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PRACTICE PARAMETERS AS A SHIELD AGAINST PHYSICIAN LIABILITY

Currently, the legal process faces far more difficulty in uncovering what the standard of care is in a particular domain of medicine than it does in adjudicating matters of fact regarding what actually took place in a particular case [of alleged medical malpractice].

How much simpler it would be if there existed a set of standards about which there could be little debate.1

The State of Maine is conducting a five-year medical liability demonstration project (Project)2 that establishes practice parameters and risk management protocols (practice parameters or parameters)3 in four med-

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3. A practice parameter defines appropriate clinical indications and methods of treatment for a specific medical condition. Id. § 2973. A risk management protocol defines standards of medical practice designed to avoid malpractice claims and to increase the defensibility of the malpractice actions that plaintiffs pursue. Id. The Project establishes practice parameters and protocols within the medical specialties of anesthesiology, emergency medicine, obstetrics and gynecology, and radiology. Id. § 2972(1). In each field, a medical specialty advisory committee (Advisory Committee) develops its respective practice parameters. Id. The Advisory Committees on emergency medicine and radiology regard practice parameters as:

- strategies of patient management, developed to assist physicians in clinical decision-making. Practice parameters include standards, guidelines, and other patient management strategies. Standards are accepted principles for patient management. Guidelines are recommendations for patient management which identify a particular management strategy or a range of management strategies. Other strategies for patient management include practice policies and practice options.

Code Me. R. §§ 02-373-022 app. 1 at 1, 026 app. 1 at 1 (1991). According to the Advisory Committee on anesthesiology, practice parameters are “standards, guidelines and other patient management strategies that result in high quality of patient care but which also recognize that there is a finite limit of resources available for health care.” Id. § 02-373-020. The Advisory Committee on obstetrics and gynecology does not define the term.

The variety of definitions and terms used by the Advisory Committees reflects the lack of consensus within the medical profession on the appropriate terminology. One commonly used term is “practice guidelines,” which are defined as “[s]tandardized specifications for care developed by a formal process that incorporates the best scientific evidence of effectiveness with expert opinion.” Lucian L. Leape, Practice Guidelines and Standards: An Overview, 16 QUALITY REV. BULL. 42, 43 (1990); see also Chassin, supra note 1, at 438 (defining practice guidelines as “statements describing specific diagnostic or therapeutic maneuvers that should or should not be performed in certain specific clinical circum-
medical specialties and gives the parameters the force and effect of law. In a medical malpractice action against a physician who participates in the Project, the physician may introduce the practice parameters into evidence as an affirmative defense. To prevail on the basis of this defense,

4. The practice parameters for anesthesiology include: (1) the Anesthesia Record; (2) Anesthesia Standards for Basic Intraoperative Monitoring; (3) Standards for Postanesthesia Care; and (4) Preoperative Laboratory Testing. Code Me. R. § 02-373-020 app. 1 at 1 (1991).

The practice parameters for emergency medicine cover: (1) Cervical Spine X-Rays for Acute Trauma Patients; and (2) Transfer of Patient to Other Hospitals. Id. § 02-373-022 app. 1 at 1-4.

The practice parameters for obstetrics and gynecology encompass: (1) Cesarean Delivery for Failure to Progress; (2) Assessment of Fetal Maturity Prior to Repeat Cesarean Delivery or Elective Induction of Labor; (3) Hysterectomy, Abdominal or Vaginal (Indication: Leiomyomata); (4) Hysterectomy, Abdominal or Vaginal (Indication: Abnormal uterine bleeding in women of reproductive age); (5) Tocolysis; (6) Presumed Ectopic Pregnancy in Clinically Stable Patient; (7) Singleton Breech Presentation; (8) Perinatal Herpes Simplex Virus Infections; (9) Intrapartum Fetal Distress; and (10) Antepartum Management of Prolonged Pregnancy. Id. § 02-373-024 app. 1 at 1.

The practice parameters for radiology cover: (1) Performance of Screening Mammography; (2) Antepartum Ultrasound; (3) Outpatient Angiography; and (4) Performance of Adult Barium Enema Examinations. Id. § 02-373-026 app. 1 at 1.

5. The Project directs the Board of Registration in Medicine (Board) to review the practice parameters that the Advisory Committees develop, to approve those appropriate for each medical specialty area, and to adopt them as rules under the Maine Administrative Procedure Act. Me. Rev. Stat. Ann. tit. 24, § 2973 (West Supp. 1991) (citation omitted). A rule is “the whole or any part of every regulation, standard, code, statement of policy, or other agency statement of general applicability . . . that is or is intended to be judicially enforceable and implements, interprets or makes specific the law administered by the agency.” Id. tit. 5, § 8002(9)(A).

6. The Project does not apply to a medical specialty unless at least 50% of the physicians licensed in Maine who practice in that field elect to participate in the Project. Id. tit. 24, § 2976. This requirement has been met in the four medical specialties covered by the Project. Telephone interview with Gordon H. Smith, Counsel, Maine Medical Association (Sept. 8, 1992).

the physician must prove compliance with the parameters. Although the physician may proffer the parameters as evidence, once the court admits them, the plaintiff may present evidence on the issue of compliance and may attempt to use the parameters against the physician. As legal predeterminations of appropriate medical care, the Project's practice parameters affect the core of medical malpractice litigation: the standard of care.

The influence of the parameters should be salutary because the standard of care that the law of negligence imposes on physicians is elusive. But "[i]f the complaint itself affirmatively demonstrates the existence and the applicability of the affirmative defense, then the defense may serve as the basis for dismissal." Cunningham v. Haza, 538 A.2d 265, 267 (Me. 1988) (citations omitted). However, this exception to the MacKerron rule is of no avail to the physician at the pleadings stage because the plaintiff cannot raise the issue of the practice parameters unless the physician has done so first. See MacKerron v. Whitten, 538 A.2d 265, 267 (Me. 1988) (citations omitted). However, this exception to the MacKerron rule is of no avail to the physician at the pleadings stage because the plaintiff cannot raise the issue of the practice parameters unless the physician has done so first. ME. REV. STAT. ANN. tit. 24, § 2975(1) (West Supp. 1991).

9. Id. § 2975(1).
10. Id. § 2975(2).
11. Gordon H. Smith, Maine's Liability Demonstration Project-Relating Liability to Practice Parameters, ST. HEALTH LEGIS. REP., Fall 1990, at 1, 3. Clearly, one aim of the Project is to protect physicians who comply with the practice parameters from legal liability. This is a defensive use of practice parameters. See Mark A. Hall, The Defensive Effect of Medical Practice Policies in Malpractice Litigation, LAW & CONTEMP. PROBS., Spring 1991, at 119, 121. Practice parameters also might have an offensive effect if they increase the liability exposure of a physician who does not comply with them. See Edward B. Hirshfeld, Practice Parameters and the Malpractice Liability of Physicians, 263 JAMA 1556, 1560 (1990); see also Eleanor D. Kinney & Marilyn M. Wilder, Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities, 22 U.C. DAVIS L. REV. 421, 450 (1989) (arguing that if "the medical profession established standards... 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"); Troyen A. Brennan, Practice Guidelines and Malpractice Litigation: Collision or Cohesion?, 16 J. HEALTH POL. POL'Y & L. 67, 68 (1991) (arguing that "guidelines should act as useful inculpatory or exculpatory evidence of the standard of care").
12. Negligence is "conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm." RESTATEMENT (SECOND) OF TORTS § 282 (1965); see also W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 31, at 169, 171 (5th ed. 1984) ("Negligence is a matter of risk—that is to say, of recognizable danger of injury... Against this probability, and gravity, of the risk, must be balanced in every case the utility of the type of conduct in question."). Medical malpractice is simply one type of negligent conduct. Id. § 32, at 185-86.

Missing from definitions of negligence is the "standard of care by which conduct can be evaluated and found to be unusually dangerous." Page Keeton, Medical Negligence—The Standard of Care, 10 TEX. TECH L. REV. 351, 351 (1979). It is simply not possible to fix definite rules in advance for all conceivable human conduct. Keeton et al., supra § 32, at 173. To remedy this problem, the law created a fictitious person: the "reasonable man of ordinary prudence." Id. at 174. The defendant is held to the standard of what the reasonable man of ordinary prudence would do in his or her place. Id. The jury makes this
at best.\textsuperscript{13} Currently, the law defines "good medical practice" as that which is "customary and usual in the profession."\textsuperscript{14} In Maine, physicians are held "to the standard of care of an ordinarily competent physician under like conditions."\textsuperscript{15} To prove a case of medical malpractice, the plaintiff must establish the appropriate standard of care, the physician's deviation from the standard, and that the physician's breach of the stan-

comparison and thus decides the issue of negligence. Keeton, supra at 352. However, in the medical malpractice context, the reasonable person approach presents unique problems because a jury is generally unqualified to judge independently the reasonableness of a physician's conduct. See infra note 17 and accompanying text.

13. Prior to 1950, the definition of the legal standard of care that courts applied in medical malpractice actions was often "imprecise, ambiguous and inconsistent." Keeton, supra note 12, at 358. During the past four decades, the standard of care imposed on physician conduct has been expressed in such various terms as the medical practice in the "same or similar community," the "national custom," and "accepted medical practices and procedures." Id. at 360-65. However, the law still "faces far more difficulty in uncovering what the standard of care is in a particular domain of medicine than it does in adjudicating matters of fact regarding what actually took place in a particular case." Chassin, supra note 1, at 448; see also Joseph H. King, Jr., In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula, 28 VANG. L. REV. 1213 (1975) (arguing for clarification and reappraisal of the standard of care in the law of medical malpractice).

14. Keeton et al., supra note 12, § 32, at 189. However, in a negligence action outside the medical malpractice context, a showing that the defendant followed the customary or usual practice is merely evidence to be considered in determining whether he or she complied with the standard of care but is not itself determinative of the standard of care. Id. § 33, at 195.

15. McLaughlin v. Sy, 589 A.2d 448, 452 (Me. 1991). However, if a physician is nationally certified and holds himself out as a specialist in a particular field of medical expertise, then he will be held to the standard of care of all physicians in that specialty. Johnson v. Gerrish, 518 A.2d 721, 722-23 (Me. 1986); Taylor v. Hill, 464 A.2d 938, 943 (Me. 1983); Roberts v. Tardif, 417 A.2d 444, 452 (Me. 1980). Maine law does not provide that the defendant's conduct is measured solely by the standard of care of the medical profession in his or her locale. McLaughlin, 589 A.2d at 452; Taylor, 464 A.2d at 942 n.1; Roberts, 417 A.2d at 451; Josselyn v. Dearborn, 62 A.2d 174, 181 (Me. 1948).

However, the Josselyn court noted that the phrase "like conditions" was broad enough to cover the degree of skill and care required of a physician practicing in the defendant's locale. Id. Thus, the jury could consider "the location of the defendant . . . , that he did not have . . . certain medicines and equipment that were available in larger centers of population, . . . [and that he] is approximately 130 miles from . . . [available] hospital and laboratory facilities." Id. Forty-three years later, the McLaughlin court limited the holding in Josselyn by concluding that "[l]ocality is, at most, a factor in the overall circumstances." McLaughlin, 589 A.2d at 452. The McLaughlin court also noted that in cases where locality had been mentioned as an element of the standard of care, the community factor had not been at issue. Id. (citing Caron v. Pratt, 336 A.2d 856, 859 (Me. 1975); Downer v. Veilleux, 322 A.2d 82, 91 (Me. 1974); Duguay v. Pomerleau, 299 A.2d 914, 917 (Me. 1973); Aronson v. Perkins, 233 A.2d 726, 728 (Me. 1967); Cyr v. Giesen, 108 A.2d 316, 318 (Me. 1954)). Therefore, Maine physicians are held to a standard of care determined "under all the relevant circumstances." Id.
standard proximately caused the alleged injury.\textsuperscript{16} Ordinarily, the plaintiff can carry this burden of proof only through expert medical testimony.\textsuperscript{17} If the plaintiff establishes a prima facie case, the physician must present contrary expert testimony.\textsuperscript{18} The resulting "battle of experts"\textsuperscript{19} obfuscates the standard of care\textsuperscript{20} and encourages the use of paid experts whose

\begin{itemize}
\item \textsuperscript{17} Patten v. Milam, 480 A.2d 774, 778 (Me. 1984); Cox v. Dela Cruz, 406 A.2d 620, 622 (Me. 1979); Downer v. Veilleux, 322 A.2d 82, 84-85 (Me. 1974); Cyr v. Giesen, 108 A.2d 316, 318 (Me. 1954). Expert medical testimony is required because the law presumes that juries are incompetent to independently judge questions of medical science or technology. Keeton et al., supra note 12, § 32, at 188; Hall, supra note 11, at 126; Kinney & Wilder, supra note 11, at 440. In a negligence action outside the medical malpractice context, expert testimony is also often used to afford guidance to the trier of fact "but rarely will be as conclusive with respect to the standard of care as it often is in medical malpractice cases." King, supra note 13, at 1236. An exception to the general rule that requires expert testimony in medical malpractice actions is recognized where the physician's conduct is so egregious as to lie within the common knowledge of laymen. Patten, 480 A.2d at 778; Cox, 406 A.2d at 622; Downer, 322 A.2d at 84; Cyr, 108 A.2d at 318. See, e.g., Lanier v. Trammell, 180 S.W.2d 818, 820-21 (Ark. 1944) (failure to wash hands and to sterilize instruments before eye operation); Laws v. Harter, 534 S.W.2d 449, 450-51 (Ky. 1975) (surgical sponge left in patient).
\item \textsuperscript{18} Kinney & Wilder, supra note 11, at 440.
\item \textsuperscript{19} "[T]he opinions of the experts on each side are often in disagreement. When this happens, . . . [the] process of comparing the defendant's conduct with established professional norms degenerates into a swearing contest." Hall, supra note 11, at 127. The expert witnesses vie to convince the jury of the appropriateness and necessity of the medical practice they endorse. Eleanor Kinney, New Standards for the Standard of Care, Legal Times, Nov. 18, 1991, at 22, 24 (Supplement entitled Health Law's Cutting Edge). Because the law leaves the definition of the standard of care and the determination of a breach of the standard to the medical profession, "[t]he 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." Kinney & Wilder, supra note 11, at 440 (emphasis added).
\item \textsuperscript{20} Lost in the exchange of conflicting expert testimony is a comparison of the physician's conduct with the medical profession's usual and customary standard of care. Hall, supra note 11, at 127. Instead, physicians [testifying as experts] rely on how they would have conducted themselves . . . in the particular situation at issue. This is particularly true if there are no standards, recommendations or guidelines . . . . As a result, a defendant physician often is held to a standard of care that reflects the "habit" of the medical expert testifying. Kinney & Wilder, supra note 11, at 442. Thus, the "battle of experts" puts in issue the credentials of the expert witnesses rather than whether the defendant complied with the medical profession's standard of care. Hall, supra note 11, at 127. Moreover, it cannot be assumed that an attorney will necessarily employ the most qualified expert. Instead, counsel "will probably choose the expert who will best support his client's cause, and, perhaps, conceal its weaknesses." Judge Theodore I. Botter, The Court-Appointed Impartial Expert,
objectivity may be suspect. Maine's practice parameters promise to rationalize the legal process of determining the appropriate standard of care.

Since the late 1980s, practice parameters have rapidly emerged as the medical profession's response to the charge that the medical standard of care "appear[s] to be arbitrary—highly variable, with no obvious explanation." Supporting this claim are studies by epidemiologists who have documented wide geographic variations in the rate of utilization of health care services and specific medical procedures. For example, in Maine...
the chance of a woman having a hysterectomy by the age of seventy varies across the state from less than 20% to more than 70%. A major cause of medical practice variation is physician uncertainty regarding the appropriate clinical indications for many forms of treatment. If the appropriate clinical indications for medical procedures are defined and widely disseminated through practice parameters for physician use, the opportunities for misuse of treatments would diminish. Thus, Maine's practice parameters could potentially improve the quality of medical care in the state and thereby reduce the incidence of iatrogenic injury.


27. John E. Wennberg, Dealing with Medical Practice Variation: A Proposal for Action, Health Aff., Summer 1984, at 6, 9. Although “[s]ome variation in practice patterns can be expected due to differences in the incidence of various diseases, patients' preferences, and the available resources, . . . these variations should be small and explainable.” David M. Eddy, Variations in Physician Practice: The Role of Uncertainty, Health Aff., Summer 1984, at 74, 75.

28. Eddy, supra note 27, at 75 (“Uncertainty creeps into medical practice through every pore.”); Alain C. Entovken, Health Plan XIX (1980) (“Uncertainty pervades medical diagnosis and treatment.”); Ann L. Greer, The State of the Art Versus the State of the Science, 4 Int'l J. Tech. Assessment Health Care 5, 8 (1988) (“[O]ne problem, viewed broadly, underlies many analyses of the culture of medicine: this is the problem of uncertainty.”) (citation omitted) [hereinafter State of the Art]; Jay Katz, The Silent World of Doctor and Patient 166 (1984) (“Medical knowledge is engulfed and infiltrated by uncertainty.”). Amid physician uncertainty is the irony that science and technology have provided a vast foundation of knowledge that physicians can draw upon to make quality health care decisions for their patients. J. Jarrett Clinton, Improving Clinical Practice, 267 JAMA 2652, 2652 (1992). Unfortunately, for the practicing physician with limited time, the amount of available information is overwhelming, typically fragmented, difficult to evaluate, and sometimes contradictory. Leape, supra note 3, at 43. Thus, widespread implementation of research-based methods to improve medical care is stymied. Clinton, supra at 2652. Medicine's challenge is to evaluate and assimilate its scientific knowledge, consider current medical practice and the results it achieves, and adopt practice parameters that will work best in practice. Id.

Other explanations for variation in medical practice include monetary incentives, patient expectations, peer opinion, physician and patient personalities, physician habits and decision-making, clinical training experience, and practice organization. See John M. Eisenberg, Doctors' Decisions and the Cost of Medical Care 12 (1986); Ann L. Greer, The Two Cultures of Biomedicine: Can There Be Consensus?, 258 JAMA 2739, 2739 (1987); State of the Art, supra at 6.

29. Leape, supra note 3, at 43.

30. See Chassin, supra note 1, at 449 (arguing that practice standards can be used to
This Comment examines the union between the legal and medical standards of care in the practice parameters of the Maine Project. Part I reviews the parameters phenomenon and examines the Project's legislative history and policy objectives. Part II examines the development of the parameters by the Project's medical specialty advisory committees and the adoption of the practice parameters as administrative rules by the Maine Board of Registration in Medicine. Part III analyzes how the Maine Rules of Evidence will govern the use of the practice parameters in medical malpractice litigation. Finally, based on the Project's policy objectives and the manner in which the practice parameters were established, this Comment concludes that Maine courts should instruct juries that the practice parameters define the legal standard of care.

I. BACKGROUND OF THE MAINE PROJECT

A. The Practice Parameters Phenomenon

Understood as summaries of information regarding standard and accepted medical practices, practice parameters have existed in one form or another for centuries. In the past, they have found expression in medical textbooks, medical journal articles, and "conversations in hospital cafeterias." Indeed, in medical malpractice litigation, evidence of the standard of care comes from such medical textbooks and journal articles. In the late 1980s, however, practice parameters shifted away from being passive aids for physician decision-making to active medical management tools. Parameters are now framed specifically to assure quality and to contain cost. The development of practice parameters also has rapidly changed from a decentralized informal process to systematic formal programs. This transformation was spurred both by medical

improve medical practice); Leahy, supra note 22, at 1491 (arguing that practice guidelines can facilitate improvement in the quality of medical care, decrease the use of inappropriate and unnecessary procedures, and lead to fewer incidences of iatrogenic harm); Kinney, supra note 19, at 25 (arguing that practice guidelines will have a positive influence on the overall quality of health care in the United States).

32. Id.
33. Hirshfeld, supra note 11, at 1556.
34. Practice Policies, supra note 3, at 880. Practice parameters address three general types of problems associated with the utilization of health care services: overuse, underuse, and improper use. Chassin, supra note 1, at 439.
35. Practice Policies, supra note 3, at 880.
36. Id.
studies that criticized the wide variation in health care utilization rates and the scientific validity of many clinical practices, and by policymakers who want to use practice parameters to allocate health care resources more efficiently. The practice parameters phenomenon promises to continue in the 1990s.

The wide variety of interests involved in the practice parameters movement contribute to its momentum. The American Medical Association (AMA), which once disdained formal standards as "cookbook medicine," is now actively involved in developing parameters. In 1989, the federal government established the Agency for Health Care Policy and Research (AHCPR) in the Department of Health and Human Services. AHCPR is developing practice parameters to help physicians

37. See supra notes 25-27 and accompanying text.
38. See, e.g., David M. Eddy & John Billings, The Quality of Medical Evidence: Implications for Quality of Care, HEALTH AFF., Spring 1988, at 19, 20 ("[F]or at least some important practices, the existing evidence is of such poor quality that it is virtually impossible to determine even what effect the practice has on patients, much less whether that effect is preferable to the outcomes that would have occurred with other options."); David M. Eddy, Clinical Policies and the Quality of Clinical Practice, 307 NEW ENG. J. MED. 343, 343 (1982) ("[T]here is reason to believe that there are flaws in the process by which the profession generates clinical policies.").
39. Leahy, supra note 22, at 1484-85.
41. "Cookbook" medicine refers to "restrict[ing] physicians to one procedure or series of procedures for a specific condition." Interview with James S. Todd, AMA Exec. V.P., AM. MED. NEWS, Jan. 6, 1989, at 47 (internal quotations omitted). This approach is objectionable to the AMA because it insists that "[n]o two patients are exactly alike and no two conditions are exactly alike." Id. (internal quotations omitted). Thus, the AMA's approach is to keep practice parameters flexible and open-ended. Id.
42. See, e.g., Office of Quality Assurance, American Medical Ass'n, Attributes To Guide the Development of Practice Parameters (1990); Office of Quality Assurance, American Medical Ass'n, Directory of Practice Parameters, Guidelines, and Technology Assessments (1990). The AMA's change in attitude was occasioned by the realization that, although the use of practice parameters as a management tool might have a desirable impact on the quality of care and health care costs, such use may have undesirable effects for practicing physicians. Practice Policies, supra note 3, at 880. "$[T]he greatest concern pertains to control. It is not stretching things too far to say that whoever controls practice controls medicine." Id.
determine how health conditions can most effectively be prevented, diagnosed, treated, and managed clinically. AHCPR is also producing standards of quality and medical review criteria for appropriate entities to use to assess the provision of health care and to assure its quality. Practice parameters have also been implemented or sponsored by state governments, private health care researchers, third-party payers, health benefit plan sponsors, medical specialty societies, and voluntary health organizations. These groups view practice parameters as a means of improving the quality and the affordability of medical care.

B. History and Objectives of the Project

The State of Maine focused on two issues of health care policy: (1) the increase in the cost of health insurance, and (2) the practice of "defensive medicine." In the late 1980s both issues were identified in a series of meetings of the Healthcare Roundtable, a Maine group that regularly

45. Id.
46. The Commonwealth of Massachusetts utilizes practice parameters in the risk management unit of the government agency responsible for licensing and disciplining physicians. Kinney, supra note 19, at 25. See also Brian McCormick, Defense Lawyers Raise Questions about Maine Parameters Project, AM. MED. NEWS, May 6, 1991, at 1, 41 (noting that the administrative rulemaking process in New Jersey has also linked practice parameters with liability).
47. Kinney & Wilder, supra note 11, at 426 (citing eight published studies on the development of practice parameters by Robert Brook, M.D., under the auspices of the Rand Corporation).
48. "The Blue Cross/Blue Shield Association commissioned the American College of Physicians [ACP] . . . to produce guidelines for the appropriateness of the fifteen most common diagnostic tests." Hall, supra note 11, at 124.
50. See, e.g., AM. SOC'y OF ANESTHESIOLOGISTS, ASA STANDARDS, GUIDELINES AND STATEMENTS (1992); COMM. ON PRE AND POSTOPERATIVE CARE, AM. COLLEGE OF SURGEONS, MANUAL OF PREOPERATIVE AND POSTOPERATIVE CARE (3d ed. 1983); CLINICAL EFFICACY ASSESSMENT PROJECT, AM. COLLEGE OF PHYSICIANS, RECOMMENDATIONS (1987); AM. ACADEMY OF PEDIATRICS, REPORT OF THE COMMITTEE ON INFECTIOUS DISEASES (Georges Peter, M.D. et al. eds., 22d ed. 1991).
52. Havighurst, supra note 22, at 87.
53. Smith, supra note 11, at 1.
meets to initiate legislation and other programs to make health insurance in Maine more affordable. Members of the Healthcare Roundtable include Blue Cross-Blue Shield of Maine, the Maine Ambulatory Care Coalition, the Maine Chamber of Commerce and Industry, the Maine Hospital Association, the Maine Medical Association (MMA), and the Maine State Employees Association. One group that has consistently opposed the efforts of the Healthcare Roundtable regarding the Project is the Maine Trial Lawyers Association.

Part of the upward pressure on the price of health insurance is the generally high cost of medical care in the United States. Because some care is medically unnecessary, expenditures on health care and health insurance reflect an inefficient allocation of consumer resources. By defining appropriate clinical indications for tests, operations, and medical procedures, practice parameters offer the opportunity to rationalize the delivery of health care and thereby reduce its overall cost. Although they may promote efficient utilization of health care resources, practice parameters generally are not driven directly by cost considerations. The AMA and MMA subscribe to this noneconomic approach to developing practice parameters.

The Healthcare Roundtable was also concerned that health care costs were artificially high because physicians in Maine were employing a wide range of tests and procedures simply to avoid or defend against a possible

54. Id.
55. Id.
56. Id. at 2; see also Gary M. Stephenson, Maine's Guidelines Experiment Ready to Begin, REP. MED. GUIDELINES & OUTCOMES RES., Dec. 1, 1991, at 1, 6 (noting that Robert Stolt, legislative chairman for the Maine Trial Lawyers Association, criticized the Project as too rigid and inflexible).
57. Americans are spending over a half a trillion dollars each year on health care. U.S. GEN. ACCOUNTING OFFICE, MEDICAL MALPRACTICE: A CONTINUING PROBLEM WITH FAR-REACHING IMPLICATIONS 1 (1990) [hereinafter GAO MALPRACTICE REPORT]. Moreover, from 1965 to 1990, spending on health care rose from 6% of the gross domestic product to about 12%; in the next decade that figure is estimated to reach 15%. Id. Since 1960, health care costs have risen at more than double the rate of general inflation. Id.
58. See supra notes 25-26, 38 and accompanying text.
60. Leape, supra note 3, at 43.
61. Ronni Scheier, Medicine by the Book, AM. MED. NEWS, Jan. 6, 1989, at 1, 22 (noting that the AMA avoids developing practice parameters based on economic considerations). But see Leahy, supra note 22, at 1517 (arguing that "cost-effectiveness analysis places priorities on alternative expenditures without assessing a dollar value on life and health").
lawsuit.63 Although the impact of defensive medicine on national health care expenditures is difficult to measure, the estimated cost for 1984 alone was $12.1 to $13.7 billion.64 The effects of medical malpractice litigation are not limited to encouraging physicians to practice defensive medicine. The increasing number of lawsuits filed65 and the rising amount of damages recovered66 have been matched by increases in medical malpractice insurance premiums.67 Physicians facing these additional

63. Physicians who conduct themselves in this manner are practicing "defensive medicine." Laurence R. Tancredi & Jeremiah A. Barondess, The Problem of Defensive Medicine, 200 SCI. 879, 879 (1978). Practiced positively, defensive medicine entails the use of diagnostic or therapeutic measures to protect physicians from being held liable for medical malpractice. Id. Typically, positive defensive medicine is unnecessary for the proper treatment of patients and may expose the patient to the risk of adverse effects from the procedure itself. Id. Practiced negatively, defensive medicine entails the withholding of diagnostic or therapeutic techniques that might be medically justified but that involve more than the usual risk of adverse effects and thus could serve as the basis for a medical malpractice claim. Id. By denying patients a potentially beneficial diagnosis or treatment, physicians may provide suboptimal medical care. Id. But see Nathan Hershey, The Defensive Practice of Medicine: Myth or Reality, 50 MILBANK MEMORIAL FUND Q. 69, 73 (1972) ("The problem in studying the phenomenon of the defensive practice of medicine is that not all of the practices motivated by liability considerations result in poor-quality medical care. It is, therefore, difficult to draw the line between where good medicine stops and defensive practice begins.").

64. Roger A. Reynolds et al., The Cost of Medical Professional Liability, 257 JAMA 2776, 2776 (1987); see also AM. MEDICAL ASS'N SPECIAL TASK FORCE ON PROFESSIONAL LIAB. AND INS., PROFESSIONAL LIABILITY IN THE '80s: REPORT 1, 3 (1984) (noting that the practice of defensive medicine may add $15 billion to $40 billion annually to health care costs). But see Project, The Medical Malpractice Threat: A Study of Defensive Medicine, 1971 DUKE L.J. 939, 943 (challenging the validity of the charge that physicians react to the increased threat of malpractice actions by practicing defensive medicine); Terese Hudson, Insurance & Liability: Experts Disagree Over the Cost of Defensive Medicine, HOSPITALS, Aug. 5, 1990, at 74, 74 (noting that "[s]ome . . . doubt that defensive medicine adds significantly to health care costs").

65. See, e.g., U.S. GEN. ACCOUNTING OFFICE, MEDICAL MALPRACTICE: SIX STATE CASE STUDIES SHOW CLAIMS AND INSURANCE COSTS STILL RISE DESPITE REFORMS 17 (1986) (noting that in some states one claim is filed for every three or four physicians); PATRICIA M. DANZON, MEDICAL MALPRACTICE: THEORY, EVIDENCE, AND PUBLIC POLICY 60 (1985) (noting that a survey from 1968 to 1975 indicated that the ratio of claims to physicians jumped from one claim per thirty-seven physicians to one claim per eight physicians).

66. See, e.g., U.S. DEP’T OF JUSTICE, REPORT OF THE TORT POLICY WORKING GROUP ON THE CAUSES, EXTENT AND POLICY IMPLICATIONS OF THE CURRENT CRISIS IN INSURANCE AVAILABILITY AND AFFORDABILITY 35-36 (1986) (finding that during the ten-year period ending 1985, the average medical malpractice jury award increased from $220,018 to $1,017,716).

67. See, e.g., GAO MALPRACTICE REPORT, supra note 57, at 3 (noting that the cost of medical malpractice insurance has increased from $1.7 billion in 1983 to $5.9 billion in 1988 for physicians and from $800 million in 1983 to $1.3 billion in 1985 for hospitals).
costs either charge their patients higher fees or stop providing high-risk services altogether. The latter prospect is especially troublesome in Maine's rural areas, where residents receive minimal health care services.

Not surprisingly, Maine's practice parameters project was part of a tort reform package that the Legislature passed in 1990. The legislation establishing the Project was drafted by the MMA in 1989 and sponsored in 1990 by an MMA ally in the Maine Senate. The Project's premise is that physicians cannot be expected to alter their treatment patterns without receiving some protection from liability for doing so. The Project also presumes that immunizing physicians from liability for practicing medicine in accordance with the practice parameters will reduce the cost of defensive medicine. Theoretically, if the practice parameters apply to the clinical circumstances at issue, there will be a corresponding decrease in the likelihood of iatrogenic harm and a corresponding increase in the overall quality of medical care provided.

Although no committee reports were produced on the Project, the

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68. See, e.g., NAT'L LEADERSHIP COMM'N ON HEALTH CARE, FOR THE HEALTH OF A NATION xxvii (1989).


70. Telephone interview with Gordon H. Smith, supra note 6.

71. An Act to Establish the Rural Medical Access Program, the 5-year Medical Liability Demonstration Project, Revise the Rules Regarding Collateral Sources and the Discovery Rule In Medical Liability Cases Without Imposing Caps On Damages, ch. 931, § 4, 1989 Me. Laws 2398, 2399-402 (codified at ME. REV. STAT. ANN. tit. 24, §§ 2971-78 (West Supp. 1991)) (establishing five-year medical liability demonstration project). The legislative package also created a rural medical access program to subsidize obstetrical care in under-served areas, id. § 5, at 2402-04 (codified at ME. REV. STAT. ANN. tit. 24-A, §§ 6301-11 (West Supp. 1991)), revised Maine's discovery rules so that a medical malpractice pre-litigation screening panel's findings are binding in a subsequent court action unless good cause is shown, id. § 2, at 2398 (codified at ME. REV. STAT. ANN. tit. 24, § 2857(3) (West Supp. 1991)), and revised Maine's collateral source rule so that a trial court must automatically reduce an award by the amount of any collateral source payments, id. § 3, at 2398-99 (codified at ME. REV. STAT. ANN. tit. 24, § 2906 (West Supp. 1991)).

72. Smith, supra note 11, at 2.

73. Id.

74. Id.

75. Leahy, supra note 22, at 1491.

floor debate on the tort reform legislation in the Maine House highlights some of the policy issues that the legislators considered regarding the development of the practice parameters.77 The parameters were to be consistent with appropriate standards of medical care and designed to help minimize future medical malpractice actions and the cost of defensive medicine.78 In addition, the parameters were to be formulated to help reduce the costly battle of experts that often occurs in medical malpractice actions.79 Generally, the legislators' remarks were supportive of the Project and its objectives,80 although one indirect aspersion was cast upon the practice parameters by a critic of the legislation's collateral source provision.81 Nevertheless, the Legislature enacted the Project and the Governor signed it into law on April 24, 1990.82

Thus, the Project's starting point is the development of practice parameters that define appropriate clinical indications for certain medical treatments. As such, the practice parameters are a means of using health care resources more efficiently, discouraging the practice of defensive medicine, improving the quality of medical care, reducing the incidence of iatrogenic harm, and rationalizing medical malpractice litigation.

II. DEVELOPMENT AND ADOPTION OF THE PRACTICE PARAMETERS

A. The Medical Specialty Advisory Committees

A perfect medical policymaking body would be absolutely objective, well funded, well informed, composed of the finest experts, and committed to improving the quality and affordability of health care.83 In reality, practice parameters are conceptualized as the product of one of two policymaking models.84 Under the professional model, practice parameters

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77. 114TH MAINE LEGISLATURE, LEGIS. REC. H756-70 (Apr. 14, 1990) [hereinafter LEGIS. REC.]. The Maine Senate passed the tort reform legislation without debate. Id. at S837.
78. See, e.g., id. at H756 (statement of Rep. Rydell); id. at H757 (statement of Rep. Paradis); id. at H767 (statement of Rep. Farnsworth).
79. See, e.g., id. at H756 (statement of Rep. Rydell).
80. See, e.g., id. at H760 (statement of Rep. Boutilier); id. at H761 (statement of Rep. Hastings); id. at H766 (statement of Rep. Stevens); id. at H769 (statement of Rep. Boutilier).
81. "[T]he demonstration project...[is] just [a] nice little shady grove[ ] around that dinosaur [the collateral source language] that is buried inside there, that [insurance companies and physicians]...have been trying to get through this body and the other body for ten years." Id. at H762 (statement of Rep. Conley).
82. Smith, supra note 11, at 1.
83. E.g., Leahy, supra note 22, at 1510.
84. Clark C. Havighurst, Practice Guidelines For Medical Care: The Policy Rationale,
are developed according to professional norms that combine scientific knowledge and an overarching dedication to patient welfare. This model provides that practice parameters should be promulgated by physicians and should accommodate medicine's full range of practice diversity rather than setting hard and fast prescriptions. By contrast, under the political model, parties outside the medical profession join those within it to develop practice parameters. This model affords the opportunity to build a consensus, both scientific and political, regarding what medical care is appropriate for society.

That the Project is based on the political model is clear from the membership of the medical specialty advisory committees (Advisory Committees) that are responsible for developing the practice parameters. Appointments to the Advisory Committees are made primarily by the Maine Board of Registration in Medicine, but the Governor and the leaders of the Legislature also appoint certain members, with the MMA and several medical specialty societies serving an advisory role. These societies include the Maine Chapter of the American Society of Anesthesiologists, the Maine Osteopathic Association, the Maine College of Family Physicians, the Maine Chapter of the American College of Emergency Medicine Physicians, the Maine Academy of Family Physicians, the Maine Chapter of the American College of Obstetricians and Gynecologists, and the Maine Radiological Society.

The Advisory Committees worked under the following legislative
mandate:

Each medical specialty advisory committee shall develop practice parameters and risk management protocols in the medical specialty area relating to that committee. The practice parameters must define appropriate clinical indications and methods of treatment within that specialty. The risk management protocols must establish standards of practice designed to avoid malpractice claims and increase the defensibility of the malpractice claims that are pursued. The parameters and protocols must be consistent with appropriate standards of care and levels of quality. 94

The Advisory Committees studied medical literature, consulted medical experts, analyzed medical malpractice liability claims data, examined the standards of national medical specialty societies in their respective fields, and considered other sources of relevant information. 95 Committee members then agreed to focus on medical procedures that represented a significant drain on health care dollars. 96

For example, members of the Advisory Committee on anesthesiology "looked at instances that were relatively rare but caused a lot of money

who practices in a medium-sized hospital; one physician who practices primarily in a rural area; one physician who is board-certified in the specialty; and two public members who represent the interests of consumers and payers of medical costs, respectively. Id. § 2972(2)(A), (D). The Advisory Committee on emergency medicine has nine members: one physician who practices in a tertiary hospital; an osteopath; one physician who practices primarily in a rural area; one family practice physician; two physicians who are board-certified in the specialty; and three public members who represent the interests of consumers, payers of medical costs, and allied health professionals, respectively. Id. § 2972(2)(B).
The allied health professional seat is held by a nurse with extensive risk management experience. Smith, supra note 11, at 3. Finally, the Advisory Committee on obstetrics and gynecology also has nine members: one physician who practices in a tertiary hospital; one physician who practices in a medium-sized hospital; one physician who practices primarily in a rural area; one family practice physician; one physician who is board-certified in the specialty; and three public members who represent the interests of consumers, payers of medical costs, and allied health professionals, respectively. ME. REV. STAT. ANN. tit. 24, § 2972(C) (West Supp. 1991). The allied health professional seat is filled by a certified nurse mid-wife. Smith, supra note 11, at 3.

95. Code Me. R. §§ 02-373-020 at 3, -022 at 3, -024 at 4, -026 at 3 (1991). The Advisory Committees studied medical malpractice claims data to identify effective strategies that would help reduce iatrogenic harm. See Richard L. Kravitz et al., Malpractice Claims Data as a Quality Control Tool, 266 JAMA 2087 (1991) (finding that medical malpractice claims in the high-risk specialties of obstetrics and gynecology, anesthesiology, general surgery, and radiology were caused by patient management errors rather than substandard technical performance or medical staff coordination problems).
96. Stephenson, supra note 56, at 5.
They also "looked at things that were done very frequently but were relatively low-cost items. In particular, . . . [they] examined inappropriate preoperative lab tests anesthesiologists might order." The Advisory Committee on obstetrics and gynecology "took a similar approach in deciding where to focus its standards." The members of the Advisory Committee on emergency medicine also focused on the "alleged excessive use of diagnostic procedures in the emergency room." By focusing on unusual payment and utilization rates, the Advisory Committees sought to identify when physicians were practicing defensive medicine. Their theory was that if the practice parameters were developed for those medical procedures commonly used to practice defensive medicine, the cost and incidence of defensive medicine would be reduced.

In formulating the practice parameters, the Advisory Committees borrowed heavily from standards and guidelines of national medical specialty societies. For example, the Advisory Committee on anesthesiology stated that it derived its practice parameters from standards and guidelines of the American Society of Anesthesiologists. Likewise, the Advisory Committee on obstetrics and gynecology borrowed from the technical bulletins, committee opinions, and quality assurance manuals of the American College of Obstetricians and Gynecologists, and from the clinical standards of the Harvard Medical Institutions and the University of Connecticut Regional Network. The Advisory Committee on emer-

97. Id. (quoting Richard M. Flowerdew, M.D., chairperson of the Advisory Committee on anesthesiology) (internal quotations omitted).
98. Id.
99. Id. (paraphrasing remarks of John Makin, M.D., chairperson of the Advisory Committee on obstetrics and gynecology).
100. Smith, supra note 11, at 2.
101. See supra notes 25-26, 38, 63 and accompanying text.
102. Smith, supra note 11, at 2. But see William B. Schwartz & Paul L. Joskow, Medical Efficacy Versus Economic Efficiency: A Conflict in Values, 299 NEW ENG. J. MED. 1462 (1978) (arguing that health care costs cannot be controlled without confronting the fact that the best health care technology can provide frequently must be foregone to achieve economic efficiency).
103. Stephenson, supra note 56, at 1.
105. Id. § 02-373-024 app. 1 at 1-15. The Advisory Committee on obstetrics and gynecology also went beyond national standards. For example, the Advisory Committee developed a practice parameter for monitoring intrapartum fetal distress. Id. at 9-13. "ACOG [American College of Obstetricians and Gynecologists] has no comparable document. While fetal distress is a widely used term, it is poorly defined . . . [The Advisory Committee defined fetal distress in terms of the timing and duration of symptoms related to fetal heart rate." Stephenson, supra note 56, at 6 (quoting John Makin, M.D., chairper-
Emergency medicine formulated its practice parameter on inter-hospital patient transfers\textsuperscript{106} from federal guidelines set forth in the Consolidated Omnibus Budget Reconciliation Act of 1985.\textsuperscript{107} Although the Project's practice parameters "are based on and strongly related to the national standards, . . . they are not necessarily identical."\textsuperscript{108} Many parameters were tailored "to fit the realities of the Maine health care environment."\textsuperscript{109} It is unlikely, however, that this tailoring amounts to a return to the locality standard of medical care under the law of negligence. Indeed, the Maine Supreme Judicial Court's decision in \textit{Johnson v. Gerrish}\textsuperscript{110} holds medical specialists to a national standard of care, and under \textit{McLaughlin v. Sy},\textsuperscript{111} local circumstances are relegated to a mere factor in the overall determination of the legal standard of appropriate medical care.

The practice parameters\textsuperscript{112} may be used for diagnosis, screening, or treatment.\textsuperscript{113} The ease with which a parameter can be assimilated into the standard of care depends upon the practice parameter's classification.\textsuperscript{114} First, diagnostic practice parameters include medical tests that help "determine the presence or absence of specific disorders in [patients] . . . with unique complaints or clinical findings."\textsuperscript{115} Whether a physician employs a particular diagnostic test depends upon his or her analysis of many clinical facts, such as the degree of the patient's illness and the likely effect of one test on another or on the patient's current medical situation.\textsuperscript{116} Second, screening practice parameters describe tests that are performed on healthy individuals who belong to specified

\textsuperscript{108} Stephenson, supra note 56, at 4 (quoting Gordon H. Smith, counsel for the Maine Medical Association) (internal quotations omitted). However, the practice parameters for radiology are virtually identical to the standards and guidelines already developed by the American College of Radiology. \textit{Id.} at 6.
\textsuperscript{109} \textit{Id.} at 4 (quoting Gordon H. Smith, counsel for the Maine Medical Association) (internal quotations omitted).
\textsuperscript{110} 518 A.2d 721, 722-23 (Me. 1986); see supra note 15.
\textsuperscript{111} 589 A.2d 448, 452 (Me. 1991); see supra note 15.
\textsuperscript{112} See supra note 4.
\textsuperscript{113} Leahy, supra note 22, at 1492.
\textsuperscript{114} \textit{Id.}
\textsuperscript{115} \textit{Id.}
\textsuperscript{116} \textit{Id.}
classes. For example, the Project provides that asymptomatic women at least forty years of age are candidates for periodic mammography. Because they are generally independent of the clinical variations among individual patients, screening parameters are easier to assimilate into a legal standard of care than diagnostic parameters. Finally, treatment practice parameters share the characteristics found in the other two classes of parameters but encompass even more clinical variables; therefore, treatment parameters are broadly drawn and difficult to assimilate into a workable legal standard of care.

B. The Maine Board of Registration in Medicine

The Advisory Committees formulated draft versions of the practice parameters and sent them for comments to all physicians in Maine practicing in the respective specialty areas. On February 14, 1991, pursuant to the rulemaking requirements of the Maine Administrative Procedure Act, the Board of Registration in Medicine (Board) held public hearings on the preliminary drafts of the parameters. The Board considered written commentary to clarify technical language in the practice parameters and the requirements for eligibility for participation in the Project. Except for the chairpersons of the Advisory Committees, who spoke in favor of adopting the practice parameters as administrative rules, no other parties spoke either for or against the practice parameters. At the conclusion of the rulemaking process, the Board adopted the practice parameters as administrative rules, thereby giving

117. Id.
119. Leahy, supra note 22, at 1493.
120. Id. at 1494. As more data on the outcomes of treatments in particular clinical circumstances is collected, the medical profession will use it to build a consensus on the appropriate treatment for those clinical circumstances, and treatment practice parameters will become more specific. Id.
121. Stephenson, supra note 56, at 5.
124. See supra note 5.
125. No public testimony was heard on the practice parameters for radiology because the Board received no requests to hold hearings on the work of the Advisory Committee on radiology. Code Me. R. § 02-373-026 at 4 (1991).
126. Id. §§ 02-373-020 at 4, -022 at 4-5, -024 at 4-5, -026 at 4.
127. Id. §§ 02-373-020 at 4, -022 at 4, -024 at 4, -026 at 4.
them the force and effect of law.\textsuperscript{130}

A statement of the factual and policy bases for the practice parameters accompanies the Board's rules.\textsuperscript{131} The Board stated that the parameters are consistent with appropriate standards of medical care and levels of quality in the practice of anesthesiology, emergency medicine, obstetrics and gynecology, and radiology in the State of Maine.\textsuperscript{132} The Board intends that physicians participating in the Project conform their care of patients to the practice parameters whenever medically appropriate.\textsuperscript{133} Hopefully, such conformity will reduce the risk of iatrogenic injury to patients and the cost of defending medical malpractice claims. While the Board found that the practice parameters define appropriate standards of care, the physician's assertion that the parameters apply to a particular case is rebuttable.\textsuperscript{134}

The need for flexibility in applying the practice parameters is evident in the Board's additional finding that "under extenuating circumstances, it may not be medically appropriate to follow these practice parameters."\textsuperscript{135} In exchange for clinical discretion, the Board requires stringent documentation by participating physicians for care provided outside the parameters.\textsuperscript{136} Physicians must timely document the patient's medical record,

\textsuperscript{130} See supra note 5. The Maine Trial Lawyers Association criticized the adoption of the practice parameters as administrative rules because future changes will also have to satisfy the procedural requirements of the Maine Administrative Procedure Act. Stephenson, supra note 56, at 6. The practice parameters will not "have the fluidity that one normally attributes to medical standards. Under this condition [of adopting the practice parameters as administrative rules], the standards will be carved in stone and will have to be followed by physicians like a recipe." Id. (quoting Robert Stolt, counsel for the Maine Trial Lawyers Association) (internal quotations omitted). Nonetheless, according to the chairperson of the Advisory Committee on anesthesiology, the practice parameters "are dynamic . . . . They will change, they should change, and they must change." Id. (quoting Richard M. Flowerdew, M.D., chairperson of the Advisory Committee on anesthesiology) (internal quotations omitted). Periodic meetings of the Advisory Committees, medical literature reviews, and solicitation of comments will provide the basis for updating the practice parameters to reflect advances in medical knowledge. Id. If the Advisory Committees conclude that changes are appropriate, recommendations will be made to the Board or the Legislature. Id.

\textsuperscript{131} The Maine Administrative Procedure Act requires the Board to adopt this statement. ME. REV. STAT. ANN. tit. 5, § 8052(5) (West 1989 & Supp. 1991).


\textsuperscript{133} Id. §§ 02-373-020 at 3, -022 at 3, -024 at 3, -026 at 3.

\textsuperscript{134} ME. REV. STAT. ANN. tit. 24, § 2975(1)-(3) (West Supp. 1991); see supra notes 7-11 and accompanying text.

\textsuperscript{135} Code Me. R. § 02-373-020 app. 1 at 1; see id. §§ 02-373-022 app. 1 at 1, -024 app. 1 at 1, -026 app. 1 at 1 (1991).

\textsuperscript{136} Stephenson, supra note 56, at 5. According to the chairperson of the Advisory Committee on anesthesiology, the practice parameters "are not so different in mandating
Practice Parameters and Physician Liability

describing any deviation from a parameter and explaining the reasons therefor.\textsuperscript{137} The Advisory Committee on radiology described the rationale for the compromise between the practice parameters and clinical discretion as follows:

It is the opinion of the committee that these practice parameters, so defined and developed, define principles of practice which should generally produce high quality radiological care. The radiologist may exceed an existing standard as determined by the individual patient and available resources. The standards should not be deemed inclusive of all proper methods of care or exclusive of other methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding the propriety of any specific procedure or course of conduct must be made by the radiologist in light of all circumstances presented by the individual situation. Adherence to these standards will not assure successful outcome [sic] in every situation.\textsuperscript{138}

Although this statement assumes that the physician is treating the patient pursuant to the practice parameters, the Project does not require physicians to use the parameters.\textsuperscript{139} Because the parameters have the force and effect of law, such a requirement would create absolutely binding standards of medical care.\textsuperscript{140} Requiring physicians to use the parameters would be imprudent due to the highly complex and variable nature of medicine.\textsuperscript{141} For the practice parameters’ to be obligatory on the physician, complete clarity regarding the parameters application to clinical situations would be required,\textsuperscript{142} and achieving that degree of exactness is unlikely. Moreover, if the parameters were strictly binding, physicians

\begin{verbatim}
what physicians do, but in their obligation to record what they do.” \textit{Id.} (quoting Richard M. Flowerdew, M.D.) (internal quotations omitted). Because physicians who participate in the Project may deviate from them, the practice parameters are not like “cookbook medicine.” \textit{Id.} Although allowing for clinical discretion may remove the taint of “cookbook medicine,” such flexibility also may affect the usefulness of the practice parameters as a defense in medical malpractice actions. \textit{See Smith, supra note 11, at 5 (questioning whether the Advisory Committees can devise practice parameters that are both sufficiently general to gain acceptance by the Maine medical profession and specific and narrow enough to be useful in the defense of medical malpractice claims).}
\end{verbatim}

\textsuperscript{137} Code Me. R. §§ 02-373-020 app. 1 at 1, -022 app. 1 at 1, -024 app. 1 at 1, -026 app. 1 at 1 (1991).

\textsuperscript{138} \textit{Id.} § 02-373-026 app. 1 at 1.

\textsuperscript{139} It is the “desire” of the Board that the physicians who are participating in the Project will conform their care of patients to the practice parameters. \textit{Id.} §§ 02-373-020 at 3, -022 at 3, -024 at 4, -026 at 3.

\textsuperscript{140} \textit{See supra note 5.}

\textsuperscript{141} \textit{See Hall, supra note 11, at 134.}

\textsuperscript{142} \textit{Id.}
pleading compliance with parameters as an affirmative defense to malpractice claims would enjoy virtual tort immunity, an objectionable result given the complexities and ambiguities of medicine. On the other hand, failure to comply exactly with compulsory parameters would raise the specter of negligence per se, regardless of Maine's rule that violation of a statute is only evidence of negligence and not negligence per se. Thus, the practice parameters shield a physician from liability only if appropriately employed and followed.

Physician discretion regarding the use of the parameters raises the issue of whether the parameters can influence physicians' treatment decisions. Merely providing physicians with practice parameters is generally regarded as inadequate to bring about the desired medical improvements. Physicians need incentives to integrate practice parameters into their daily clinical practice. Whether physicians use the parameters also depends upon the quality of the practice parameters in terms of

143. Id.
144. Havighurst, supra note 22, at 105 (arguing that "any injury-causing violation of a practice guideline is very likely to be treated by a jury as negligence per se even if it is not regarded as such in law").
146. E.g., Chassin, supra note 1, at 439.
147. A study of hospitals and obstetricians in Ontario, Canada before and after the release of a widely distributed and nationally endorsed consensus statement that recommended decreases in the use of cesarean sections highlights the importance of incentives. Jonathan Lomas et al., Do Practice Guidelines Guide Practice?, 321 New Eng. J. Med. 1306 (1989). The study found that "the practices of physicians are influenced by many things besides research evidence, even when such evidence is packaged in a set of clear and concrete recommendations." Id. at 1310. Implementation of practice parameters may be blocked by "perceived threats of malpractice litigation from potentially dissatisfied parents, . . . economic and socioeconomic incentives to perform elective cesarean section[,] . . . or even pressure from women who were offered the opportunity to avoid a potentially painful and prolonged vaginal delivery." Id. Without strategies to overcome these other influences, "the dissemination of . . . practice guidelines . . . is unlikely to have much effect on inappropriate practices that are sustained by powerful nonscientific forces." Id. The anesthesia quality assurance program in Massachusetts is an example of economic incentives causing the integration of practice parameters into clinical practice. Leape, supra note 3, at 44. In July 1987, the Commonwealth's Medical Malpractice Joint Underwriting Association (JUA) established a quality assurance program based on the practice parameters of the American Society of Anesthesiologists (ASA). Id. The JUA, the only underwriter of medical malpractice insurance in Massachusetts, discounted premiums for physicians who participated in the program. Kinney, supra note 19, at 25. A year after initiating the program, "the JUA reported that for the first time, no episodes of hypoxic brain damage had occurred during the year in patients for whom the anesthetists had followed the ASA guidelines." Leape, supra note 3, at 44. The JUA thereafter announced a 20% reduction in malpractice insurance fees for participating physicians. Id.
their clarity and clinical relevance.\textsuperscript{148} Under the Maine Project, physicians have several strong incentives to utilize the practice parameters in clinical practice.

One incentive is that physicians will have the benefit of a known medical standard "that cannot be challenged by experts within or outside the State [of Maine]."\textsuperscript{149} Thus, the plaintiff will be forced to focus on whether the practice parameters applied to the clinical circumstances or whether the physician complied with them.\textsuperscript{150} Physicians still may be vulnerable if compliance implicates questions of judgment and discretion.\textsuperscript{151} Another incentive is that compliance with the parameters is an affirmative defense for a physician who is sued for medical malpractice. Only the physician may introduce the parameters as evidence at trial,\textsuperscript{152} and if the physician does not introduce the parameters, their existence will not arise in the litigation.\textsuperscript{153} However, the physician's compliance with the parameters is subject to attack once the affirmative defense is raised.\textsuperscript{154} A third incentive is that the physician's alternative to invoking the parameters is the unsatisfactory system of a jury determination of the standard of care based on a battle of experts.\textsuperscript{155} A fourth incentive is that the parameters do not threaten the physician's clinical judgment and discretion.\textsuperscript{156} Finally, peer pressure among physicians is likely to influence utilization of the parameters.\textsuperscript{157} "[T]he physicians all had a hand in writing or reviewing the standards. . . . Maine physicians had the final say in developing their own standards."\textsuperscript{158}

In sum, the practice parameters reflect a variety of interests in Maine


\textsuperscript{149} Smith, supra note 11, at 3.

\textsuperscript{150} Telephone interview with Gordon H. Smith, supra note 6.

\textsuperscript{151} Hall, supra note 11, at 134.

\textsuperscript{152} ME. REV. STAT. ANN. tit. 24, § 2975(1)-(2) (West Supp. 1991).

\textsuperscript{153} Smith, supra note 11, at 4.

\textsuperscript{154} See ME. REV. STAT. ANN. tit. 24, § 2975(2) (West Supp. 1991).

\textsuperscript{155} The legal principles that establish the standard of care in a medical malpractice action can be conceptualized as a triangle. Hirshfeld, supra note 11, at 1559. The broadest rule, which governs all individual conduct, comprises the triangle's base. \textit{Id.} The court supplies narrower rules to build up the sides, as a matter of law, and the litigants further shape the result through competing evidence elicited in the "battle of experts." \textit{Id.} At the apex of the triangle is the specific legal standard of care for the particular case. \textit{Id.} The jury completes the triangle at this point. \textit{Id.}

\textsuperscript{156} See Code Me. R. §§ 02-373-020 app. 1 at 1, -022 app. 1 at 1, -024 app. 1 at 1, -026 app. 1 at 1 (1991).

\textsuperscript{157} Leape, supra note 3, at 45.

\textsuperscript{158} Stephenson, supra note 56, at 4.
both within and outside the medical community. They are the product of extensive scientific investigation into certain misutilized medical procedures. The parameters are rooted in standards and guidelines of national medical specialty societies, but also fit the realities of practicing medicine in the State of Maine. The parameters are consistent with appropriate standards of care and levels of quality in the practice of the respective medical specialty areas in the state. Finally, they have the force and effect of law as administrative rules, and several strong incentives support their use in clinical practice.

III. Practice Parameters as Evidence of the Standard of Care

A. The Maine Rules of Evidence

To assert an affirmative defense based on the practice parameters in a medical malpractice action, the physician must introduce the parameters into evidence as proof of the standard of care under the clinical circumstances being litigated.\(^{159}\) Of course, any proffer of evidentiary proof is subject to the rules of evidence.\(^{160}\) Since “only the physician . . . may introduce into evidence . . . the existence of the practice parameters,” the burden of satisfying these evidentiary requirements is on the physician.\(^{161}\) In general, the physician must prove three evidentiary points: (1) that the practice parameters are relevant to the clinical circumstances at issue;\(^{162}\) (2) that the parameters are admissible as evidence despite the rule against hearsay;\(^{163}\) and (3) that the parameters are authentic representations of what they purport to be.\(^{164}\) Of particular importance to the physician’s successful use of the affirmative defense is the deference that Maine courts give the practice parameters.\(^{165}\)

Evidence is relevant if it has “any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.”\(^{166}\) If, for example, the clinical indications for a medical procedure are at issue, the physician must demonstrate that the practice parameters address

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159. Hirshfeld, supra note 11, at 1556.
162. ME. R. EVID. 402.
163. ME. R. EVID. 802.
164. ME. R. EVID. 901.
165. See Brennan, supra note 11, at 77-78.
166. ME. R. EVID. 401.
those clinical indications. If a standard of care itself is at issue, the physician must prove that the parameters define the standard of care. Expert medical testimony will be required to establish the relevancy of the practice parameters, and the physician will be required to qualify his or her witness as a medical expert. However, the key issue will be whether the practice parameters apply to the facts of the case rather than whether the practice parameters set forth valid standards of care. To deny the physician the affirmative defense of compliance, the plaintiff may argue that the parameters are irrelevant and inadmissible, or may assert that the physician's expert witness has an insufficient basis for expressing an opinion regarding the relevancy of the parameters.

Assuming that the practice parameters are relevant to the clinical circumstances at issue, the physician must further establish that the parameters are admissible despite the hearsay rule. The parameters are hearsay because they are out-of-court statements offered to prove the truth of the matter asserted therein—namely, the standard of care. Hearsay is inadmissible because it cannot meet the three conditions under which testimony is ordinarily received: oath, personal presence at trial, and cross-examination. The physician, however, may be able to introduce the parameters as evidence of the standard of care under certain exceptions to the hearsay rule.

One exception to the hearsay rule is for “learned treatises,” which are “statements contained in published treatises, periodicals, or pamphlets on a subject of . . . medicine . . . established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice.” However, the learned treatise exception has

167. Brennan, supra note 11, at 75.
168. Id.
169. Me. R. Evid. 702. See Kinney & Wilder, supra note 11, at 446 (noting that most courts would not accept practice parameters as evidence of the standard of care without accompanying expert medical testimony).
170. Me. R. Evid. 402.
171. Me. R. Evid. 705(b).
172. Me. R. Evid. 802.
173. Me. R. Evid. 801(c).
174. Me. R. Evid. 802.
175. Strong et al., supra note 160, § 245, at 426.
176. Me. R. Evid. 803.
177. Me. R. Evid. 803(18).
178. Id. Maine courts are unlikely to take judicial notice of the practice parameters. “A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to resources whose accuracy cannot reasonably
several limitations. First, because expert testimony is required to establish the reliability of the treatise, the exception raises the problems of witness credibility and battling experts. Second, the treatise may be read into evidence but may not be received as an exhibit. Finally and most importantly, the Maine hearsay exception for a learned treatise applies "to the extent [the learned treatise is] called to the attention of an expert witness upon cross-examination." The physician likely will also want to introduce the practice parameters on direct examination of his or her expert witness when seeking to establish the affirmative defensive of compliance.

The exception to the hearsay rule for public records and reports may be more useful for Maine physicians. This exception covers "records, reports, statements, or data compilations in any form of a public office or agency setting forth ... matters observed pursuant to duty imposed by law and as to which there was a duty to report, or factual findings resulting from an investigation made pursuant to authority granted by law." The practice parameters appear to satisfy this definition as data compilations or factual findings made by a public agency pursuant to statutory authority. Under this exception to the hearsay rule, offering the parameters as evidentiary exhibits or on direct examination is allowed. Another advantage to the public records and reports exception is that expert testimony is not required to establish the materials as reliable authority. Thus, the hearsay exception for public records and reports offers the physician more flexibility in using the practice parameters as evidence than the hearsay exception for learned treatises.

be questioned." Me. R. Evid. 201(b). Another complication is that Maine courts can only take judicial notice of adjudicative facts under Rule 201(a) of the Maine Rules of Evidence, and the practice parameters are arguably legislative facts. See Kenneth C. Davis, An Approach to Problems of Evidence in the Administrative Process, 55 Harv. L. Rev. 364, 404-07 (1942) (distinguishing between adjudicative and legislative facts); see also Leahy, supra note 22, at 1522-27 (arguing for the use of judicial notice to give legal force to practice parameters based on procedural and substantive advantages).

179. See supra notes 19-21 and accompanying text.
180. Me. R. Evid. 803(18).
181. Id.
182. Under the Federal Rules of Evidence, the learned treatise exception applies "to the extent [the learned treatise is] called to the attention of an expert witness upon cross-examination or relied upon by the expert witness in direct examination." Fed. R. Evid. 803(18).
183. Me. R. Evid. 803(8)(A).
184. Id.
185. See supra note 5.
186. Me. R. Evid. 803(8)(A).
The final evidentiary requirement is that the physician must demonstrate that the practice parameters are what they purport to be.\textsuperscript{187} To facilitate this identification, the physician may rely on the rule that extrinsic evidence of authenticity is not required for a document or certified copy bearing both the seal of the State of Maine and a signature purporting to be an attestation or execution.\textsuperscript{188} Because the law requires the Secretary of State of Maine to make available copies of rules for all state agencies,\textsuperscript{189} the practice parameters are self-authenticating, thus easing their introduction as evidence at trial.\textsuperscript{190}

Practice parameters have been used in several cases as evidence of the standard of care outside of Maine, but these precedents involved plaintiffs using practice parameters against physicians to prove medical malpractice.\textsuperscript{191} At present, there are no reported cases of physicians using practice parameters defensively to prove due care in medical malpractice actions.\textsuperscript{192} When used to inculpate physicians, courts have refused to rely on parameters on the issue of the standard of care.\textsuperscript{193} The lack of deference to parameters is defensible under such circumstances because plaintiffs can characterize physician conduct as negligent by strategically selecting their practice parameters, and because physicians may be able

\begin{itemize}
\item \textsuperscript{187} ME. R. EVID. 901(a).
\item \textsuperscript{188} ME. R. EVID. 902(1), (4).
\item \textsuperscript{189} ME. REV. STAT. ANN. tit. 5, § 8056(3)(A) (West 1989 & Supp. 1991).
\item \textsuperscript{190} ME. R. EVID. 902(4).
\item \textsuperscript{191} See, e.g., Bradford v. McGee, 534 So. 2d 1076, 1080-81 (Ala. 1988) (finding evidence of negligence in failure to follow American College of Obstetricians and Gynecologists' practice parameter recommending that physicians perform fetal non-stress testing on patients beginning in the 42nd week of pregnancy); James v. Woolley, 523 So. 2d 110, 112 (Ala. 1988) (finding evidence of negligence in failure to follow American College of Obstetricians and Gynecologists' practice parameter recommending that physicians deliver babies in excess of 4000g by cesarean section); Pollard v. Goldsmith, 572 P.2d 1201, 1203 (Ariz. Ct. App. 1977) (finding that the American College of Surgeons' practice parameter on Prophylaxis Against Tetanus and Wound Management established a standard of care for that condition); see also Darling v. Charleston Community Memorial Hosp., 211 N.E.2d 253 (Ill. 1965) (finding that national hospital accreditation standards are relevant when determining responsibilities of a hospital in its care of patients); Cornfeldt v. Tongen, 262 N.W.2d 684 (Minn. 1977) (finding the hospital accreditation standards of the Joint Commission for the Accreditation of Hospitals admissible as evidence of accepted medical practice in hospitals); Gwen M. 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 (1984) (arguing in favor of the admission of practice parameters to help eliminate the elusiveness surrounding the standard of care concept).
\item \textsuperscript{192} See Hall, supra note 11, at 131. The Maine Medical Association expects a case involving the defensive use of the practice parameters to arise within two to three years. Telephone interview with Gordon H. Smith, supra note 6.
\item \textsuperscript{193} See Hall, supra note 11, at 131.
\end{itemize}
to justify deviations from those parameters.\textsuperscript{194} However, when parameters are used as an exculpatory defense, courts should defer on the issue of the standard of care.\textsuperscript{195} Indeed, Maine courts have several important policy reasons for instructing juries to defer to the practice parameters on the issue of the standard of care.

\textbf{B. Policy Considerations}

First, the intended use of the practice parameters warrants judicial deference.\textsuperscript{196} The State Legislature mandated that the parameters be consistent with appropriate standards of care and levels of quality in the practice of anesthesiology, emergency medicine, gynecology and obstetrics, and radiology in Maine.\textsuperscript{197} Implementing this charge, the Board found that physician compliance with the parameters would reduce the risk of iatrogenic injury and the cost of defending medical malpractice claims.\textsuperscript{198} Thus, the parameters are intended to improve medical care and to control health care costs by prospectively prescribing the appropriate standard of care for certain clinical indications.\textsuperscript{199} When the clinical indications covered by the parameters are at issue in medical malpractice actions, the Maine courts should instruct juries that the practice parameters define the standard of care.\textsuperscript{200} This instruction will also depend on the practice parameters being prescriptive (instructing treatment for specific clinical indications prospectively) and precise (identifying when they do and do not apply).\textsuperscript{201} Conversely, when the practice parameters and the clinical indications at issue are not identical, the practice parameters

\textsuperscript{194} See \textit{id}.

\textsuperscript{195} See Brennan, \textit{supra} note 11, at 77 (arguing that compliance with practice parameters by an individual practitioner “will be important, if not totally exculpatory, evidence in a common law proceeding”); see also Hall, \textit{supra} note 11, at 131 (arguing that “because it in not necessary for a doctor to show that unanimous professional consensus supports his [or her] conduct, a defense is sufficiently established if the doctor shows only that . . . [he or she] complied with at least one respectable body of opinion”).

\textsuperscript{196} See Hirshfeld, \textit{supra} note 11, at 1559-60 (noting that compliance with practice parameters can be a significant factor in determining the standard of care); Kinney & Wilder, \textit{supra} note 11, at 447-48 (noting that protocols or standards developed by national medical organizations can be persuasive evidence on the issue of compliance with the appropriate standard of care).

\textsuperscript{197} ME. REV. STAT. ANN. tit. 24, § 2973 (West Supp. 1991).

\textsuperscript{198} Code Me. R. §§ 02-373-020 at 3, -022 at 3, -024 at 4, -026 at 3 (1991).

\textsuperscript{199} See supra notes 78-79 and accompanying text.

\textsuperscript{200} See Hirshfeld, \textit{supra} note 11, at 1560; Kinney & Wilder, \textit{supra} note 11, at 447.

\textsuperscript{201} See Deborah W. Garnick et al., \textit{Can Practice Guidelines Reduce the Number and Costs of Malpractice Claims?}, 266 JAMA 2856, 2859 (1991); Hall, \textit{supra} note 11, at 142-43; Hirshfeld, \textit{supra} note 11, at 1560.
are due less deference as evidence of the standard of care.\textsuperscript{202}

Second, the sponsorship of the practice parameters supports judicial deference.\textsuperscript{203} The membership of the Advisory Committees that developed the parameters reflects not only the prestige and imprimatur of the Maine medical profession—physicians, allied health professionals, and state chapters of national medical specialty societies—but also the interests of consumers and third-party payers.\textsuperscript{204} Maine physicians "had the final say in developing their own [practice parameters] . . . . [The physicians] tailored many of them to fit the realities of the Maine health care environment."\textsuperscript{205} Thus, the Maine medical profession’s approval of the parameters is clear. In addition, the parameters were promulgated by the Maine Board of Registration in Medicine, which has the legal duty to regulate the practice of medicine in the state.\textsuperscript{206} Most importantly, the practice parameters express what the citizens of the State of Maine deem to be appropriate standards of medical care.\textsuperscript{207}

Finally, the character of the practice parameters argues for judicial deference.\textsuperscript{208} The parameters reflect Advisory Committee studies of medical literature, consultations with medical and scientific experts, analyses of medical malpractice liability claims data, examinations of the standards of national medical specialty societies, and consultations with other relevant sources.\textsuperscript{209} Furthermore, the parameters are related to national medical specialty society guidelines that other courts have considered as evidence of the standard of care.\textsuperscript{210} As Board promulgated administrative rules, the parameters also have the force and effect of law.\textsuperscript{211} The fact that physician compliance with the practice parameters is not compulsory is wise public policy\textsuperscript{212} and does not undermine their validity as

\textsuperscript{202} See Hall, supra note 11, at 143; Hirshfeld, supra note 11, at 1560.

\textsuperscript{203} See Garnick et al., supra note 201, at 2858-59; Hall, supra note 11, at 140-42; Kinney & Wilder, supra note 11, at 448-49.


\textsuperscript{205} Stephenson, supra note 56, at 4 (quoting Gordon H. Smith, counsel, Maine Medical Association) (internal quotations omitted).


\textsuperscript{207} See supra notes 90-93 and accompanying text.

\textsuperscript{208} See Kinney & Wilder, supra note 11, at 449-50 (stating that “too much deference is accorded to custom evidence in medical malpractice”).


\textsuperscript{210} See supra note 191 and accompanying text.

\textsuperscript{211} See Hirshfeld, supra note 11, at 1560 (arguing that legislative statutes and government regulations may affect the evidentiary weight of practice parameters).

\textsuperscript{212} See supra notes 139-145 and accompanying text.
appropriate standards of medical care. Obligatory use of the parameters regardless of any unique clinical circumstances may very well increase the incidence of iatrogenic injury, contrary to the aims of the Project. Maine physicians, however, have several strong incentives for incorporating the parameters into their clinical practice whenever appropriate. Maine courts should encourage physician utilization of the practice parameters because they define "good medical practice."

IV. CONCLUSION

"[I]f the program succeeds in Maine, it will serve as a compelling argument for broadening the use of standards elsewhere in the nation." Maine courts can contribute to the Project’s success by instructing juries that, where applicable and followed, the practice parameters define the standard of care. This judicial deference is justified in terms of the purpose, broad societal support, and medical and scientific validity of the practice parameters. Thus, the Maine judiciary can bolster the Project’s efforts to use health care resources more efficiently, to discourage the practice of defensive medicine, to improve the quality of medical care, to reduce the incidence of iatrogenic injury, and to rationalize medical malpractice litigation.

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213. See supra notes 94-121 and accompanying text.
214. See Hirshfeld, supra note 11, at 1560 (arguing that forcing physicians to follow practice parameters may be harmful in some cases).
215. See supra notes 149-158 and accompanying text; see also Garnick et al., supra note 201, at 2859 (arguing that physicians will benefit from fewer injuries and lawsuits).
216. See supra notes 131-133 and accompanying text.