603, 607, 614-20 (1982 & Supp. 1988).

[109] Keeton, *supra* note 100, at 358; Keeton, *Professional Malpractice*, 17 WASHBURN L.J. 445, 455 (1978); King, *In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula*, 28 VAND. L. REV. 1213, 1235-36 (1975).

physicians rely on how they would have conducted themselves or how they believe other physicians in the applicable comparison group would have conducted themselves in the particular situation at issue. This is particularly true if there are no standards, recommendations or guidelines published by medical specialty societies, physician groups or an acknowledged medical text to guide the testifying physician. As a result, a defendant physician often is held to a standard of care that reflects the "habit" of the medical expert testifying.[110] Some commentators have decried this situation and have exhorted courts to move toward a standard of care based on what ought to be done, rather than relying on "customary" practice.[111]

Not all courts, however, accept "customary" practice as an absolute determinant of the standard of care in medical malpractice cases, and in some instances courts have concluded that "customary" practice in itself is negligent.[112] In *Helling v. Carey*,[113] the most famous example of such a judicial departure from the usual rule, the trial court ruled that compliance with customary practice within the medical profession is not conclusive evidence that a physician was not negligent. In *Helling*, defendant physicians did not test the young female plaintiff for glaucoma for five years while she was under their care and, when she was finally tested at age 32, some vision had been irreparably lost. Both plaintiffs' and defendants' medical experts testified that physicians do not customarily test for glaucoma for patients under 40 years of age. Nevertheless, the Supreme Court of Washington concluded that the jury could find the defendants liable for negligence even though the physicians followed an established professional custom.[114]

3. Governing Evidentiary Principles

A very important aspect in understanding the current and potential use of medical standards in malpractice litigation is the rules of evidence that govern the introduction of evidence of any standards at trial.

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[110] *See* Keeton, *supra* note 100, at 361-62.

[111] King, *supra* note 109, at 1213.

[112] *See, e.g.*, Toth v. Community Hosp., 22 N.Y.2d 255, 239 N.E.2d 368, 292 N.Y.S.2d 440 (1968); Morgan v. Sheppard, 188 N.E.2d 808 (Ohio Ct. App. 1963); *see* Keeton, *supra* note 100, at 456-57.

[113] 83 Wash. 2d 514, 519 P.2d 981 (1974).

[114] The Washington legislature sought to mitigate the decision by statute although the Washington Supreme Court subsequently opined that the statute did not overrule Helling v. Carey. *See* Gates v. Jensen, 92 Wash. 2d 246, 595 P.2d 919, *rev'g*, 20 Wash. App. 81, 83, 579 P.2d 374, 376 (1979) (in which appellate court ruled that WASH. REV. CODE ANN. § 4.24.290 overruled Helling v. Carey).

As indicated above, only a medical expert witness can testify to the applicable standard of care, whether the defendant's conduct did or did not breach that standard, and, in many cases, whether the defendant's breach was the legal cause of the plaintiff's damage.

The applicable evidentiary principles depend on how the medical standard is to be used at trial. The first distinction is whether a witness will testify as to the standard of care and use the medical standard as a resource, or will testify that the standard itself should be admitted as documentary evidence of the standard of care. The second important distinction is whether the medical standard is to be used to establish the standard of care or to impeach the testimony of an opposing expert witness. In any event, two requirements must be met before the medical standard, or any other evidence, can be used as proof at trial: the evidence must be demonstrated to be both authentic and admissible under the principles of evidence law for the jurisdiction.[115]

If a document contains a standard that a party wishes to offer as substantive evidence, the normal procedure is to use a witness with knowledge of the standard and its origin to verify the authenticity of the document's origins and content and to explain how the document should be used.[116] This witness, whom the court must qualify as an expert witness, will describe the standard, its development, and that the standard is accepted by the applicable professional group sponsoring the standard.[117]

The critical barrier to admissibility of evidence regarding industry customs is the hearsay rule. This rule bars all out-of-court statements offered as proof of the matter contained therein as evidence at trial.[118] Documents describing standards are technically "hearsay" evidence because they are effectively out-of-court statements offered for the truth of the matter that the standards are industry customs.[119] However, most courts generally admit documentary evidence of industry standards under an exception to the hearsay rule called the learned treatise excep-

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[115] J. McCORMICK, McCORMICK ON EVIDENCE § 51 (Cleary 3d ed. 1984); 1 W. WIGMORE, WIGMORE ON EVIDENCE § 9 (Tillers rev. 1983).

[116] *See generally* J. McCORMICK, *supra* note 115, §§ 321, 324.2; 6 W. WIGMORE, *supra* note 115, § 1694.

[117] *See generally* J. McCORMICK, *supra* note 115, § 321, at 899; 6 W. WIGMORE, *supra* note 115, § 1694.

[118] *See generally* J. McCORMICK, *supra* note 115, § 321, at 899; 2 W. WIGMORE, *supra* note 115, § 657.

[119] *See* J. McCORMICK, *supra* note 115, § 321, at 899; 2 W. WIGMORE, *supra* note 115, § 657.

tion.[120] This exception is defined in the Federal Rules of Evidence as follows:

> To the extent called to the attention of an expert witness upon cross-examination or relied upon by him in direct examination, statements contained in published treatises, periodicals or pamphlets on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice, if admitted, the statements may be read into evidence but may not be received as exhibits.[121]

Most states, either judicially or legislatively, have adopted the learned treatises exception to the hearsay rule.[122] But jurisdictions tend to permit evidentiary use of established treatises, including medical treatises only when the major policy considerations for invocation of the hearsay rule can be met.[123]

Some states have statutes that specifically permit, at the court's discretion, the admission of learned medical treatises in medical malpractice litigation without accompanying expert testimony.[124] States with such statutes include Massachusetts, Nevada, Kansas, and Rhode Island.[125] The express purpose of these statutes is to permit plaintiffs in medical malpractice cases to introduce a treatise into evidence liberally in order to establish the proper standard of care for a physician without the need for direct expert testimony to establish the treatise as a reliable authority.[126]

The oldest statute is Massachusetts'[127] and it appears that the statute,

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[120] *See* J. McCORMICK, *supra* note 115, § 321, at 900; 6 W. WIGMORE, *supra* note 115, §§ 1690-1700.

[121] FED. R. EVID. 803(18); *see also* Imwinkelried, *The Use of Learned Scientific Treatises Under Federal Rule of Evidence 803(18)*, TRIAL, Feb. 1982, at 56.

[122] J. McCORMICK, *supra* note 115, § 321; 6 W. WIGMORE, *supra* note 115, §§ 1690-1698.

[123] J. McCORMICK, *supra* note 115, § 321; 6 W. WIGMORE, *supra* note 115, §§ 1690-1698; Pierce, *Admissibility of Expert Testimony in Hearsay Form*, 5 AM. J. TRIAL ADVOC. 277 (1981).

[124] J. WALTZ & F. INBAU, MEDICAL JURISPRUDENCE 85-87 (1971).

[125] *See* KAN. STAT. ANN. § 60-460(cc) (Supp. 1987); MASS. ANN. LAWS ch. 233, § 79 (Law Co-op. 1986); NEV. REV. STAT. § 52.040 (1985); 1969 R.I. Pub. Laws. 1833 (1969); *see also* J. WALTZ & F. INBAU, *supra* note 124, at 85.

[126] *See supra* note 125.

[127] Massachusetts's statute provides in pertinent part:

> Statements of facts or opinions on a subject of science or art contained in a published treatise, periodical, book or pamphlet shall, in [the discretion of the court, and if] the court shall find that [they are] relevant and that the writer of such statements is recognized in his profession or calling as an expert on the subject, be admissible in actions of contract or tort for mal-

in keeping with legislative intent, has not operated to permit admission of treatises into evidence without accompanying medical testimony.[128] Specifically through the statutory provision according judicial control over the operation of the exception, Massachusetts' courts have severely limited the ability of trial counsel to introduce treatises to establish the standard of care or other facts without accompanying testimony of a medical expert.[129] For example, in *Reddington v. Clayman*,[130] the Massachusetts Supreme Court upheld the exclusion of medical treatises on grounds that plaintiff's counsel failed to prove that the authors of the treatise were experts on the subject despite the proffer of biographical data from the *Directory of Medical Specialists* and an English version of *Who's Who*.[131]

Clearly, it is possible for medical standards to get into evidence in a malpractice suit to establish the standard of care in a malpractice lawsuit. Indeed, in the seminal case, *Darling v. Charleston Community Memorial Hospital*,[132] recognizing malpractice liability for hospitals, the Illinois Supreme Court ruled that the hospital accreditation standards for the Joint Commission for the Accreditation of Hospitals (JCAH), were admissible as evidence of minimum standards for the hospital's conduct.[133] Subsequent to *Darling*, the Supreme Court of Minnesota ruled JCAH standards were admissible evidence on the issue of accepted hospital practice.[134]

However, the learned treatise exception of the hearsay rule is viewed conservatively by most courts, including its statutory corollary aimed

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> practice, error or mistake against physicians, surgeons, dentists, optometrists, hospitals and sanitaria, as evidence tending to prove said facts or as opinion evidence; provided, however, that the party intending to offer as evidence any such statements shall, not less than thirty days before the trial of the action, give the adverse party . . . notice of such intention, stating the name of the writer of the statements, the title of the treatise, periodical, book or pamphlet in which they are contained . . . . .

MASS. GEN. LAWS ANN. ch. 233, § 79(C) (West 1986).

[128] *See* Kehoe, *Massachusetts Malpractice Evidentiary Statute — Success or Failure?*, 44 B.U.L. REV. 10 (1964).

[129] *Id.* at 24-26.

[130] 334 Mass. 244, 134 N.E.2d 920 (1956).

[131] Kehoe, *supra* note 128, at 21-24.

[132] 33 Ill. 2d 326, 211 N.E.2d 253 (1965), *aff'g*, 50 Ill. App. 2d 253, 200 N.E.2d 149 (1964).

[133] *Id.* at 332, 211 N.E.2d at 257; *see* Schockemoehl, *Admissibility of Written Standards as Evidence of the Standard of Care in Medical and Hospital Negligence Actions in Virginia*, 18 U. RICH. L. REV. 725, 728-31 (1984).

[134] *See* Cornfeldt v. Tongen, 262 N.W.2d 684 (Minn. 1977); *see also* Schockemoehl, *supra* note 133, at 729-30.

specifically at the use of learned treatises in malpractice litigation to prove the standard of care. This conservatism results in judicial reluctance to admit learned treatises when clear evidence of the stature and veracity of the treatise do not mitigate the basic policy of the hearsay rule — prohibiting out-of-court statements as evidence for the truth of the matter asserted when there is no opportunity for cross-examination. Thus, and most important, courts are reluctant to admit treatises as evidence without accompanying expert testimony as to the qualifications of the treatises' authors to serve as experts.

As a practical matter, whether the learned treatise exception and its corollary would permit admission of a medical standard would depend largely on the standard's authorship. Certainly the standard would have to be written by a physician. Further, the physician author would probably have to be in the medical specialty that dealt with the medical problem addressed. It would likely be necessary to have a medical expert testify as to the authenticity of the standard, the expert nature of the author's credentials, and the reputation of the author as expert. Also, it would be necessary in most cases to have a medical expert witness testify as to whether the standard would actually apply to the medical situation involved in the malpractice case and, then, as to whether it would establish the standard of care in that situation.

It is essential to appreciate that at this point it would be unlikely that most courts would accept medical standards as evidence of the standard of care without accompanying medical expert testimony. Thus, as a practical matter, the "mechanics" of putting on proof of the standard of care in a malpractice lawsuit are fundamentally unaffected by the use of medical standards to establish the standard of care.

B. Use of Medical Standards in Medical Malpractice Litigation

Nevertheless, medical standards can be used in medical malpractice trials as evidence of the standard of care. In the past, expert witnesses would testify as to the standard of care and breach of the standard. A medical standard brought to the attention of a court or jury may have a much greater impact because it was developed by physicians and, perhaps, endorsed by a large number of prestigious physicians.[135] Thus, with the development of clinical practice and utilization review protocols, new "experts" have emerged.

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[135] This situation may apply to a standard adopted by a medical specialty society, government, or a voluntary health organization. *See supra* notes 23-47 & 53-55 and accompanying text.

The influence of a given standard in a medical malpractice suit is dependent upon three factors: the standard's intended use, its sponsorship, and its character. The purpose of a standard may be critical in determining its role in malpractice litigation. For example, clinical practice protocols prescribing the course to take in a clinical situation will be persuasive in a malpractice case involving the same clinical situation much in the way that industry standards are used in conventional tort litigation. But if the purpose of the standard is not to describe specifically what steps to take in the medical care of a particular disease, then it may be less useful in establishing what standard of care is required of a physician in terms of specific steps in the management of the plaintiff patient. However, a standard that prescribes certain requirements that should be present in a facility could be probative evidence of negligence on the part of the institution if a sufficient causal link can be demonstrated between the deficiency and the injury. For example, if the standard prescribes certain requirements as to the level of nursing staff that should be present when a general anesthetic is administered, a deficiency of nursing staff could be probative evidence of negligence if the deficiency is shown to be causally related to the patient's injury from anesthesia.

It is less likely that utilization review protocols would be used effectively to establish the standard of care in malpractice litigation because they define standards for the use of resources rather than prescribe procedures for managing a particular disease or condition. However, this is not to say that they could never be used to establish the standard of care in a malpractice suit. For example, if a reputable utilization review protocol recommended inpatient hospital care for a plaintiff's condition and the plaintiff was not admitted to the hospital and suffered injury as a result, the utilization review protocol might be persuasive evidence that hospitalization was both customary and medically necessary.

In one important recent case, *Wickline v. State*,[136] the plaintiff was discharged inappropriately but in accord with a utilization review protocol of the California Medicaid program. The plaintiff, who developed complications following discharge that resulted in the amputation of her leg, sued the California Medicaid program for bad faith in denying her benefits. The California appellate court, reversing the trial court,

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[136] 192 Cal. App. 3d 1630, 228 Cal. Rptr. 661 (1986). *See generally* Smith, *Insurance Carrier Liability As A Result of Pre-Admission Screening and Hospital Stay Guidelines*, 12 OHIO N.U.L. REV. 189 (1985); Note, Wickline v. State*: The Emerging Liability of Third Party Health Care Payers*, 24 SAN DIEGO L. REV. 1023 (1987).

refused to impose liability on the state. The court emphasized that the treating physician had an obligation to request the extended hospitalization he thought necessary, even if he felt the Medicaid officials would not authorize it. The court stated:

> There is little doubt that Dr. Polonsky was intimidated by the Medi-Cal program but he was not paralyzed by [the reviewing physician's] response nor rendered powerless to act appropriately if other action was required under the circumstances. If, in his medical judgment, it was in his patient's best interest that she remain in the acute care hospital setting for an additional four days beyond the extended time period originally authorized by Medi-Cal, Dr. Polonsky should have made some effort to keep Wickline there. . . . It was his medical judgment, however, that Wickline could be discharged when she was. . . .[137]

Thus, *Wickline* suggests that a doctor may not defend himself by claiming that his own professional judgment was swayed by fear of an adverse utilization review decision.

The persuasiveness and, in some cases, the use, of both utilization review and clinical protocols at trial is largely dependent on their sponsorship. Protocols developed by national medical specialty societies and other groups of prestigious physicians may be highly influential because of their origins and imprimatur of approval. It is intuitively obvious that a jury of lay people would be impressed by standards sponsored or authored by organizations with which they were familiar, such as the American Cancer Society, or by organizations of prestigious physicians like the American College of Physicians.

Individually sponsored, institution-specific standards are generally intended to be minimal standards of quality care for *that* institution[138] and, because they are institution-specific, may not be generally accepted within the medical profession as a whole. Thus, it would be easier to vitiate the persuasiveness of these standards as one physician's opinion of quality and not as a generally accepted standard within the profession. In some cases, however, because of the prestige of the institution for which they are developed, the prestige of the authors, or the fact of their publication in national professional journals, these standards may be persuasive evidence of the standard of care in a medical malpractice suit outside their intended area of influence. Still, such standards might not serve as conclusive evidence of the appropriate standard because they are institution-specific and their authors have presumably made no attempt to identify conventional practice in the applicable geographic

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[137] *Wickline*, 192 Cal. App. 3d at 1645-46, 228 Cal. Rptr. at 671.

[138] *See* Eichorn, *Harvard Anesthesia Standards*, *supra* note 72, at 1017; Raffin, *supra* note 26, at 390.

area.

On the other hand, individually sponsored standards may play a crucial role in a suit against a physician in the institution for which the standard was created, particularly if the institution can impose some kind of sanction for failure to comply with the standard. For example, an anesthetist at a hospital affiliated with Harvard Medical School is required by hospital policy to follow the standards developed for the anesthesiology department by Harvard Medical School physicians. In fact, courts have found a defendant negligent for failure to follow his own hospital's policy.[139]

Commercial consultation guides, if developed by physicians, may have the effect of other clinical practice protocols. However, if they are not established by a nationally recognized association of physicians or an acknowledged expert in the field, they should be more readily challenged as hearsay evidence. In any event, they have to be introduced by expert testimony at trial from a physician witness who would essentially endorse the commercial consultation guide.

The final critical factors influencing the persuasiveness of a medical standard as evidence of the standard of care in a medical malpractice suit are the character of the standard and whether or not compliance with the standard is somehow enforceable. Most medical standards are not enforceable but are, in effect, only guidelines or recommendations. On the other hand, the designation of a standard by a national medical specialty society for a particular clinical practice is persuasive as to what "ought" to be the practice, if it is not in fact the accepted or customary practice in the nation or the community.

The medical profession's increasingly active role in the development of medical standards and particularly clinical practice protocols and the use of these medical standards to establish the standard of care in malpractice cases is highly desirable. The medical profession, the health care industry, and patients are well served by this development. As discussed earlier, too much deference is accorded to "custom" evidence in medical malpractice cases.[140] Without stated medical standards, there is no assurance that the standard of care being applied in a malpractice case reflects the preferred or proven mode of practice with respect to the medical situation presented in the case. Indeed, as pointed out above, in the worst but not unusual case, the defendant physician may

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[139] *See, e.g.*, French v. Fischer, 50 Tenn. App. 587, 362 S.W.2d 926 (1962); Kalmus v. Cedars of Lebanon Hosp., 132 Cal. App. 2d 243, 281 P.2d 872 (1955).

[140] *See* MEDICAL MALPRACTICE (D. Yaggy & P. Hodgson eds. 1986); *supra* notes 110-12 and accompanying text.

be held to a standard of care that may only reflect the "habit" of the medical expert testifying rather than an established standard of the profession.

If the leaders in the medical profession established standards for the diagnosis and treatment of various diseases as well as for the performance of specific procedures and medical experts relied on those standards in testifying at trial, defendant physicians would have a greater chance of being held to an appropriate standard of care. Further, over time physicians would become better informed as to what these standards are and have greater incentive to conform their clinical practice to these standards. In addition, payors would have better information about what constitutes quality health care in specific situations and could tailor their utilization review and payment policies to promote desirable practices.

CONCLUSION

Utilization review and clinical practice protocols as well as other medical standards are now an established factor in the practice of medicine. Their role in medical malpractice litigation is one of increasing influence. Their use and influence depends on the sponsorship or authorship of the standard and the degree to which it applies to the given treatment situation at issue in the lawsuit. Given the constraints imposed by the rules of evidence in most states and the long history of using expert witnesses to establish medical "custom" and, thus, the standard of care in medical malpractice cases, the procedures by which medical standards are introduced into evidence and used in medical malpractice cases will not change substantially from current practice.

Nevertheless, because of the availability of medical standards and the increasingly enthusiastic embracing of these standards by medical professional organizations, medical standards will certainly play an increasingly important role in establishing the standard of care in medical malpractice cases. This is a positive development. Medical standards, especially those clinical practice protocols authored or sponsored by medical specialty societies and organized medicine, are more likely to reflect standards for high quality care.