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Government Created Medical Practice Guidelines: The Opening of Pandora's Box

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GOVERNMENT CREATED MEDICAL PRACTICE GUIDELINES: THE OPENING OF PANDORA'S BOX

WILLIAM R. TRAIL¹
BRAD A. ALLEN²

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I. INTRODUCTION

Few topics have dominated the concern of the American people over the last few years as much as health care. Despite a recent decrease in the inflation of health care costs, health care costs continue to rise at frightening levels in the United States.³ Even if costs stabilize, many persons will be unable to afford care at current cost levels.⁴ Furthermore, cost control solutions that focus only on direct costs to consumers overlook two important factors in the rise in health care costs: defensive medicine and malpractice insurance.⁵

The General Accounting Office (GAO) defines defensive medicine as the alteration of modes of medical practice, induced by the threat of liability, for the principal purpose of preventing lawsuits by patients and providing a defense if medical negligence lawsuits are initiated.⁶ The Office of Technology Assessment (OTA) defines defensive medicine as "physicians' ordering of tests and procedures, or avoidance of high-risk patients or pro-cedures [sic], primarily (but not necessarily solely) to reduce their exposure to malpractice risk."⁷ By either definition, the practice of defensive medicine is not based on the exercise of expertise by a health care professional and is an indirect cost of the current medical malpractice system.⁸

It is difficult to accurately estimate the costs attributable to the practice of defensive medicine. The use of defensive medicine to avoid or defend medical malpractice actions may be only one of many factors prompting the physician's defensive behavior.⁹ Nevertheless, the cost of defensive medicine is significant.¹⁰ Estimated costs of defensive medicine ranged \$12 to \$14 billion in 1989,¹¹ and \$5 to \$15 billion a year thereafter.¹² Any solution to our current

³Richard Price & Richard Rimkunas, *Health Care Fact Sheet: 1993 National Health Spending*, CRS REPORT FOR CONGRESS, (EPW No. 94-952) (Dec. 1, 1994).

⁴See Marshall B. Kapp, *Medical Malpractice Reform as Part of Health Care Reform 1994 Version*, 68 FLA. B. J. 28 (1994).

⁵OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, *IMPACT OF LEGAL REFORMS ON MEDICAL MALPRACTICE COSTS 5-7* (1993) [hereinafter *IMPACT OF LEGAL REFORMS*].

⁶GENERAL ACCOUNTING OFFICE, U.S. CONGRESS, *MEDICAL MALPRACTICE: MAINE'S USE OF PRACTICE GUIDELINES TO REDUCE COSTS 2* (1993) [hereinafter *GAO*].

⁷*IMPACT OF LEGAL REFORMS*, *supra* note 5, at 6.

⁸*Id.*

⁹GAO, *supra* note 6, at 2.

¹⁰Richard E. Leahy, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines*, 77 CAL. L. REV. 1485, 1490 (1989).

¹¹*Id.*

¹²OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, *DEFENSIVE MEDICINE AND MEDICAL MALPRACTICE 3*, 158-59 (1994) [hereinafter *DEFENSIVE MEDICINE*].

health care cost crisis must address the health care provider's perceived need to adopt defensive medicine practices.¹³

Solutions that reduce the perceived need to practice defensive medicine and medical insurance premiums should not be confused with proposals that eliminate equity by not requiring health care providers to be responsible for their errors and omissions. Policy makers must examine the relationship between the perceived need to practice defensive medicine and the health care provider's fear of medical negligence lawsuits.¹⁴ One solution that purports to provide cost containment, improved quality of care, and maintain physician responsibility is medical practice guidelines.¹⁵

Medical practice guidelines, when used properly, can reduce the practice of defensive medicine and the frequency of malpractice claims by enhancing physician knowledge, improving hospital protocols,¹⁶ and providing physicians with a legitimate defense to medical negligence actions.¹⁷ The creation and enforcement of medical practice guidelines by state government agencies, with assistance from the medical community, can increase the quality of care and reduce malpractice litigation if the guidelines: (1) are carefully evaluated by physicians and other qualified personnel; (2) are continuously updated and generally available through a communication system; (3) create an affirmative defense for physicians; and (4) are admissible as evidence with probative value by potential plaintiffs.¹⁸

This article will discuss the background and creation of medical practice guidelines in part II. Next, we will define and discuss in Part III the two primary types of medical practice guidelines: privately created guidelines and government created guidelines. In Part IV, we will compare and contrast the current medical practice guidelines programs in operation. Finally, we will recommend in section V that a medical practice guidelines program offering an affirmative defense to complying physicians should be implemented on the state level.

II. BACKGROUND

A. What are Medical Practice Guidelines?

The Agency for Health Care Policy & Research (AHCPR), a part of the Public Health Service, was established by Congress in December of 1989 to enhance the quality, appropriateness, and effectiveness of health care services and

¹³ See GAO, *supra* note 6, at 1-9, 18.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ GAO, *supra* note 6, at 1-9, 18.

¹⁸ TMA'S HOSPITAL MEDICAL STAFF SECTION SUBCOMMITTEE ON PRACTICE PARAMETERS, TEXAS MEDICAL ASS'N, PRACTICE PARAMETERS: A PRIMER 9-12, (1994) [hereinafter TMA].

access to those services.¹⁹ The Congressional legislation creating the AHCPR also established, within the AHCPR, the Office of the Forum for Quality and Effectiveness in Health Care (the Forum).²⁰ "The Forum has primary responsibility for facilitating the development, periodic review, and updating of clinical practice guidelines," which are designed to "assist practitioners in the prevention, diagnosis, treatment, and management of clinical conditions".²¹ The AHCPR defines clinical practice guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical conditions."²²

Similarly, the American Medical Association (AMA) defines practice parameters as "strategies for patient management, developed to assist physicians in clinical decision making."²³ Practice parameters is a generic term and is used synonymously with a variety of terms, including practice options, practice guidelines, practice policies, and practice standards.²⁴ The generic form of the term medical practice guidelines as defined by the AHCPR will be used as the standard for this article since the AHCPR's definition embraces the AMA definition of practice parameters.

¹⁹DEFENSIVE MEDICINE, *supra* note 12, at 140. The AHCPR was established in December 1989 under Public Law 101-239 (Omnibus Budget Reconciliation Act of 1989) to enhance the quality, appropriateness, and effectiveness of health care services and access to these services. AGENCY FOR HEALTH CARE POLICY AND RESEARCH, U.S. DEPT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE, CLINICAL PRACTICE GUIDELINE: DEPRESSION IN PRIMARY CARE: TREATMENT OF MAJOR DEPRESSION (inside cover), (1993) [hereinafter DEPRESSION].

²⁰DEPRESSION, *supra* note 19, (inside cover).

²¹*Id.*

²²*Id.*

²³AMERICAN MEDICAL ASSOCIATION, LEGAL IMPLICATIONS OF PRACTICE PARAMETERS (1990).

²⁴*Practice Options*—are those practice statements on which physicians seriously lack agreement; also outcomes of the option are incomplete or inconclusive;

Practice Guidelines—systematically developed statements to assist physician decisions about appropriate health care for specific clinical circumstances; guidelines are policies that the strong majority of patients prefer;

Practice Policies—recommendations issued for the purpose of influencing decisions about health interventions; and *Practice Standards*—practice policies in which the economic consequences of an intervention are sufficiently well known to permit decisions, and there is virtual unanimity among physicians about the desirability or undesirability of the intervention and about the proper use or nonuse of the intervention.

TMA, *supra* note 18, at 3.

Many hospitals, regional and national medical associations, and the AHCPR are already creating and implementing clinical guidelines.²⁵ Medical practice guidelines were introduced almost 50 years ago²⁶ in an attempt to standardize some aspects of health care practice. This attempt to standardize care currently includes 60 organizations that have produced over 1600 medical practice guidelines.²⁷ The plethora of information of medical practice guidelines is available in a directory available from the AMA.²⁸

What originated as an attempt to create some standardization has expanded to include other goals like establishing an educational resource for physicians in clinical patient care management by providing alternative care options;²⁹ strategies or suggestions;³⁰ limiting physician liability;³¹ and containing costs.³²

Medical practice guidelines provide cost savings in three primary ways. First, the guidelines reduce the need for defensive medicine. By complying with guidelines that insulate the physician from liability, if properly followed, the doctor will order only those tests and procedures that are medically indicated.³³ Second, guidelines can reduce medical insurance cost by reducing the number of injuries and medical malpractice claims.³⁴ Third, by reducing the number of injuries and medical malpractice claims, the amount of money spent on settlements and litigation should proportionately decrease.³⁵

²⁵John T. Kelly & Margaret C. Toepp, *Practice Parameters: Evaluation, Dissemination and Implementation*, 18 QUALITY REV. BULL. 405, 405 (1992).

²⁶John D. Ayres, *The Use and Abuse of Medical Practice Guidelines*, 15 J. LEGAL MED. 421, 421 (1994).

²⁷*Id.*

²⁸A listing of practice parameters is available for a price through the AMA's Directory of Practice Parameters, Practice Parameters Update, and CD-ROM. AMERICAN MEDICAL ASSOCIATION, IMPLEMENTING PRACTICE PARAMETERS ON THE LOCAL/STATE/REGIONAL LEVEL 4 (1994) [hereinafter IMPLEMENTING].

²⁹Ayres, *supra* note 27, at 421. See also Kelly & Toepp, *supra* note 25, at 405; John T. Kelly & James E. Swartwout, *Development of Practice Parameters by Physician Organizations*, 16 QUALITY REV. BULL. 54 (Feb. 1990).

³⁰Kelly & Toepp, *supra* note 25, at 406.

³¹*Id.*

³²*Id.*

³³GAO, *supra* note 6, at 1-5. See also NATIONAL HEALTH LAWYERS ASSOCIATION, COLLOQUIUM REPORT ON LEGAL ISSUES RELATED TO CLINICAL PRACTICE GUIDELINES 2-3 (1995) [hereinafter NHLA].

³⁴See GAO, *supra* note 6, at 1-8.

³⁵*Id.* See also NHLA, *supra* note 33, at 1-2.

B. How are Medical Practice Guidelines Distinct from Utilization Review Guidelines?

In addition to these cost savings, cost containment benefits also arise from utilization review. It is important to distinguish medical practice guidelines from guidelines developed for the limited purpose of cost containment. Utilization review is one of the most common strategies for controlling health care costs.³⁶ "Utilization review refers to external case by case evaluation[s] conducted by third-party payers, purchasers, health care organizers, or utilization review contractors to evaluate the necessity and appropriateness (and sometimes quality) of medical care."³⁷ "It is a strategy that attempts to control costs by limiting demand."³⁸ Retrospective or prospective review is used to determine whether medical care will be paid for by an insurer.³⁹ Guidelines are established procedures appropriate for a specific medical condition, and such procedures are approved for payment.⁴⁰ This form of cost containment is used primarily by medicare and medicaid systems.⁴¹ The Agency for Health Care Policy and Research (AHCPR) currently creates medical practice guidelines that are different from guidelines used in utilization review for Medicare and Medicaid payments. There appears to be a movement to have the AHCPR create guidelines needed for these areas as well.⁴² Opponents to such action argue that this will result in the AHCPR over-emphasizing cost containment in the creation of practice guidelines, and thus reduce their overall value.⁴³

The guidelines used by Medicare and Medicaid are solely for the purpose of cost containment.⁴⁴ Scholars have noted that the use of these guidelines primarily for cost containment removes them from the debate concerning quality of care.⁴⁵ Medicaid guidelines in fact have little to do with clinical guidelines concentrating on quality of care, defense of malpractice cases, and solving the inappropriate use of medical care (primarily but not solely defen-

³⁶Barry R. Furrow et al., *THE LAW OF HEALTH CARE ORGANIZATION AND FINANCE* 364 (1991).

³⁷*Id.*

³⁸*Id.*

³⁹*Id.*

⁴⁰Colleen M. Grogan et al., *How Will We Use Clinical Guidelines? The Experience of Medicare Carriers*, 19 *J. HEALTH POL., POL'Y & L.* 7, 7 (1994).

⁴¹*See id.* at 7-11.

⁴²*Id.* at 7, 10.

⁴³*Id.*

⁴⁴*See Grogan, supra* note 40, at 7-9.

⁴⁵*Id.*

sive medicine).⁴⁶ Medicare and Medicaid guidelines have been criticized by scholars as the model of inefficiency, disorganization, delayed updating, and a general lack of concern for anything but cost containment.⁴⁷

These complaints are caused by two basic characteristics of the Medicaid guidelines. First, the goal of these guidelines is only cost containment. Second, poor communication dominates the creation, implementation, use, and modification of the guidelines.⁴⁸ The emphasis on cost containment could actually increase malpractice litigation if quality of care is not adequately addressed.⁴⁹

Even though these problems are noted in government utilization review cases, they essentially raise the problems and concerns aligned with poorly created and implemented guidelines.⁵⁰ This is of minor concern to the federal government because of sovereign immunity. However, physicians and hospitals do not have the luxury of immunity akin to the federal government. The *Wickline v. State of California* case is still noted for holding physicians liable for care, even if the payment guidelines are contrary to the physicians judgment.⁵¹ In fact, private and state agencies that create guidelines have some liability concerns that the federal government probably does not have in light of *Wilson v. Blue Cross of Southern California*.⁵² Despite the concerns mentioned, a well thought-out medical practice guideline program on a national level could reap cost-containment benefits and improved quality of care.⁵³ Reality notes that this is an unlikely prospect until further results are obtained on the state programs.⁵⁴

Utilization review does not advance either the educational or guidance objectives that practice guidelines perform because it emphasizes cost-containment, not quality of care.⁵⁵ Utilization review also does not serve as a defense to the liability of a practicing physician (*Wickline v. State of*

⁴⁶*Id.*

⁴⁷*Id.*

⁴⁸Grogan, *supra* note 40, at 14-15.

⁴⁹*See id.* at 18-19. *See also* Kapp, *supra* note 4.

⁵⁰Ayres, *supra* note 27, at 421, 425-26; Leahy, *supra* note 10, at 1523-24.

⁵¹239 Cal. Rptr. 810 (Cal. Ct. App. 1986); *see infra* text accompanying note 53 for a discussion of the *Wickline* case.

⁵²271 Cal. Rptr. 876 (Cal. Ct. App. 1990); *see infra* for text accompanying note 54 for a discussion of the *Wilson* case.

⁵³*See* James F. Holzer, *The Advent of Clinical Standards for Professional Liability*, 16 QUALITY REV. BULL. 71-79 (1990); Eleanor D. Kinney & Marilyn M. Wilder, *Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities*, 22 U. C. DAVIS L. REV. 421-50 (1989).

⁵⁴Edward B. Hirshfeld, *Should Practice Parameters be the Standard of Care in Malpractice Litigation?*, 266 JAMA 2886-91 (1991).

⁵⁵*Id.*

California),⁵⁶ or to the creator of the cost-containment guidelines (*Wilson v. Blue Cross of Southern California*).⁵⁷ Even though utilization review and medical practice guidelines share the use of guidelines to advance their objective, the similarities end there. Utilization review is solely a cost-containment method. Medical practice guidelines serve that purpose in addition to several others. Therefore, medical practice guidelines should be viewed as the next logical step in the evolution of health care management.

A recent student note argued for the use of utilization review in a managed care setting as opposed to the use of medical practice guidelines. The author opposed the use of medical practice guidelines due to the cost to implement the program. Furthermore, the note favored utilization review for its potential to contain costs.⁵⁸

This approach overlooks two important factors. First, the cost for the creation of practice guidelines do not have to be recovered in the first year to have a net cost savings. The bulk of the costs are related to the creation of the program, while the savings should continue to grow for several years, thus a net savings will be realized. Second, utilization review's cost-containment is primarily achieved by the establishment of guidelines, just like medical practice guidelines. While utilization review focuses only on cost-containment, medical practice guidelines evolve to the next level and also improve quality of care.

Whether arising from government or private utilization review systems, the *Wickline* and *Wilson* cases illustrate the problems and concerns aligned with

⁵⁶In *Wickline*, a California Medicaid patient suffered complications after surgery. Medi-Cal (California's Medicaid Agency) approved ten days of post-operative care. Wickline's doctor requested an eight day extension to the care approved by Medi-Cal. Medi-Cal's utilization review consultant, a board certified general surgeon, reviewed the case and approved an extension of only four days. The physician did not use the Medi-Cal appeal process and released Wickline after four days. Wickline later returned to the hospital and had to have her right leg amputated. Wickline sued Medi-Cal for harm caused by the implementation of the utilization review guidelines (used for cost-containment). Wickline won at the trial court level, but lost on appeal because the attending doctor did not use the appeals process that was available. *Wickline*, 239 Cal. Rptr. 810 (Cal. Ct. App. 1986). *Wickline* warned providers and payers that they faced liability risks from incautious use of practice guidelines. Richard L. Peck, *Practice Guidelines: The Legal Issues*, 14 (5) BEHAV. HEALTH MGMT. 10 (1994).

⁵⁷In *Wilson*, a psychiatric patient was hospitalized for 10 days for several conditions including major depression. Wilson's doctor recommended an additional three to four weeks of treatment before release. Blue Cross refused to pay for additional treatment, and the physician released Wilson when he was unable to pay for further treatment. The decedent committed suicide three weeks later. The parents of the deceased lost on summary judgment at the trial court level based upon *Wickline*. The case was remanded on the appellate level because of, "substantial evidence that [the utilization review] decision not to approve further hospitalization was a substantial factor in bringing about the decedent's demise." *Wilson*, 271 Cal. Rptr. 876, 883 (Cal. Ct. App. 1990).

⁵⁸The most recent argument for the use of utilization review versus practice guidelines can be found by Michael Daly, *Attacking Defensive Medicine Through the Utilization of Practice Parameters*, 16 J. LEGAL MED. 101 (1995).

poorly created and implemented guidelines.⁵⁹ The *Wickline* case is noted for acknowledging the potential for physician liability for care, even if the payment guidelines are contrary to the physician's judgment.⁶⁰ In fact, private and state agencies that create guidelines have liability concerns in light of *Wilson*.⁶¹

Despite the concerns mentioned, a well conceived medical practice guideline program on a national level could generate cost-containment benefits and improve the quality of care.⁶² This is an unlikely prospect until further positive results are obtained from initial state programs.⁶³

III. TWO PRIMARY TYPES OF MEDICAL PRACTICE GUIDELINES

There are two primary types of medical practice guidelines: privately created and government created guidelines.

Although the inception, creation, modification, and use of these guidelines may be very similar, their legal ramifications may be sharply different. The nature of government created guidelines make them more of a risk, however, there are also enhanced benefits. Government created guidelines law requires legislative action. Anytime the legislative process is engaged, one can never be certain what will actually happen because of the various interests seeking to influence the legislators. It is akin to opening pandora's box. What will come out of pandora's box?

A. Privately Created Guidelines

A variety of private organizations produce medical practice guidelines. Hospitals and some local organizations create guidelines, sometimes called operating protocols, that control conduct within the hospital.⁶⁴ Many times these guidelines are adopted from other organizations. Local and state organizations also create guidelines, but the majority of published guidelines appear to be produced by national medical organizations. These include the AMA, Joint Commission on Accreditation of Health care Organizations (JCAHO), and most national academies, colleges, and societies for medical specialties.⁶⁵ Even though some of these organizations were opposed to medical practice guidelines at first, they now generally support the concept.⁶⁶ The American Medical Association (AMA) first dismissed practice guidelines

⁵⁹Ayres, *supra* note 27, at 421, 425-26; Leahy, *supra* note 10, at 1523-24.

⁶⁰See *supra* note 56 for a discussion of the *Wickline* case.

⁶¹See *supra* note 57 for a discussion of the *Wilson* case.

⁶²See Holzer, *supra* note 53; Kinney & Wilder, *supra* note 50, at 421-50.

⁶³Hirshfeld, *supra* note 54, at 2886-91.

⁶⁴NHLA, *supra* note 33, at 1-2.

⁶⁵Kelly & Toepp, *supra* note 25, at 406.

⁶⁶NHLA, *supra* note 33, at 12-13. See also GAO, *supra* note 6, at 17.

as "cookbook medicine."⁶⁷ As support for guidelines grew, the AMA changed its official policy to one of grudging support for the guidelines.⁶⁸ In 1990, the AMA, in conjunction with the Practice Parameters Partnership and Practice Parameters Forum, published *Attributes to Guide the Development of Practice Parameters*.⁶⁹ The five primary attributes for good medical practice parameters listed in that publication are as follows:

- 1) Practice parameters should be developed by, or in conjunction with, physician organizations whose members possess scientific and clinical expertise in the subject area relevant to the parameter.
- 2) Practice parameters should be based on reliable methodologies that integrate relevant research findings and appropriate clinical expertise.
- 3) Practice parameters should be precise and comprehensive, and should specify the clinical management strategies necessary to accomplish their goals.

⁶⁷ See generally GAO, *supra* note 6, at 17. In fact, the AMA now distinguishes practice guidelines from "cookbook medicine." In an official statement before the House Committee on Energy and Commerce the AMA through John T. Kelly, M.D., Ph.D., Director of the AMA's Office of Quality Assurance, stated, "They [practice parameters] are not like a cookbook, which provides only one course of action. Instead, practice parameters outline the *range* of appropriate tests and procedures for a given clinical situation. The advantage of practice parameters is to identify the boundaries between appropriate and inappropriate treatments." *Medical Practice Guidelines: Hearing Before the Subcomm. on Health and the Environment of the Comm. on Energy and Commerce House of Representatives*, 101st Cong., 1st Sess. 7 (1989) (statement of Robert E. McAfee, M.D. & John T. Kelly, M.D., Ph.D. [hereinafter MEDICAL PRACTICE GUIDELINES]). It is important to note that some still consider practice guidelines "cookbook" medicine. Marshall B. Kapp, "Cookbook" Medicine: A Legal Perspective, 150 ARCHIVES OF INTERNAL MED. 496, 497 (1990).

⁶⁸ The AMA's official policy on practice parameters as of 1989 was, "The AMA (1) supports the development by physician organizations of clinically relevant practice parameters designed to assure that patients receive high quality medical care; (2) believes that practice parameters should be: (a) developed by physician organizations primarily for use by physicians in their day-to-day practice; (b) based on sound research findings and the clinical experience of practicing physicians; (c) based upon consideration of the various clinical conditions of individual patients; (d) based on quality rather than cost considerations; (e) based on use of reliable methodologies that are explicitly stated; (f) accompanied by adequate explanatory information on appropriate uses of the practice parameters and sufficient disclaimers to prevent inappropriate use; and (h) made widely available to physicians in a practical and useful format; (3) supports establishing a process to evaluate practice parameters on an ongoing basis, endorsing those that meet the foregoing AMA principles, and developing practice parameters as needed in clinical areas not otherwise addressed; and (4) supports working with the Federation to assure the dissemination of AMA endorsed practice parameters." AMA Policy on Practice Parameters, Through December 1994, (Policy 410.998). The AMA reaffirmed this policy in 1994, (Policy 410.975). See also GAO, *supra* note 6, at 17.

⁶⁹ Kelly, *supra* note 25, at 406.

- 4) Practice parameters should be based on current information, and should have been updated within the past three years.
- 5) Practice parameters should be widely disseminated in peer-reviewed and other widely circulated publications.⁷⁰

These five points are valid factors to be considered when creating medical practice guidelines. The AMA has 11 additional guidelines for the implementation of guidelines on the local, state, and regional levels.⁷¹ Some of the medical organizations previously mentioned which promulgate medical practice guidelines also assist the AHCPR in the creation of national guidelines. The AHCPR, as mentioned earlier, is a government agency charged with the duty to create practice guidelines.⁷²

B. Government Created Guidelines

The medical practice guidelines created by the AHCPR were developed by an independent multidisciplinary panel of health care consumers and other experts convened by the AHCPR.⁷³ The panel employs an explicit, science-based methodology and expert clinical judgment to develop specific statements on patient assessment and management for the clinical condition selected.⁷⁴ It conducts an extensive literature search of the medical topic as well as a peer review of the completed guidelines.⁷⁵ These guidelines can be instrumental in establishing the standard of care a physician owes to a patient.⁷⁶ The impact on the physician's duty is the primary difference between

⁷⁰*Id.*

⁷¹The eleven step process is as follows: (1) Issue identification; (2) Issue refinement; (3) Identification of relevant practice parameters; (4) Evaluation of practice parameters; (5) Selection and modification of practice parameters; (6) Local development of practice parameters; (7) Dissemination of practice parameters; (8) Implementation of practice parameters; (9) Evaluation of the impact of practice parameters; (10) Periodic review of practice parameters; and (11) Departure from practice parameters. AMA, *supra* note 28, at 3-10.

⁷²TMA, *supra* note 18, at 5.

⁷³*Id.*

⁷⁴*See id.* at 11.

⁷⁵*See id.*

⁷⁶Most medical malpractice cases are based upon the tort theory of negligence. Negligence is "conduct which involves an unreasonably great risk of causing damage', or, more fully, 'conduct which falls below the standard established by law for the protection of others against unreasonable risk of harm.'" W. PAGE KEETON, ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 31, at 169 (5th ed. 1984). The elements of a negligent cause of action are as follows: (1) "A duty . . . requiring the person to conform to a certain standard of conduct, for the protection of others against unreasonable risk; (2) a breach of the duty; (3) A reasonably close causal connection between the conduct and the resulting injury, including the proximate cause and the cause in fact; and (4) Harm, actual loss or damage resulting to the interest of another. *Id.* § 30, at 164-65.

private and some government created guidelines.⁷⁷ Expert witnesses may use private practice guidelines to establish the standard of care in a specific case. In contrast, government established guidelines have the impact mandated by the enabling legislation, providing they do not offend either state or federal restraints on the legislative process.

C. The Standard of Care

A central question in medical malpractice litigation is: "What is the standard of care?"⁷⁸ Currently the standard of care in most jurisdictions is that of "an ordinary competent and prudent physician under like conditions."⁷⁹ Expert testimony is used to define this standard of care in each case.⁸⁰ The law presumes that jurors cannot independently evaluate questions of medical science or technology.⁸¹ The result is a battle of experts debating what is the standard of care for the particular procedure under consideration. The "battle of the experts" has been attacked for numerous reasons, including:

- 1) Objectivity may be suspect because the experts are paid for their testimony by that side (plaintiff or defendant).⁸²
- 2) Without guidelines, physicians are held to a standard of care that reflects habit, not necessarily a "good standard of care."⁸³
- 3) Experts are likely to be picked based on who they will best support, rather than most qualified to testify or objectivity.⁸⁴
- 4) While jurors endeavor to remain objective and evaluate the conflicting testimony provided by the expert witnesses, it is unrealistic to expect laymen to comprehend intricate and detailed medical procedures and related information.⁸⁵

Medical Practice Guidelines can establish a clear standard of care, but clarity will depend on the quality of the creation of the guidelines. Poorly designed guidelines will offer no help⁸⁶ and can be avoided by investing the proper

⁷⁷See GAO, *supra* note 6.

⁷⁸Gary W. Kuc, *Practice Parameters as a Shield Against Physician Liability*, 10 J. CONTEMP. HEALTH L. & POLY 439 (1994).

⁷⁹*Id.* at 442.

⁸⁰*Id.* See also W. Page Keeton, *Medical Negligence - The Standard of Care*, 10 TEX. TECH L. REV. 351 (1979).

⁸¹Kuc, *supra* note 78, at 442.

⁸²*Id.* at 444-45.

⁸³*Id.*

⁸⁴*Id.*

⁸⁵Kuc, *supra* note 78, at 444-45.

⁸⁶See Ayres, *supra* note 27, at 423-24, 430; Kelly & Toepp, *supra* note 25, at 406.

resources in the creation of medical practice guidelines.⁸⁷ By establishing medical practice guidelines as the legal standard of care, the jury will primarily be charged with deciding whether the practicing physician breached this duty to the patient, instead of deciding what the standard of care is.⁸⁸ This is a task that most jurors are more qualified to perform.⁸⁹

There are various concerns generated by a proposal to create government medical practice guidelines. For example, there is a legitimate concern that government guidelines might have an offensive effect by increasing the exposure of doctors who do not use the guidelines.⁹⁰ The benefits and disadvantages of government created medical practice guidelines depend on the type of system adopted. There are four basic types of government created medical practice guidelines.

D. Type I—State Created Affirmative Defense

1. Maine

The Maine Liability Demonstration Project has received more attention than any other medical practice guideline program.⁹¹ This is a result of the fact that Maine was the first state to create and implement a medical practice guideline program. Another significant factor is the impact of the state implemented guidelines on medical malpractice litigation.⁹² The guidelines in Maine were promulgated by the Maine Board of Registration in Medicine. These rules have the full force and effect of law under Maine administrative law.⁹³ The Maine Liability Demonstration Project is a classic example of a state created program offering complying physicians an affirmative defense in medical malpractice litigation. The goals of the Maine project are: 1) to create parameters for defined specialties; 2) to avoid malpractice claims; and 3) to increase the defensibility of the malpractice claims that are pursued.⁹⁴ The Maine project creates a standard of care through practice guidelines.⁹⁵ In Maine, judges are required to instruct applicable juries that the guidelines are the standard of care.⁹⁶

⁸⁷*Id.*

⁸⁸Kuc, *supra* note 78, at 435.

⁸⁹*Id.*

⁹⁰NHLA, *supra* note 33, at 16-18; *see* Kapp, *supra* note 4.

⁹¹GAO, *supra* note 6, at 1.

⁹²IMPACT OF LEGAL REFORMS, *supra* note 5, at 32-3.

⁹³GAO, *supra* note 6, at 6, 19.

⁹⁴ME. REV. STAT. ANN. tit. 24, § 2973 (West Supp. 1995).

⁹⁵ME. REV. STAT. ANN. tit. 24, § 2855 (West Supp. 1995).

⁹⁶*Id.* *See also* Kuc, *supra* note 78, at 445-46.

Physicians participating in the project have a defined standard of care with which their conduct will be compared if they are sued for malpractice.⁹⁷

The regulations create several requirements that operate as conditions that must be satisfied before the state created guidelines can be used to define the standard of care. The conditions include the following items:

- 1) The litigant identifies relevant guidelines;
- 2) The physician elected to participate in the practice guidelines program along with at least 50% of the other physicians in the specialty; and
- 3) The physician proves compliance with the guideline(s) so as to establish an affirmative defense.⁹⁸

To use the guidelines in a particular case the guidelines must be applicable to the specific procedure at issue in the case. Maine created medical specialty advisory committees to establish medical practice guidelines in four areas: 1) Anesthesiology, 2) Emergency Medicine, 3) Ob/Gyn, and 4) Radiology.⁹⁹

These four areas of medicine were selected because they are high risk areas of medicine that, for the most part, already operated under guidelines created on a national level.¹⁰⁰ The use of nationally created guidelines was designed to guarantee high quality guidelines.

Section 2855 makes the compliance with the medical practice guidelines an affirmative defense to a malpractice claim.¹⁰¹ An affirmative defense is defined as a, "matter asserted by defendant which, assuming the complaint to be true, constitutes a defense to it."¹⁰² In short, the affirmative defense means that the defending doctor cannot lose on the applicable cause of action if the defense is activated.¹⁰³

One concern expressed by guideline proponents was that guidelines should not have an offensive impact in litigation. The concern was that, if deviation from guidelines could be used to establish a claim of medical malpractice, the guidelines might increase rather than decrease litigation.¹⁰⁴ Section 2977 of the Maine statute makes the Maine guidelines admissible only by the defending

⁹⁷ME. REV. STAT. ANN. tit. 24, § 2973 (West Supp. 1995); see also GAO, *supra* note 6, at 26; NHLA, *supra* note 33, at 16-17.

⁹⁸GAO, *supra* note 6, at 26-27; see ME. REV. STAT. ANN. tit. 24, §§ 2972, 2973, 2855 (West Supp. 1995); DEFENSIVE MEDICINE, *supra* note 12, at 144.

⁹⁹ME. REV. STAT. ANN. tit. 24, § 2972 (West Supp. 1995).

¹⁰⁰GAO, *supra* note 6, at 31-33.

¹⁰¹ME. REV. STAT. ANN. tit. 24, § 2855 (West Supp. 1995).

¹⁰²BLACK'S LAW DICTIONARY 60 (6th ed. 1990).

¹⁰³*Id.*

¹⁰⁴See Kapp, *supra* note 4; AMA, LEGAL IMPLICATIONS OF PRACTICE PARAMETERS, 4-8 (1990).

doctor or doctor's hospital.¹⁰⁵ A plaintiff cannot introduce the Maine guidelines into evidence.¹⁰⁶ A plaintiff could address or use the guidelines once they have already been admitted as evidence by the defending doctor or hospital.¹⁰⁷ A physician must elect to be part of the Maine project before a cause of action accrues against her to be able to use the guidelines as a defense.¹⁰⁸

Opponents of the Maine project object to the restriction on the use of the guidelines only by defendants.¹⁰⁹ The Trial Lawyers's Association of Maine expects a constitutional challenge to this restriction on the use of the guidelines because "a new group of people are denied compensation when they are injured by using standards that are different than standards used in other parts of the country."¹¹⁰ The legal advisor of the demonstration project's advisory committee stated, however, that he does not believe that there will be a successful constitutional challenge to the affirmative defense because patients still have an absolute right to a jury trial.¹¹¹ Furthermore, the plaintiff can rebut the doctor's argument in court that the practice guidelines admitted are the applicable standard of care.¹¹² For example, if a doctor relies on the Ob/Gyn guidelines and the plaintiff can prove those are not the appropriate standards for that particular case, then the affirmative defense is not available. The plaintiff could provide such proof in one of two ways. First, the plaintiff could prove the case is not an Ob/Gyn case. A second argument would concede that the case is an Ob/Gyn case, but that the guidelines do not cover the particular treatment or scenario as presented in the plaintiff's cause of action.¹¹³ Otherwise, the plaintiff can not object to guidelines as the appropriate standard of care in Maine.

2. Florida

Although the Florida project is not nearly as detailed or as well organized as the Maine project, it contains the same basic structure and concepts. Part of Florida's 1992 health care reform law was title xxix, section 408.02, which authorizes the creation of practice parameters to assist doctors in clinical deci-

¹⁰⁵ME. REV. STAT. ANN. tit. 24, § 2977 (West Supp. 1995).

¹⁰⁶*Id.*

¹⁰⁷*Id.*

¹⁰⁸GAO, *supra* note 6, at 26.

¹⁰⁹GAO, *supra* note 6, at 26. *See also*, William A. Beltz ed., *Maine's Practice Guidelines*, BNA HEALTH L. REP. 749, 754 (1994).

¹¹⁰GAO, *supra* note 6, at 26-27.

¹¹¹*Id.*

¹¹²Kuc, *supra* note 78, at 457-59.

¹¹³*See id.*

sion making.¹¹⁴ The state Agency for Health Care Administration (AHCA) is required to develop practice guidelines that physicians can voluntarily use as protection against medical malpractice claims.¹¹⁵ The AHCA may work with other organizations to create the guidelines.¹¹⁶ In fact, the AHCA has decided to pursue this option. The agency plans to adopt standards already developed by national specialty societies or the AHCPR.¹¹⁷ The AHCA also plans to utilize the Florida medical community to help adopt the guidelines to gain support for the project.¹¹⁸

The medical practice guidelines created or adopted by the AHCA will be effective when they are adopted as rules by the agency—similar to the process used in Maine.¹¹⁹ The Florida guidelines also share other similarities with the Maine project. For example, participating physicians may use the Florida guidelines as an affirmative defense to a liability claim.¹²⁰ In addition, a doctor must elect to participate in the Florida program or she cannot employ the affirmative defense protection.¹²¹

However, unlike the Maine statute which expressly prevents a plaintiff from admitting the guidelines as part of her case, the Florida statute contains no provision regarding the plaintiff's ability to utilize the guidelines in proving a malpractice claim. There is concern that this omission will increase litigation in Florida.¹²² The guidelines in Florida, as in other applicable states, are guidelines—not absolute standards.¹²³ Most medical practice guidelines carry a disclaimer akin to that published by the AHCPR. The inside cover to the AHCPR guidelines states, "The recommendations [from the guidelines] may not be appropriate for use in all circumstances. Decisions to adopt any particular recommendation must be made by the practitioner in light of available resources and circumstances presented by individual patients."¹²⁴

Essentially, this statement means that practice guidelines establish a general standard of good/proper care and doctors should be able to deviate without penalty if that is what the prudent doctor would do in that situation.¹²⁵ The

¹¹⁴FLA. STAT. ANN. § 408.02 (West 1993).

¹¹⁵*Id.*; see also GAO, *supra* note 6, at 96.

¹¹⁶FLA. STAT. ANN. § 408.02 (West 1993). See also GAO, *supra* note 6, at 96.

¹¹⁷FLA. STAT. ANN. § 408.02 (West 1993). See also GAO, *supra* note 6, at 96.

¹¹⁸GAO, *supra* note 6, at 96-97.

¹¹⁹FLA. STAT. ANN. § 408.02 (West 1993).

¹²⁰*Id.*

¹²¹*Id.*

¹²²See *id.*

¹²³NHLA, *supra* note 33, at 16-17; see generally IMPLEMENTING *supra* note 28.

¹²⁴DEPRESSION, *supra* note 19, at ii.

¹²⁵Kuc, *supra* note 78, at 453; see generally DEPRESSION, *supra* note 19.

ability to deviate under unusual circumstances without penalty is a necessity for proper use of medical practice guidelines.¹²⁶ Otherwise, the claims of "cookbook medicine" would come to fruition. Many physicians argue that "cookbook medicine," referring to substandard care placing compliance with the "cookbook" as the prime directive over all other concerns, removes the art from medicine.¹²⁷ Such a rigid use of guidelines in Florida, or any other state, would likely create more problems than it solves. However, medical practice guidelines can avoid the trap of creating "cookbook medicine" by incorporating the flexibility allowed by most guidelines for unusual circumstances. While deviation from a relevant standard may prove a part of the plaintiff's case, the plaintiff must also prove the existence of a duty, cause, and harm.¹²⁸ Guidelines offered by a plaintiff in Florida provide evidence as to what the standard of care is, but no more. Non-compliance with guidelines does not create a prima facie case of negligence.¹²⁹ Physicians will be allowed to demonstrate the circumstances and reasons justifying any deviation from the Florida guidelines.¹³⁰

Even though the Florida project is not as detailed or as well organized as the Maine project, it contains the same basic structure and concepts. The admissibility of the guidelines by the plaintiff is the critical difference between the two programs.

3. Minnesota

Minnesota practice guidelines are similar to Florida's rules, except that the Minnesota guidelines have distinct rules concerning the admissibility of practice guidelines by plaintiffs. Minnesota passed health care reform legislation in 1992. The Minnesota program allows the Minnesota Health Care Commissioner to approve and disseminate practice guidelines to use as a defense against malpractice claims.¹³¹ It appears that the Minnesota defense will operate in essentially the same manner as the affirmative defense in Florida and Maine.¹³² As of March 1995, no guidelines had been approved in Minnesota.¹³³

¹²⁶Kuc, *supra* note 78, at 453; *see also* DEPRESSION, *supra* note 19.

¹²⁷*See* Kapp, *supra* note 69.

¹²⁸Keeton, *supra* note 80.

¹²⁹ME. REV. STAT. ANN. tit. 24, § 2977 (West Supp. 1995); FLA. REV. STAT. ANN. § 408.02 (West 1993); NHLA, *supra* note 33, at 17-18.

¹³⁰NHLA, *supra* note 33, at 17-18; *see also* AMA, LEGAL IMPLICATIONS OF PRACTICE PARAMETERS 9 (1990).

¹³¹GAO, *supra* note 6, at 96; DEFENSIVE MEDICINE, *supra* note 12, at 145-46.

¹³²DEFENSIVE MEDICINE, *supra* note 12, at 145-46.

¹³³OTA reported that no guidelines had been reported as of May, 1994. *Id.* On-line searches found no listing of approved guidelines at the time of publication.

Like the Maine statute, Minnesota's law also prohibits the plaintiff from introducing the guidelines as evidence that the physician failed to meet the standard of care.¹³⁴ Even though the Minnesota project offers little empirical evidence for evaluation because no guidelines have been approved as of yet, it is another good example of the type I medical practice guidelines program. Furthermore, Minnesota is yet another example of a state frustrated with the current status of medicine, law, and health costs.

E. Type II—State Created Guidelines with Probative Value

Type II state created guidelines are those that are created by the state and are admissible as evidence of the standard of care. The guidelines are not *the* standard of care as with Type I guidelines. Type II guidelines may be challenged like any other evidence offered to establish the standard of care.¹³⁵ Physician compliance with these guidelines does not create an affirmative defense. The guidelines function as expert testimony concerning the standard of care.¹³⁶

Vermont created a Type II practice guidelines program with health care reform legislation in 1992.¹³⁷ The program, implemented in 1994, allows the guideline to be admitted as evidence of the standard of care by either the plaintiff or the defendant. The Vermont Health Care Authority (VHCA) will designate one or more organizations to make recommendations on medical practice guidelines.¹³⁸

F. Type III—State Created Guidelines that are Not Admissible as Evidence

Maryland's program typifies the third type of state created medical practice guidelines. Type III guidelines are state created, but cannot be admitted as evidence.¹³⁹ The Maryland program, initiated on April 13, 1993, "mandates the development of state guidelines but explicitly prohibits introduction [of the guidelines] as evidence by any party in a malpractice suit."¹⁴⁰

G. Type IV—Federal Guidelines

National guidelines passed on the federal level are unlikely until medical practice guidelines test and prove beneficial on the state level. Without knowledge of the consequences of such programs, the federal government

¹³⁴IMPACT OF LEGAL REFORMS, *supra* note 5, at 32.

¹³⁵GAO, *supra* note 6, at 96; IMPACT OF LEGAL REFORMS, *supra* note 5, at 33.

¹³⁶IMPACT OF LEGAL REFORMS, *supra* note 5, at 33.

¹³⁷*Id.*

¹³⁸*Id.*

¹³⁹*Id.*

¹⁴⁰IMPACT OF LEGAL REFORMS, *supra* note 5, at 33; DEFENSIVE MEDICINE, *supra* not 12, at 146.

monitors the state programs at this time.¹⁴¹ The federal government showed interest in the Maine Medical Liability Demonstration project by authorizing evaluations by the General Accounting Office (GAO) and the Office of Technology Assessment (OTA).¹⁴² In addition to the federal agencies' investigations, the House Subcommittee on Health and the Environment, Committee on Energy and Commerce conducted several congressional hearings.¹⁴³ The investigating agencies also examine the other states that are experimenting with medical practice guidelines projects. Likewise, several states are also looking into the prospect of such a program, but have not taken definitive action yet.¹⁴⁴

The AMA and other organizations have encouraged the federal government to provide funds to conduct experiments and research into the use of medical practice guidelines.¹⁴⁵ The primary response from Congress was the creation of the AHCPR.¹⁴⁶ As discussed earlier, the AHCPR is already in the process of producing medical practice guidelines on a national level.¹⁴⁷ Unlike type I or type II guidelines, compliance with AHCPR guidelines does not create an affirmative defense for complying doctors.¹⁴⁸

However, this lack of a defense does not leave the AHCPR guidelines without merit. Producing national guidelines conforms with the trend of moving national standards of practice in specialties and deviates from the tradition of the locality rule.¹⁴⁹ Furthermore, states use AHCPR guidelines as a starting point to create state medical practice guidelines.¹⁵⁰ The AHCPR guidelines significantly benefit states and medical organizations by providing a model for states interested in drafting their own practice guidelines.¹⁵¹

Some states have considered using AHCPR guidelines for Medicare and Medicaid programs as part of the cost control mechanism. Although the AHCPR guidelines differ from the guidelines used in utilization review for

¹⁴¹The federal government is "monitoring" medical practice guidelines through the AHCPR. DEPRESSION, *supra* note 19; GAO, *supra* note 6, at 9; DEFENSIVE MEDICINE, *supra* note 12, at 140.

¹⁴²See GAO, *supra* note 6; IMPACT OF LEGAL REFORMS, *supra* note 5.

¹⁴³MEDICAL PRACTICE GUIDELINES, *supra* note 67.

¹⁴⁴Michigan, New York, North Carolina, Virginia, and Hawaii are all considering medical practice guidelines programs. Beltz, *supra* note 109, at 753-54.

¹⁴⁵*Id.*

¹⁴⁶DEPRESSION, *supra* note 19; NHLA, *supra* note 33, at 4-6.

¹⁴⁷DEPRESSION, *supra* note 19.

¹⁴⁸*Id.*; see Andrew L. Hyams et al., *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POL. POL'Y & LAW 289, 308 (1996).

¹⁴⁹Kuc, *supra* note 78, at 455-56; Leahy, *supra* note 10, at 1495-1502.

¹⁵⁰GAO, *supra* note 6, at 1-5.

¹⁵¹TMA, *supra* note 18, at 9-12; Leahy, *supra* note 10, at 1490.

Medicare and Medicaid payments, there appears to be a movement to have the AHCPR create guidelines for Medicare and Medicaid as well.¹⁵² Opponents argue that the movement will result in the AHCPR over-emphasizing cost-containment in the creation of practice guidelines, and thus reduce the guidelines' overall value.¹⁵³

As noted earlier, the Medicare and Medicaid guidelines are primarily related to cost-containment¹⁵⁴ and differ from clinical guidelines which focus on quality care, malpractice defense, and inappropriate medical care.¹⁵⁵ Therefore, the AHCPR should keep the medical practice guidelines it creates separate from utilization review standards. The AHCPR will play a vital part in any national medical practice guidelines programs created in the future. However, making practice guidelines conform with pure cost-containment goals may compromise the AHCPR guidelines.¹⁵⁶ Compromised guidelines could hinder national and state efforts to create medical practice guidelines programs.¹⁵⁷

A well-conceived medical practice guideline program on a national level could improve quality of care. However, a national solution is unlikely until further results are obtained on the state programs.

IV. COMPARISONS OF THE DIFFERENT MEDICAL PRACTICE GUIDELINES PROGRAMS

A. General Benefits of Medical Practice Guidelines

Medical practice guidelines offer numerous benefits to the medical community and the health care consumers. Some of the benefits available are applicable to all medical practice guideline systems, while others are limited to specific types of programs.

In general, most medical practice guidelines programs provide the same basic benefits:

- 1) They provide a degree of uniformity in fixing the standard of care;¹⁵⁸
- 2) They decrease the actual and perceived need for defensive medicine by eliminating the rationale for engaging in such practices;¹⁵⁹

¹⁵²Grogan, *supra* note 40, at 7-10.

¹⁵³*Id.* at 8.

¹⁵⁴*Id.* at 7-9.

¹⁵⁵*Id.*

¹⁵⁶See generally sources cited *supra* note 50.

¹⁵⁷See generally Hirshfeld, *supra* note 54.

¹⁵⁸Leahy, *supra* note 10, at 1483, 1490.

¹⁵⁹DEFENSIVE MEDICINE, *supra* note 12, at 155-59.

- 3) They serve an educational function by continuing to update physicians as to the standard of care for treatments covered by the guidelines;¹⁶⁰
- 4) They offer some cost-containment, primarily through the reduction of defensive medicine and reduction of insurance premiums;¹⁶¹ and
- 5) They reduce medical insurance and insurance premiums as a result of the improved quality of care. Therefore, the number of malpractice cases should significantly decrease.¹⁶²

The benefits of a medical practice guidelines program relate—their collective impact may exceed the sum of individual provisions. The guidelines are designed to improve the quality of care that should reduce the number of errors and need for defensive medicine. Reduced errors decrease litigation and insurance premiums. Reduced litigation and insurance affects costs, enabling money to be efficiently used to increase access and quality, and so on. The Type I practice guidelines program maximizes the benefits through the use of the affirmative defense as a strong enforcement mechanism.

B. Type I is the Optimal Practice Guidelines Program

Among existing medical practice guideline programs, the type I practice guideline program offers the best combination of benefits. Programs that offer an affirmative defense to participating physicians who comply with the practice guidelines have a key advantage over other forms of practice guidelines (Types II, III, and IV).¹⁶³ If complying doctors have an affirmative defense, then physicians have a strong incentive to participate in the program.¹⁶⁴ This inducement may sufficiently cause a majority of doctors to elect to participate in the program.¹⁶⁵ The affirmative defense should make doctors more willing to rely on the guidelines. The cost-containment benefits of reducing defensive medicine and insurance premiums may be maximized through reduced malpractice litigation. Doctors are more likely to keep up with published practice guidelines if they know the standard of care.¹⁶⁶ Therefore, the focused attention devoted to standards should advance the educational goals of the program.

¹⁶⁰NHLA, *supra* note 33, at 6.

¹⁶¹See generally sources cited *supra* note 50.

¹⁶²*Id.*; see also Leahy, *supra* note 10, at 1491.

¹⁶³IMPACT OF LEGAL REFORMS, *supra* note 5, at 33.

¹⁶⁴GAO, *supra* note 6, at 20-22.

¹⁶⁵*Id.*

¹⁶⁶*Id.*; see also, NHLA, *supra* note 33, at 6.

Guidelines, admissible as the standard of care, may likely reduce suits.¹⁶⁷ For example, if a potential plaintiff thinks she has a cause of action, but it can be proven that the practicing physician can prove full compliance with applicable practice guidelines, the plaintiff is less likely to file suit. Guidelines and subsequent compliance will benefit doctors even if such information is not revealed until pretrial arbitration or discovery.¹⁶⁸ Practice guidelines that do not offer an affirmative defense simply can not offer litigation benefits.

C. Type II, III, and IV programs are not as effective as Type I

Types II, III, and IV programs do not offer an affirmative defense to participating doctors and are less likely to be as effective as a Type I program. The ineffective programs may or may not allow admission of the guidelines in court to establish the standard of care owed by the doctor to the patient.¹⁶⁹ Some states' rules of evidence prohibit the admission of expert testimony in written form as hearsay. Such rules of evidence will prevent the admission of medical practice guidelines without an appropriate foundation.¹⁷⁰ Absent legal protection, doctors may continue their current behavior, and thus defensive medicine and insurance premiums will remain at current levels.¹⁷¹ Another key issue is deciding which guidelines doctors should follow.¹⁷² Type I guidelines to be followed are those guidelines established by statute or rule as legal standard of care. In Type II, III, and IV programs, physicians will be understandably confused in identifying which guidelines to follow.¹⁷³ As stated earlier, the AMA has documented the fact that 1,600 guidelines have been created by over sixty agencies.¹⁷⁴ Which guidelines will be used to establish the standard of care? Which guidelines will have more weight, if any, in a court of law? This potential confusion is clearly undesirable and may actually do

¹⁶⁷IMPACT OF LEGAL REFORMS, *supra* note 5 at 32-33.

¹⁶⁸*Id.* at 25-29.

¹⁶⁹NHLA, *supra* note 33, at 16-18; Leahy, *supra* note 10, at 1520-28.

¹⁷⁰The battle of evidence has elevated to a new plateau with the Supreme Court ruling in *Daubert v. Merrell Dow Pharms.*, 113 S. Ct. 2786 (1993). The issue has been frequently described as the debate over whether "junk science" would be permitted in the courtroom. *Daubert* now places the burden on the judge to ensure that an expert's testimony rests on a reliable foundation, following a five point test, and is relevant to the task at hand. Alice G. Gosfield, *Clinical Practice Guidelines and the Law: Applications and Implications*, in HEALTH LAW HANDBOOK 80-84 (1994 ed.). Creating a state government program that clearly establishes the evidentiary value of medical practice guidelines can avoid the troubles and complexity that *Daubert* has brought the courts. See also Katherine M. Atikian, *Nasty Medicine: Daubert v. Merrell Dow Pharmaceuticals, Inc. Applied to a Hypothetical Medical Malpractice Case*, 27 LOY. L.A. L. REV. 1513 (1994).

¹⁷¹Gosfield, *supra* note 170, at 86-88; GAO, *supra* note 6, at 8.

¹⁷²NHLA, *supra* note 33, at 16-17.

¹⁷³*Id.*

¹⁷⁴Ayres, *supra* note 27, at 421.

more harm than good.¹⁷⁵ Although potential confusion may exist with practice guidelines that offer an affirmative defense, confusion diminishes when guidelines define the legal standard of care. Thus, a physician in Florida or Maine could still face the issue of compliance with state guidelines that differ from hospital or other guidelines. The choice is made easier by the anticipated uniformity that will come from the creation of legislative guidelines and the insulation from tort liability provided by statute.

As mentioned earlier, Type III guidelines are inherently inferior because the guidelines are inadmissible in courts.¹⁷⁶ Type II guidelines could be informative to physicians, but may less likely alter either physician behavior or institutional costs.¹⁷⁷ Type II and III programs lack enforcement mechanisms to alter physician behavior, thus their benefits are limited, unlike a Type I program which contains the power of persuasion.

V. GOAL AND SOLUTION

The adoption of a Type I medical practice guidelines program would benefit the individual states passing such a program and to American health care system in general. To ensure that maximum benefits are received and minimum disadvantages are incurred, the program must be carefully constructed and implemented.¹⁷⁸ Eight primary steps should be taken to ensure a high quality medical practice guidelines program.

First, an investment in resources must be made in the program's enabling legislation.¹⁷⁹ States should take note of the specificity and detail placed by the Maine's legislature in the enabling legislation for the Maine medical liability demonstration project.¹⁸⁰ Specific detail enables the program to properly function. Other states creating similar programs should take the time, effort, and money to invest in their state's medical future.¹⁸¹ Medical practice guidelines projects that are less detailed, like Florida, are more likely to encounter problems and ineffectiveness. Creating medical practice guidelines is an investment in the future of medical care on which it is worth spending a significant amount of time and money.

Second, the guidelines should be carefully crafted by a joint committee of private and government representatives. The participants should certainly include physicians, but other disciplines and interests should be represent-

¹⁷⁵NHLA, *supra* note 33, at 16-17.

¹⁷⁶IMPACT OF LEGAL REFORMS, *supra* note 5, at 32.

¹⁷⁷*Id.* at 32-33.

¹⁷⁸See generally TMA, *supra* note 18, at 4. AMA, *supra* note 28, at 3-10.

¹⁷⁹TMA, *supra* note 18, at 4.

¹⁸⁰See generally ME. REV. STAT. ANN. tit. 24, §§ 2971-78.

¹⁸¹*Id.*

ed.¹⁸² Maine created panels representing a variety of societal interests to ensure high quality guidelines capable of a broad based appeal.¹⁸³ The creation and implementation of guideline committees offers a unique way to get a complete analysis of medical care from all societal interests. The improved communication through the committees can offer benefits beyond the creation of medical practice guidelines.

Third, states should create an affirmative defense for doctors who prove they complied with applicable medical practice guidelines. Without an affirmative defense, the program will lack the enforcement power to change physician behavior and will bring an end to the significant benefits sought.¹⁸⁴ As noted earlier, programs without an affirmative defense are less effective than those with the defense. An affirmative defense provides physicians with the incentive they need to alter their procedures and habits to bring about the desired results.

Fourth, it is important that a proper communication system be established so that physicians, hospitals, medical organizations, courts, attorneys, and the general public will have access to the most current set of medical practice guidelines.¹⁸⁵ Updates to guidelines can be efficiently distributed through on-line services, CD-ROM, direct mailings, or other prompt notification methods.¹⁸⁶ The importance of notification can not be underestimated, for the program is only as good as the communication and notification systems. As previously mentioned, poor communication plagues many utilization reviews, Medicare, and Medicaid programs. An effective communication system designed from the start will avoid the problems experienced by other programs.

Fifth, the system should follow the Florida model which allows a plaintiff to admit the guidelines into evidence.¹⁸⁷ There is, however, a potential to increase litigation.¹⁸⁸ This problem can be minimized or even avoided by taking several precautions—which takes us to the sixth step.

Sixth, the guidelines should have a disclaimer clearly printed in the introduction—similar to the disclaimer printed in guidelines by the AHCPR.¹⁸⁹ The disclaimer should state that if a plaintiff admits the guidelines into evidence, the guidelines have no greater value than any other evidence or

¹⁸²Kelly & Toepp, *supra* note 25, at 406-07. See IMPLEMENTING, *supra* note 28.

¹⁸³GAO, *supra* note 6, at 19.

¹⁸⁴*Id.* at 20-22, 26-27.

¹⁸⁵IMPLEMENTING, *supra* note 28, at 6; Grogan, *supra* note 40, at 8-10.

¹⁸⁶IMPLEMENTING, *supra* note 28, at 4.

¹⁸⁷See *supra* notes 114-30 and accompanying text.

¹⁸⁸Jan M. Harvey & Colin J. Roberts, *Clinical Guidelines, Medical Litigation, and the Current Medical Defense System*, 1 LANCET 145-47 (1987).

¹⁸⁹DEPRESSION, *supra* note 19.

testimony concerning the standard of care. Furthermore, the guidelines do not create a prima facie case of negligence or malpractice if physicians deviate from them. The disclaimer should be backed by inclusion of the disclaimer in the enabling legislation of the project. Subsequently, it will be reversible error if a judge allows deviation from guidelines to create a prima facie case or presumption. Physicians should completely document all deviations from the guidelines along with the reasons for them.¹⁹⁰ This information will be needed to rebut any inference (if any) of malpractice for deviation from the guidelines.¹⁹¹

Seventh, states may want to reconsider the creation of pretrial screening panels for medical malpractice.¹⁹² This device was used in the 1970s in response to the perceived medical malpractice crisis, however, it was not well integrated into a system that was comprehensive in nature.¹⁹³ The Maine mandatory pretrial screening process panel is used to review the merits of the case.¹⁹⁴ This pretrial screening process creates an opportunity for the parties to take a realistic look at their case.¹⁹⁵ For example, if a plaintiff brings a claim to the pre-screening panel and the panel finds that the defending doctor complied with appropriate guidelines and therefore has an affirmative defense, then the plaintiff will rarely pursue the claim further. The use of the pre-screening panels has been declared unconstitutional for violating state constitutional guarantees of right to trial and access to courts in six states.¹⁹⁶ Although the implementation of pre-screening panels could magnify the benefits of medical practice guidelines with an affirmative defense, the issue is more complicated than with what has been presented here.¹⁹⁷ However, because state constitutional issues may preclude a pre-screening panel, this is an issue that merits further investigation on a state by state basis.¹⁹⁸

Eighth, the guidelines should be constantly and thoroughly evaluated and updated on a regular basis.¹⁹⁹ This is mandatory (not an option), after all, the program can only be as effective as the guidelines. Out of date guidelines will

¹⁹⁰IMPLEMENTING, *supra* note 28, at 9.

¹⁹¹*Id.*

¹⁹²IMPACT OF LEGAL REFORMS, *supra* note 5, at 25-29.

¹⁹³Jona Goldschmidt, *Where Have All the Panels Gone? A History of the Arizona Medical Liability Review Panel*, 23 ARIZ. ST. L. J. 1106 (1991).

¹⁹⁴IMPACT OF LEGAL REFORMS, *supra* note 5, at 28-29.

¹⁹⁵*Id.* at 25, 28.

¹⁹⁶*Id.* at 29.

¹⁹⁷See generally P.E. Carlin, *Medical Malpractice Pre-Trial Screening Panels: A Review of Evidence*, Washington D.C.: Intergovernmental Health Policy Project, The George Washington University, 1980; Goldschmidt, *supra* note 193, at 1065.

¹⁹⁸Carlin, *supra* note 197, at 4-6.

¹⁹⁹IMPLEMENTING, *supra* note 28, at 8.

result in out of date care. Following the recommendation of the AMA, the Florida program is required to be updated once every three years by law.²⁰⁰ This may not be enough.²⁰¹ Although the three year requirement may be sufficient in many cases, there will undoubtedly be exceptions when guidelines will need to be updated before the three years pass. Therefore, a provision should be included to require guidelines to be updated sooner if needed. As mentioned earlier, proper communication arrangements should be made so that physicians and other interested parties will receive prompt notification of all updates.

Compliance with these eight steps should put states on course for projects destined to improve health care. Existing empirical evidence supports the theory that medical practice guidelines can be beneficial.²⁰² Although investigations are still proceeding on the current state programs, some information has been derived from these projects. Several publications have stated that the initial reports on the Maine project were inconclusive.²⁰³ Furthermore, a small sample of doctors, hospitals, and physicians have raised the question whether a small state like Maine could ever provide enough information to justify adopting medical practice guideline programs in every state—or on the federal level.²⁰⁴ Considering the size and number of physicians in Maine, it would not be wise to act based solely on the Maine project.²⁰⁵ However, those that argue that the Maine project is inconclusive as to what should be done nationally are only partially correct. It is more correct to say that initial reports on the Maine project found the information non-conclusive as to whether or not every state should adopt a program similar to that of Maine.²⁰⁶ Because the benefits to be derived are ultimately results from changed physician behavior, enough time must pass with the guidelines in effect before a change could possibly occur in Maine, Florida, or any of the other experimenting states. The GAO reported on October 25, 1993 that "Maine had been successful so far in gaining broad involvement of physicians and patients in the use of practice guidelines."²⁰⁷ A small, yet significant, insurance premium savings has been reported. Although the savings is small, approximately .5%,

²⁰⁰FLA. STAT. ANN. § 408.02 (West 1995).

²⁰¹AMA, *supra* note 28, at 8.

²⁰²GAO, *supra* note 6, at 26; *see generally* Beltz, *supra* note 109, at 749.

²⁰³Beltz, *supra* note 109, at 749, 754.

²⁰⁴*Id.*

²⁰⁵*Id.*

²⁰⁶The GAO and the OTA report wide physician acceptance of the program in Maine. *See generally*, GAO, *supra* note 6; IMPACT OF LEGAL REFORMS, *supra* note 5. Furthermore, Maine's state insurance superintendent reported an estimated 0.5% savings in malpractice premiums attributed to the demonstration project. Beltz, *supra* note 109, at 749, 753.

²⁰⁷Beltz, *supra* note 109, at 749, 753.

it is a start.²⁰⁸ It is important to note that the figure does not include savings from the reduction of the practice of defensive medicine, which would be greater savings than the decreased insurance premiums.²⁰⁹ Other economic figures not included are: savings from decreased litigation and improved quality of care. The Maine Medical Association notes that "'people believe' that doctors are performing fewer medical procedures because of the guidelines."²¹⁰ This, combined with the wide acceptance reported by the GAO, indicates that significant savings should be calculable in the future.²¹¹

The AMA's support for medical practice guidelines should also be noted. As mentioned earlier, the AMA officially supports demonstration projects of medical practice guidelines.²¹² This support has served as a foundation for joint projects with the Rand Corporation²¹³ and other organizations investigating the benefits of practice guidelines.²¹⁴ The AMA continues to support medical practice guidelines even after the investigation.²¹⁵ The AMA's support of guidelines appears to be based on the perceived potential gains from practice guidelines.²¹⁶ The result of the implemented guidelines is an improved quality of care that should proportionately decrease malpractice litigation.²¹⁷ Litigation is reduced by fewer causes of action arising from physician error and the affirmative defense created for complying physicians.²¹⁸

The benefits already noted from privately created guidelines can be expected to flow equally from the use of state created practice guidelines. According to the Congressional Research Service (CRS), medical practice guidelines can use outcome research to identify more effective treatment methods to increase the quality of care and reduce expensive defensive medicine.²¹⁹

In addition to these benefits, the muddy waters of various guidelines can be purified with the uniformity of state created guidelines. This "purification" can only occur if the guidelines are properly construed according to the standards

²⁰⁸*Id.*

²⁰⁹*Id.*

²¹⁰*Id.*

²¹¹See generally Beltz, *supra* note 109, at 749.

²¹²See IMPLEMENTING, *supra* note 28.

²¹³See generally, Kelly & Toepp, *supra* note 25, at 405.

²¹⁴*Id.*

²¹⁵See generally, IMPLEMENTING, *supra* note 28.

²¹⁶*Id.*

²¹⁷Kelly & Swartwout, *supra* note 29, at 56-57.

²¹⁸*Id.* at 57.

²¹⁹Bernice Reyes-Akinbileje, *Outcomes Research, Clinical Practice Guidelines, and the Agency for Health Care Policy and Research*, Congressional Research Service Report for Congress 1, June 10, 1994.

previously mentioned. If done properly, these guidelines will evolve past utilization review and can become a valuable part of the American health care system. Medical practice guidelines are a truly rare reform concept that show real potential for improving the quality of care, decreasing costs, and reducing malpractice litigation all through one program.

VI. CONCLUSION

The creation and enforcement of medical practice guidelines by state government agencies, utilizing assistance from the medical community, can increase the quality of care and reduce malpractice litigation if the guidelines are: (1) carefully construed; (2) continuously updated; (3) create an affirmative defense for physicians; and (4) are admissible as evidence with probative value by potential plaintiffs. Even though medical practice guidelines have been around for over fifty years, they did not provoke intense interest until recently. Although more guidelines are currently produced by private means, the greatest interest is in government created guidelines. Within government created guidelines, there are four primary types: (1) those offering an affirmative defense to doctors; (2) guidelines that are admissible as evidence; (3) guidelines that are not admissible as evidence; (4) and federal guidelines. A federal government program is unlikely to come into existence until the state programs prove themselves worthy of such legal enforcement on a national scale. Overall, state government created programs that offer an affirmative defense to participating and complying physicians provide the most benefits.

Benefits from properly-implemented practice guidelines programs include: (1) decreased expenditures on defensive medicine; (2) decreased medical insurance premiums; (3) decreased medical malpractice litigation; and (4) improved quality of care. Few medical reform concepts offer as many benefits as medical practice guidelines. Because the AHCPD and states like Maine and Florida have already created medical practice guidelines suitable for adoption, the time is ripe for other states to create medical practice guidelines projects.

Because government created medical practice guidelines are a relatively novel idea, statistical data is almost non-existent. However, this article has examined the anecdotal evidence that is available. Even though the anecdotal evidence is extremely supportive of creating a medical practice guidelines project, there is some uncertainty due to the innovative nature of the concept. Creating and implementing a state medical practice guideline system is an opening of Pandora's box, but it looks good so far.