The Role of Clinical Practice Guidelines in Health Care Reform

Arnold J. Rosoff
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I. INTRODUCTION

AFTER A YEAR'S HIATUS, the push for national health care reform has again risen to national prominence. Leading the charge this time is the "Republican Revolution" and its desire to reduce federal spending on "entitlements," starting with the reform of Medicare, then moving on to revisions in Medicaid and, finally, in private health insurance. Despite the fervor and momentum of GOP reformers, major revisions to federal health care programs are far from assured. But, no matter what happens in the congressional arena, reforms will still take place around the country. Several states have cost containment and cost-effectiveness programs in progress or under consideration, and countless initiatives are under way in the private sector. At every level, Americans are committed to getting more for the resources we expend on health care.

Figuring prominently in this picture is an increasing interest in and reliance upon "Clinical Practice Guidelines" (CPGs), also known by a variety of other terms: "practice parameters," "critical pathways," "clinical algorithms," and the like.1 The use of CPGs is an approach widely believed to have substantial potential to contain the cost as well as to assure the quality of medical services. But this innovation, strongly favored in some circles, evokes concern and reservation in others. CPGs are the subject of much debate, both as to their concep-

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1. The American Medical Association prefers the term "parameters" to "guidelines," believing the former to be less prescriptive. Edward Hirshfeld, Should Practice Parameters Be the Standard of Care in Malpractice Litigation?, 266 JAMA 2886, 2887 (1991).
tual and scientific validity and as to their practical, financial, and legal implications for the professional practice of medicine and the organization and delivery of health services. This Article reviews the development of the CPG movement and assesses its implications for health care reform at all levels, emphasizing the legal significance of CPGs and, in particular, their use in medical malpractice litigation.

II. WHAT ARE CLINICAL PRACTICE GUIDELINES?

Put simply, clinical practice guidelines (CPGs) are sets of suggestions, commonly set forth as decision rules, that reflect informed opinion on how to treat a certain illness or condition. CPGs are generally derived from scientific studies comparing the effectiveness of various clinical approaches to treating a particular medical situation. The Institute of Medicine has defined CPGs as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances." Professor Troyen A. Brennan describes them as "standardized specifications for care, either for using a procedure or for managing a particular clinical problem." Whatever their specific form, CPGs are intended to point the way toward higher quality and more cost-effective care by making readily accessible the clinical knowledge distilled from outcomes research.

CPGs can differ substantially, however, depending upon their auspice and purpose. Most current interest focuses on their use as cost-containment measures by health plans of various types. Brennan distinguishes "'standard of care' guidelines," which are intended to improve outcomes, from "'appropriateness' guidelines," which are oriented toward cost-

2. INSTITUTE OF MEDICINE, CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM 8 (Marilyn J. Field & Kathleen N. Lohr eds., 1990) [hereinafter CPG DIRECTIONS].


4. For example, CPGs may be developed to assure quality of care, to reduce inefficient utilization, or to maximize profits of third-party payors. See John Ayres, The Use and Abuse of Medical Practice Guidelines, 15 J. LEGAL MED. 421, 436-38 (1994).
effectiveness. In other words, CPGs can be principally "quality-enhancing" or "cost-reducing" — recognizing that in some happy situations a CPG-defined protocol can both improve quality and contain cost. For the most part, however, these two objectives are a trade-off, and the current enthusiasm for CPGs is largely driven by the desire for cost containment. The primary objective is to shift practice patterns toward more cost-effective treatment; quality becomes a consideration only in that no one wants to let it suffer unduly — whatever that means — in the process.

III. THE PROMISE OF CPGs

As a beginning matter, CPGs clearly have the potential to both improve the quality and help contain the cost of health care. A large and well-documented body of evidence — typified by the work of John Wennberg at Dartmouth — reveals significant, even substantial, variations in clinical practice patterns from one region to another, and even from one institution to another in the same locale. Procedures commonly used in one place may not be used much in another, hospital lengths of stay differ widely, and there are numerous other differences that cannot be justified or, in some cases, even explained. This observed variation in practice approaches implies either that practitioners do not really know what works in medicine and, so, are just "firing blind," or else that some do know what works and are doing it right while others, for some reason, are not. The challenge, of course, is determining what works best and guiding practitioners to adopt and use therapeutic approaches which have a proven ability to deliver a good result.

Increasingly, modern medical science can determine through clinical outcomes and effectiveness research, what is

5. Brennan, supra note 3, at 70.
the better approach for certain kinds of cases and treatments. With more powerful computer technology and more and better treatment data with which to work, our ability to undertake discriminating analysis of how care is rendered and what the results of that care are is greatly enhanced. We can determine what care is truly effective and what is not. David Eddy, M.D., of Duke University, is one of the leaders in outcomes research; but many other individuals and groups are also contributing to the rapidly advancing science of medical decision making.

Not only can we determine what works well and what does not; we also can expand the analysis to consider the costs of the care rendered and thus assess which treatment approaches are cost-effective and which are not. Some tests and procedures, despite adding cost, do nothing to improve outcomes and can be dismissed as worthless. Others may improve the probability of achieving a desired clinical outcome, but not at a substantial enough rate to dictate that they must be used. In this latter case, the hard choice arises of whether the added benefit is worth the added cost.

To use a concrete example, consider the use of the newer drug TPA instead of the older medicine, Streptokinase, to treat heart attacks. Assuming that TPA is one percent more effective — that is, it will save one person in one hundred that Streptokinase would not — and that it costs two thousand dollars more per patient to use, the total cost of saving each patient is $200,000.00. Saving the life of just one hundred more heart attack victims per year using TPA would add twenty million dollars in annual cost to the nation's health care system. At the societal, or "macro," level is it "worth" twenty million dollars


The emerging science of outcomes research has spawned a variety of professional organizations, such as the Society for Medical Decisionmaking, based at George Washington University, which publishes a quarterly journal, Medical Decisionmaking. Other publications recently joining this veteran include The Journal of Outcomes Management.

9. The cost figures used in this example are just rough estimates used to illustrate the general concept.
annually to save one hundred more lives? Outcomes research and cost-effectiveness studies, and the CPGs developed from them, cannot make these hard choices for us. They only allow us to make them more knowledgeably and thus, one would hope, make them smarter and better. But in this context "smarter and better" does not necessarily mean easier and with less pain. Hard choices can sometimes be more difficult and painful to make when done with eyes wide open, with full knowledge of the consequences. Moreover, framing the issue this way implies that we could, if we chose, provide TPA treatment to all who might benefit by it. That, of course, is not the case. In a very real sense, our society is bumping up against the sharp edges of what we can afford to do.

IV. CPGs: A RECENT HISTORY

Although CPGs have been around, in various forms, for much longer, the last half-decade or so has seen a dramatic increase in the attention given to them. Federal legislation, the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), created the Agency for Health Care Policy and Research (AHCPR) within the Public Health Service, a subdivision of the Department of Health and Human Services (DHHS), and assigned to it the responsibility for the Department's "Medical Treatment Effectiveness Program." This program's purpose, and AHCPR's charge, was to support research, data development, and other activities to "arrange for the development and periodic review and updating of clinically relevant guidelines, standards of quality, performance measures, and medical review criteria" and to "enhance the quality, appropriateness, and effectiveness of health care services," not just for federal health programs but more broadly. AHCPR's functions include fostering public-private enterprise to develop, disseminate, and evaluate CPGs, largely through its "Forum for Quality and Effectiveness in Health Care." Continuing the strong academic orientation of its predecessor organization, the National Center

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12. *Id.* § 299b.
13. *Id.* § 299b-1.
for Health Services Research (NCHSR), AHCPR's work is, in many respects, more focused on expanding knowledge than on applying it. A big part of that activity is methodologic: studying, developing, and refining the process for generating practice guidelines and assuring their regular updating and revision. An important policy question, addressed later in this Article, is whether AHCPR's destiny is to be the sole official generator of CPGs, a government facilitator to foster their development by others, the official body for reviewing and certifying CPGs—the "blessing" function, as it has been called by some—either for use in governmental health programs or more broadly, or some combination of the above or other functions.

V. PROVIDERS' REACTIONS AND IMPLICATIONS FOR MEDICAL PRACTICE

Reflecting their current prime purpose of cost-containment, CPGs are finding their greatest use in managed care settings, including HMOs, PPOs, and other entities with a stake in fostering the cost-conscious and cost-effective use of health services. Adherence to CPGs, at some level at least, may be a condition of participation for physicians and other providers joining HMOs or other cost-constrained health plans. In some cases, providers may be told explicitly upon joining that the plan's CPGs are a key part of the "rules of the game" and they must either follow the CPGs or take some special action to justify deviation in a particular situation. In other cases, CPGs are a less apparent part of the plan's supervisory infrastructure, a fact that becomes known to the doctor over time as the plan agrees or refuses to authorize certain kinds of care in given circumstances.15

14. See infra part VI.B.2.
15. The different uses for CPGs relates to the earlier discussion of terminology. See supra text accompanying notes 2-5. For example, some commentators have recognized a distinction between advisory and prescriptive guidelines, using the terms "boundary" and "pathway" guidelines. "Boundary guidelines are used by payers to define a range of practice options within which physicians could act without incurring financial or other sanctions. Pathway guidelines are employed primarily by providers and serve as a beacon for clinical practice and a standard around which practice patterns should converge." Havighurst, supra note 8, at 778 (citing Lewin & Erickson, Leadership in the Development of Practice Guidelines: The Role of the Federal Government and Others 3 (prepared for the Physician Payment Review Commission's Conference on Practice Guidelines, Washington, D.C., Oct. 11, 1988) (revised April 24, 1989). A useful discussion of the interaction between the semantics of CPGs and concerns about the use to which they will
One of the things that has affected how key stakeholders view CPGs is the above-mentioned variability in their auspice, orientation, and purpose. Some who supported the guidelines movement in its earlier stages, when the focus was on quality enhancement, are not inclined to be supportive now that the focus has changed. There are several reasons for this retreat, some of which revolve around the role and independence of the physician.

The goal of effectiveness studies and CPGs is not, despite what some physicians may believe, to remove all elements of discretion and professional judgment from medical care. There will always be the need — and, one would hope, the latitude — for the exercise of professional judgment. Still, as the body of what is knowable and what is known grows, the degree of latitude will inevitably be impacted by the extant knowledge base. When one does not know what is right or wrong, everything is fair game to do. Knowledge brings limitations, or at least, the basis for limitations to be imposed. As an Institute of Medicine committee on Practice Guidelines has stated, the formal recognition of the practice guidelines movement "can be seen as part of a significant cultural shift, a move away from unexamined reliance on professional judgment toward more structured support and accountability for such judgment." This last observation suggests an important reason many physicians tend to resist the CPG movement. As professionals do generally, physicians fear reduction of their practice autonomy and independent judgment: both things they prize greatly. Moreover, just as physicians do not want to give up autonomy, they also may be concerned about the potential for guidelines to freeze the state of medical knowledge and practice by trying to direct what is "the right thing" to do.

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16. See, e.g., Ed Hirshfeld, Use of Practice Parameters as Standards of Care and in Health Care Reform: A View from the American Medical Association, 19 J. On Quality Improvement 322, 323 (1993) (explaining why the AMA believes that CPGs should not be mandatory but should instead be used as a source of evidence for the appropriate standard of care).

17. Id. See also Havighurst, supra note 8, at 778 (stating that CPGs should be advisory only).

18. CPG DIRECTIONS, supra note 2, at 2.
There are other possible explanations for physicians' antipathy toward CPGs. First, some physicians simply may not believe in their validity. While, as scientists, physicians have a high regard for empirical proof generally, at times they may tend to weight their own clinical experience and personal observations over general statistics. Physicians also may have reasonably grounded doubts about the applicability of a CPG to the particular situation they are currently facing. CPGs, by their nature, are generalizations that do not necessarily apply in a given instance.

Physicians' attitudes toward CPGs also may be driven by a cautious solicitude for the welfare of their patients. Physicians know that in some cases guidelines may be used to limit treatment options or deny payment on a cost-benefit rationale for care they believe their patients' welfare requires, regardless of the cost. Intertwined with that concern is another, more self-protective motivation. In an era of widespread medical malpractice litigation, physicians are wary of anything that could pressure them to provide a lesser degree of care if so doing might expose them to liability. This results in the phenomenon known as the defensive practice of medicine, to which extensive study and comment have been directed. Although physicians' fears of being sued when they render less than the maximum care possible in a particular treatment situation may be out of proportion to the actual risk they face, those fears still greatly influence what physicians do.

Another important hindrance to the development of a constituency for widespread use of CPGs, especially within the medical community, is the uncertainty as to how the law will come to treat them in cases challenging the quality of health care. Will they be a relatively neutral addition to the legal...
landscape or will they, as some fear, be an additional goad to and support for legal challenges against health care providers? This fear has affected and will continue to affect the way in which the CPG movement evolves. Conversely, the direction this evolution takes will determine the reaction and response of the health care community.

VI. LEGAL IMPLICATIONS OF USING CPGs IN PRACTICE

What will be the application and effect of guidelines in suits against providers who do or do not follow them? This is a complex, interesting, and practically important question that turns on several factors: (1) Who developed the guideline in question, and how was it developed? (2) Did a designated government body (state or federal) certify, endorse, or “bless” the guideline? (3) Is there only one guideline for the condition or treatment in question, or are there multiple, competing guidelines? And finally, (4) who is asserting the guideline in court — e.g., the plaintiff or defendant — and for what purpose? These factors will be examined in greater depth later, but first let us consider the variety of ways that courts can treat and apply CPGs in a litigation setting.

A. How Will CPGs be Applied in Malpractice Litigation?

The following is a brief overview of the ways that courts could treat CPGs in the context of medical malpractice litigation. This enumeration, sufficient for the present analysis, is not exhaustive. While most of the states are largely similar with regard to their definitions of medical negligence and the evidentiary requirements for proving and rebutting malpractice claims, there are also significant differences. The treatment of CPGs obviously will depend upon the underlying legal terrain. Following this same reasoning, the categories below are not mutually exclusive; a given court could adopt more than one treatment of CPGs, depending upon the particular case and the way it was presented.

This part of the analysis builds upon state law foundations and makes the implicit working assumption that the role of CPGs will be determined as a matter of state law. Given the possibility of national health care reform — however unlikely it may seem to some — this developmental path is not inevitable.
If there is federal health care reform legislation, an important and interesting question, beyond the scope of this Article, is whether the federal government could impose any of the CPG approaches on the states. 21 Medical malpractice law has historically been a state law matter, not subject to federal control. This tradition is true of tort law generally and, in fact, is true of most health care and health insurance regulation. The division of authority and responsibility for financing, providing, and regulating health care involves weighty constitutional questions of states' rights and separation of powers. 22 It also arguably implicates several important federal statutory schemes, including the McCarran-Ferguson Act, 23 the Employee Retirement Income Security Act (ERISA), 24 and the federal antitrust laws. 25 Setting these complications aside for the present discussion, state courts might use CPGs in one or more of the following ways.

1. As Evidence of Customary Practice

The most obvious possibility, and the one most consistent with current legal conventions, is that a court could view a


22. The core issue is the potential conflict between the power to regulate interstate commerce granted to Congress under Article I, § 8, cl. 3 of the U.S. Constitution and the sovereign rights reserved to the states under the 10th Amendment. Given the impact on interstate commerce that medical malpractice litigation can cause, can the federal government legitimately impose innovative tort law doctrine on the states? While federal preemption of the field — i.e., taking the control of malpractice suits away from the states entirely — would be controversial enough, it is a more complex question whether the federal government can leave such litigation to the states but dictate what liability determining rules they must apply. This controversy is especially true if these rules would make the state's judicial processes more difficult and costly. These issues are explored by Professor Hoke, see supra note 21, at 558-59 (discussing the problems that the states may encounter in implementing federal malpractice reform proposals).

A related issue, which Professor Hoke also addresses, is whether resolution of the jurisdictional dilemma may lie within the "spending power" of Congress, granted under Article I, § 8, cl. 1 of the Constitution. Id. at 571-72. If Congress were to enact some form of national health care or health insurance system, the provision of federal money to the states thereunder could provide the nexus for broader federal control of state action.


CPG as evidence — perhaps highly or even conclusive evidence — of the customary practice in the medical profession. Thus a doctor who practiced in conformity with a CPG would be shielded from liability to the same extent as one who can establish that she or he followed professional custom. In most jurisdictions and in most circumstances, adherence to prevalent professional standards is an adequate defense to a claim of medical negligence.26

To a court taking this approach to CPGs, the guideline would serve roughly the same function as a well-qualified expert witness. It would inform the court as to the professional consensus and standard practice, which would be a welcome and valuable contribution. By providing the court with objective, neutral, and highly credible evidence of the standard of care, CPGs would help to counter current dissatisfaction with the quality of expert testimony on scientific issues.27 Brennan suggests that guidelines will initially be used along with expert testimony, essentially playing the role of very important review articles.28

In courts treating CPGs as evidence of professional custom, the auspice of a guideline should be very significant in determining the weight to be given to it. A hierarchy of authority and influence readily suggests itself. For example, CPGs issued by a well-regarded professional body, such as the American College of Obstetrics and Gynecology (ACOG) would presumably carry more weight than CPGs issued by an HMO.29 CPGs issued by the federal AHCPR would likely be more influential than those issued by ACOG. In fact, the au-

26. The classic exception to this general principle is Helling v. Carey, 519 P.2d 981 (Wash. 1974) (holding that, while professional custom is highly persuasive as to what is reasonable care, it does not wholly determine the legal standard to be applied). Helling has been followed in only a small number of cases. See, e.g., Lundahl v. Rockford Mem. Hosp. Ass'n, 235 N.E.2d 671, 674 (Ill. App. Ct. 1968); Favalora v. Aetna Casualty & Surety Co., 144 So.2d 544 (La. Ct. App. 1962); Toth v. Community Hosp. at Glen Cove, 239 N.E.2d 368, 373 (N.Y. 1968).


29. Professor Mehlman has advocated that the only appropriate auspice is a nationally recognized group if CPGs are to assume the proper level of importance. Mehlman, supra note 3, at 377. See also Eleanor D. Kinney & Marilyn M. Wilder, Medical Stan-
The authoritative status of AHCPR-generated guidelines might be prescribed by federal law. The party offering the CPG would qualify the guideline much as one would qualify an expert witness or a learned treatise. Of course, if a set of guidelines is well enough known or issued from a sufficiently prestigious and credible auspice, a court might simply take "judicial notice" of the CPG without having to qualify it more specifically as a reliable source of accurate information.

A key problem exists in treating CPGs as evidence of professional custom, however. In the case of a newly developed CPG, the treatment approach it calls for may differ, perhaps substantially, from prevailing practice in the relevant field. This disparity is particularly likely when cost-reducing guidelines have evolved from studies concluding that the conventional practice "overtreats" the patient, wasting resources without yielding discernible or sufficient benefit by improving treatment outcomes. Over time, if the guideline is widely adopted and followed by the medical community, it will increasingly become a statement of the customary practice. In the interim, however, the guideline may reflect just the opposite, a statement of what the profession at large does not currently do.

30. Various commentators have reasoned that courts will allow CPGs in evidence under the "learned treatise" exception to the hearsay rule. Brennan, supra note 3, at 75; Kinney & Wilder, supra note 29.

31. Mehlman, supra note 3, at 378 (proposing that courts presume that the national standards from reputable medical organizations be used to establish the minimum legal standard); Richard E. Leahy, Comment, Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines, 77 CAL. L. REV. 1483, 1506-08, 1522-27 (1989) (proposing judicial notice of CPGs as the legal standard of care).

32. Under some approaches to CPG generation, the CPG must, by definition, reflect a practice consensus. In other words, there must be a substantial body of people using the treatment approach and generating favorable outcomes with it. It would be possible, however, for that body to be confined to a particular geographic locale or type of practice setting (such as an academic medical community). If there was enough experience with this treatment approach to conclude with confidence that it is adequately safe and more cost-effective, it could be incorporated into a CPG that was substantially at odds with conventional practice across the medical community generally.

33. CPGs differ significantly in this regard from the more traditional Medicare utilization review (UR) protocols that are based upon "professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice." See 42 U.S.C. § 1320c-3(a)(6)(A) (1988) (outlining the review standards to be used by peer review organizations.
2. As Evidence of the Practice of a "Respectable Minority"

Some states allow as a medical malpractice defense that the defendant acted according to the custom of at least a "respectable" (or "reputable") minority of the relevant profession. In some jurisdictions and under some circumstances, this approach could pose the same problem as discussed above with regard to customary practice. That is, the guideline in question may be so new that virtually no one in the relevant community yet follows it. However, if this problem were to exist, it obviously would be of shorter duration than the one raised regarding customary practice.

3. As Evidence of "Reasonable Prudence"

Adherence to a legitimate CPG could be treated by the court as evidence of the provider's "reasonable prudence," even if it were not established that anyone other than the defendant had yet applied the guideline in actual clinical practice. Some courts define the physician's legal obligation of due care as reasonable prudence rather than as adherence to professional custom. These courts could choose to regard a physician's reasoned compliance with a legitimately developed CPG as meeting the standard of reasonable prudence.
4. As Evidence of What the Profession Considers "Acceptable Practice"

As Professor Joseph King advocates, a court could choose to regard a treatment approach sanctioned by an appropriate CPG as "acceptable practice" within the medical community without considering the number of practitioners who actually were following this practice at the time in question. This approach would be very similar to direct application of the CPG as the applicable legal standard, which is discussed next. It is also similar in underlying concept to the notion of "respectable minority," discussed above. If the medical community respects a practice as having been carefully considered and found acceptable by reputable members of the profession, courts would not regard the practice as inadequate, regardless of the number of clinicians who had actually adopted it as of the time in question. The key to the court's recognition of the CPG as the legal standard would, in any case, be the medical profession's acceptance of the CPG as authoritative. Obviously, this acceptance would depend upon the power and reputation of the body developing, endorsing, or adopting the CPG.

5. Direct Application as the Legal Standard of Care

The most straightforward and complete acceptance of CPGs, of course, would be for a court simply to treat the CPG as defining acceptable practice, adopting it as the legal standard without going through any intermediate steps based upon professional adoption or custom. According this recognition to a CPG could conceivably be achieved through judicial extension of existing legal doctrine, for example, as a logical extrapolation from the respectable minority rule. In most jurisdictions, however, giving direct application to CPGs would be a substantial departure from existing law. Thus, elevation of CPGs to a legal standard could more directly and confidently


37. See infra part VI.A.5.

38. Seeinfra part VI.A.2.

39. See King, supra note 36, at 1235 (citing, inter alia, the classic work of Allan H. McCoid, The Care Required of Medical Practitioners, 12 Vand. L. Rev. 549, 605-09 (1959)).
be achieved through legislative action. Although legislation might be the simpler route conceptually, it is by no means clear that it would be feasible as a political matter, since detaching standard setting from professional consensus has far-reaching implications.\textsuperscript{40}

If the CPG were to be adopted as the legal standard, the question remains how firmly that standard would be applied. The strongest use would be as a *per se* standard. Thus, courts would conclusively (that is, irrebuttably) presume that the provider was negligent if she or he did not follow the standard and would conclusively presume that the care was reasonable if she or he did.\textsuperscript{41} A somewhat weaker approach would be to treat compliance with a relevant guideline as raising a *rebuttable* presumption that the physician acted correctly. The opposing party could counter this presumption with appropriate evidence.\textsuperscript{42} Another dimension to the fullness of applying the legal standard is whether both the plaintiff and the defendant could use the CPG in court. The recent evolution of applying CPGs as a legal standard has favored their use only as a defense by the health care provider. Whether CPGs should be applied in such an asymmetrical manner will be considered below.\textsuperscript{43}

Direct application of CPGs as setting the legal standard for medical care is an extreme recognition that seems inappropriate and unlikely at this relatively early stage of development of CPGs. Public, professional, and judicial confidence in CPGs would have to be far greater than it is now for the legal system to accord this much weight to them. Before such confidence could be gained, many more issues about CPGs, their auspice,

\textsuperscript{40} For an interesting example of professional reaction to judicial attempts at disconnecting legal standards from professional custom, and the resulting legal tug-of-war, see Gates v. Jensen, 595 P.2d 919 (Wash. 1979).

\textsuperscript{41} This approach is followed in Minnesota. See Minn. Stat. § 62J.34(3)(a) (1994) (authorizing adherence to approved practice parameters as an absolute defense). See also infra note 57 and accompanying text.

\textsuperscript{42} This is the approach contemplated in the Health Equity and Access Reform Today (HEART) Act of 1993, which was proposed by Senator John H. Chafee (R., R.I.) and others. See S. 1770, 103d Cong., 1st Sess. § 4025 (1993). Under HEART, adherence to state-developed guidelines that had been certified by the Secretary of HHS would establish a rebuttable presumption of appropriate care that could be overcome only by "clear and convincing evidence," a stricter evidentiary standard favoring the party complying with the guideline. Id. See also S. 223, 103rd Cong., 1st Sess. § 302 (1993); S. 314, 102nd Cong., 1st Sess. § 501 (1991) (use of guidelines creates rebuttable presumption of reasonable care).

\textsuperscript{43} See infra part VI.B.4.
development, and the like would have to be addressed and satisfactorily resolved. Since these conditions have not been met yet, the American Medical Association (AMA) now opposes direct adoption of CPGs as a legal standard. The AMA urges instead that CPGs be used only as evidence of the customarily observed professional standard of practice and that their degree of authority depend on the degree of their acceptance among medical practitioners.44

B. Factors Affecting the Courts' Treatment of CPGs

The way the courts regard CPGs and apply them in medical malpractice cases will likely be affected by multiple factors. The following factors seem the most significant.


The weight to be accorded to a CPG will be affected by its perceived accuracy and authoritativeness. This perception will inevitably depend upon the reputation of the developer and sponsor of the guideline. In large part, the guideline's credibility will ride the coattails of its source; a "prestigious national group," such as a respected professional organization, presumed to have both the technical expertise and objectivity to know and speak accurately and honestly, will be the most powerful auspice for a CPG.45

Besides its "auspice legitimacy," the guideline can be assessed based on the process by which it was generated and the motivation underlying its creation. A guideline generated by scientists of acknowledged competence that shows evidence of extensive data-gathering and careful analysis and that is oriented toward improving or maintaining quality of care will, quite naturally, carry more weight than a guideline assembled from limited data by a little known managed care organization and intended to support an aggressive cost-containment program. While a court could conduct a detailed inquiry into the process and purpose underlying the creation of a given CPG, it

44. See Hirshfeld, supra note 16, at 323 (discussing the AMA position that a practice guideline should serve as a source of evidence for the standard of care depending on how well it is accepted among practicing physicians).

45. Mehlman, supra note 3, at 377 (citing Kinney & Wilder, supra note 29, at 448).
is likely that the reputation of the sponsor — the auspice legitimacy — will become a common proxy for the quality of the guideline itself. One possibility, of course, is to have guidelines issued only from a single governmental agency, at either the federal or state level. This issue is addressed below as part of the discussion of whether multiple guidelines should be allowed.\textsuperscript{46}

2. Is the Guideline “Certified?”

One way to assure the quality of CPGs before according them legal weight is to have some mechanism for grading them or screening from the system entirely those of inadequate quality. Such quality control review would presumably be done by a governmental body, at either the state or the federal level. If done at the federal level, the logical candidate is the AHCPR, which has thus far carried the federal government’s charge to develop the process for generating guidelines.\textsuperscript{47} The governmental agency could certify, that is endorse or “bless,” the guideline. Courts could ban the use of uncertified guidelines or, perhaps more likely, allow their use but accord them a lower legal status. A certified guideline might be granted “direct application” as the legal standard without further inquiry into its legitimacy; by contrast, an uncertified CPG might be treated in one of the other ways detailed above — for example, as evidence of the customary practice or the practice of a respectable minority of medical practitioners.

Certification of a CPG initially upon its issuance would be only part of the legitimizing protocol. A mechanism also is needed for periodic updating of the CPG.\textsuperscript{48} As new evidence accumulates on the effectiveness of the treatment approach embodied in the CPG and on its merit relative to other emerging treatment approaches, a mechanism to reassess the guideline based upon this newly acquired knowledge must be developed. It would be wrong to have a certified guideline that is out of

\textsuperscript{46} See infra text at notes 50-53.

\textsuperscript{47} For an overview of the work on guidelines development done by the AHCPR and other federal (and private) agencies, see OFFICE OF TECHNOLOGY ASSESSMENT, supra note 8, at 145-47.

\textsuperscript{48} See Ayres, supra note 4, at 432 (noting that much of the information used to develop practice parameters quickly becomes outdated); Mehlman, supra note note 3, at 378 (explaining the need to update minimum standards).
synch with the latest and best confirmed knowledge in the field. Moreover, allowing a guideline to stay in place and according it legal weight after medical knowledge had advanced significantly would tend to freeze the state of the medical art. As Edward Hirshfeld states the position of the AMA, "Out of respect for the evolution of medicine, the AMA is concerned that making a set of practice guidelines mandatory standards of care would stifle innovation and the dissemination of medical advances."49

3. Is There a Single Guideline or Are There Multiple Guidelines?

Another key factor affecting the weight a court might accord to a CPG is whether it is the only relevant guideline recognized. If so, it almost certainly would receive greater weight than if there were multiple guidelines that differed on one or more material and relevant points. While parts of the above analysis implicitly presume a unitary system with only a single guideline covering each condition, illness, or treatment, many commentators favor a pluralistic approach allowing multiple guidelines issued by different auspices.50 However, a pluralistic system allowing alternative, conflicting guidelines is inherently untidy and undoubtedly would complicate matters by inviting controversy over which guideline should be regarded as authoritative, or more authoritative. Instead of the traditional "battle of the experts" in medical malpractice cases, there would be a "battle of the guidelines." Perhaps this would lead to better, more confident judicial decisionmaking; perhaps it just would lead to more confusion.51

50. See, e.g., id. at 325-26 (recommending the use of states as testing grounds). Professor Havighurst, true to his hallmark advocacy of approaches allowing consumer choice, also supports a pluralistic approach. See Clark C. Havighurst, Medical Practice Guidelines as Legal Standards Governing Physician Liability, 54 LAW & CONTEMP. PROBS. 87, 113 (1991).
51. See Arnold J. Rosoff, A Response to the (ABA) Policy Subcommittee and James Rosenblum, NEWSL. OF THE TORT AND INS. PRAC. SEC. MED. & L. COMM. (ABA), Spring 1991, at 20. In this point-counterpoint exchange, attorney James Rosenblum argued that the wider use of guidelines would escalate the difficulty of proving medical negligence and encumber the courts. See Practice Parameters/Practice Guidelines: From the Operating Room to the Courtroom, NEWSL. OF THE TORT AND INS. PRAC. SEC. MED. & L. COMM. (ABA), Spring 1991, at 16, 17-20. Professor Rosoff countered that greater reliance on
Whatever the implications for judicial efficiency, adopting a unitary, or monopolistic, system for CPGs will centralize power in a single body, whether governmental or private, and impede innovation in clinical practice. Pluralism is very much the American tradition owing to an abiding belief that competition in goods, services, and ideas will bring about the best of each for the greater benefit of the society. Absent compelling evidence that a pluralistic approach is not workable in the case of CPGs, this approach should be preferable.

A key issue that will have to be addressed if multiple guidelines are allowed is how a court should determine whether a guideline is authoritative enough to be admissible as evidence and, if admissible, whether and how to assess the relative weight to be accorded to competing guidelines. Several approaches are possible. First, as noted above, the court could allow only guidelines developed by a recognized professional body, using what might be termed "auspice validation." Second, it could seek to determine the extent that the guidelines in contention had been adopted, according greater weight to the guideline more widely followed. This approach might be called "use validation." The search to discover which guideline was more "popular" could be an undertaking of substantial difficulty and questionable value. A desire to avoid such inquiry may have been a significant factor in the development of the "respectable minority" and "different schools of thought" doctrines. Finally, the court could inquire into how the guideline was developed, including the ongoing process for periodic updating and revision. This approach might be termed "process validation." Each approach has its advantages and its obvious drawbacks.

Many of these issues could be avoided if the court recognized as admissible only those guidelines that had undergone a reliable review process and had been certified. In such case, the court's job would not be to decide whether the defendant followed the best guideline but, instead, whether she or he followed an acceptable guideline. This method has much in com-
mon conceptually with the "respectable minority" and "schools of thought" doctrines. In practical effect, all certified guidelines would be on an equal footing legally, and a defendant would be deemed to have acted reasonably by following any one of them (assuming that the situation in question fell within the appropriate reach of the guideline followed).

4. Who is Asserting the Guideline in Court and for What Reason?

A final element affecting how a court would treat a CPG in a given case is who is asserting the guideline, the plaintiff or defendant, and for what purpose? Will it be equally available to both the plaintiff and the defendant? Development of the guidelines movement in the 1990s suggests that the legal application of CPGs will be asymmetrical. Health care provider defendants will be able to introduce CPGs to prove their practice was adequate in that it satisfied the guideline (used as a "shield"); but they will not be available to the plaintiff to show that the defendant(s) did not live up to the standard articulated by the guideline (used as a "sword"). The principal example of this uneven application is the widely discussed 1990 Maine Medical Malpractice Demonstration Project, which set up a five-year experiment apparently allowing shield use of guidelines by physicians while prohibiting sword use by patient-plaintiffs. Some other states, notably Minnesota, are also tak-

54. See Paul McGinn, Practice Standards: MDs' Shield or Plaintiffs' Spear?, AM. MED. NEWS, Jan. 6, 1989, at 21.

55. ME. REV. STAT. ANN., tit. 24, § 2972(1) (West Supp. 1994). See generally GENERAL ACCOUNTING OFFICE, GAO/HRD-94-8, MEDICAL MALPRACTICE: MAINE'S USE OF PRACTICE GUIDELINES TO REDUCE COSTS (1993) (describing the Maine demonstration); Stephen J. Schanz, The Emerging Status of Practice Parameters, MED. STAFF COUNS., Fall 1993, at 31 (noting that Maine allows physicians to use practice parameters as an affirmative defense, while plaintiffs may use them as evidence only in limited circumstances).

56. Although this distinction was the clear intent of the legislation, some have raised doubts about whether it would actually have this effect in practice. Bob Stolt, who opposed the guidelines experiment for the Maine Trial Lawyers Association when it was before the legislature, predicts courts will allow both sides to introduce guidelines in malpractice litigation. Professional Liability: Maine's Experiment with Practice Guidelines Produces Little Evidence, 3 HEALTH L. REP. (BNA) 753, 754 (June 9, 1994) [hereinafter Maine's Experiment].
This kind of uneven application has come about basically as a political barter, with proponents of guidelines saying, in effect, "If you doctors will support the development and adoption of guidelines, we will see that they cannot be used against you." Whether such protection is needed is far from clear. Experts have considered both the inculpatory and exculpatory potential of practice guidelines without conclusion or consensus as to which side they are most likely to favor. My personal belief is that, even absent any rule explicitly limiting their use by plaintiffs, guidelines more often will be helpful to the defendant. Still, it seems clear that assuring providers that using guidelines will be skewed in their favor was an important factor in gaining their support. But providing by statute for asymmetrical application of guidelines — that is, allowing "shield" use but not "sword" use — raises disturbing questions of fairness. To put it simply, what is sauce for the goose is sauce for the gander. If a court will treat a guideline as an authoritative statement of what is appropriate medical care in a given situation, why should not the failure of a physician to follow that guideline be taken as evidence of inappropriate care? Not only does one-sided application make the malpractice litigation playing field uneven; it also may be grounds for federal constitutional challenges under the Fifth and Fourteenth Amendments’ requirements of "equal protection of the laws, and perhaps under state constitutional principles as well."

To date, no such challenges have been mounted. Reflecting the fact that Maine has relatively few physicians and a small volume of medical malpractice litigation generally, there have been no suits involving the use of the guidelines since the law

57. MINN. STAT. § 62J.34(3)(a) (1994) (providing an absolute defense for providers). Florida and Vermont also have adopted this approach, and several other states — e.g., Colorado, Pennsylvania, Rhode Island, Virginia, and Hawaii — also have considered or are considering adoption of guidelines legislation. Maine's Experiment, supra note 56, at 753; Schanz, supra note 55, at 33-34.
58. See H.R. 4469, 103d Cong., 2d Sess. § 441 (1994).
59. GENERAL ACCOUNTING OFFICE, supra note 55, at 26-27.
61. Mehlman, supra note 3, at 378. But see Hirshfeld, supra note 1, at 2889-90 (providing arguments against the unconstitutionality of asymmetric application).
took effect in January 1992. Other evidence of their impact — for example, a reduction of health care costs reflecting a lesser incidence of defensive medical practice — is inconclusive, despite reports that doctors are performing fewer medical procedures prompted by legal considerations. The state's insurance superintendent has estimated that the demonstration project resulted in a 0.5% savings in malpractice premiums statewide, but as yet there is no hard data to support this projection. The Maine official overseeing the project, Dr. Edward David, chairman of the state's Board of Registration in Medicine, concedes that in a small state like Maine, five years may not be long enough to evaluate the program's effectiveness, and the program may never be able to prove a reduction in the cost of medical care or of malpractice litigation. Physicians in the four specialties originally targeted by the legislation, anesthesiology, emergency medicine, obstetrics and gynecology, and radiology have been supportive of the project. However, other specialties have not taken advantage of a 1993 legislative amendment to expand the project into their areas of practice, and there has been no move to extend it beyond its originally authorized five-year term.

C. How Will the Use of CPGs Affect Malpractice Litigation?

Whatever the mechanism by which they feed into court determinations, guidelines could reduce the volume and complexity (and thus the cost) of malpractice litigation. In the first place, one would hope this might occur by reducing the incidence of the actual, underlying malpractice. Better care will mean fewer people harmed, which in turn will mean less cause for suits. Second, anything that makes the decision process more rational and thus makes the outcome of litigation easier to predict will increase the likelihood of dismissal or settlement of suits before trial. Third, for those suits going to trial, the application of CPGs should greatly facilitate determining

62. General Accounting Office, supra note 55, at 19; Maine's Experiment, supra note 56, at 753.
63. Maine's Experiment, supra note 56, at 753.
64. Id. at 754.
65. See id. at 753 (noting that the process to write and to evaluate guidelines makes the timeframe impractical).
whether a given treatment approach is medically, and thus legally, acceptable.

Clearly, however, judicial recognition of guidelines, even according them great weight, will still leave many issues to litigate when one sues upon a claim of harm caused by negligent medical care. These issues include, but are not limited to, the following: Was the guideline followed the appropriate one for the given situation? Did the provider, as a factual matter, actually follow the guideline? If the guideline allowed latitude for discretion in treating the patient, did the provider exercise that discretion in an appropriate and acceptable manner? If any of these three questions is answered in the negative, was that the cause of the patient's damage? Although the first three questions go to the existence vel non of negligence, this fourth question raises the essential requirement of proving causation, that is, that the negligence caused the injury(ies) suffered. A related question is how responsibility should be allocated if multiple parties were implicated in the negligent care of the patient. Questions also will remain as to the nature and extent of the plaintiff's injuries and the proper amount of damages to be awarded. If multiple defendants are involved, the question of how to allocate responsibility among them also will arise.

The above listing is not exhaustive, but it should suffice to avert any naïve assumption that guidelines will be a panacea for the many difficulties of malpractice litigation. Whatever regime the law creates, disputes inevitably will arise in trying to live under that regime. Nonetheless, it is worthwhile to work toward establishing a more rational set of rules; surely the issues to be addressed will be fewer and more readily soluble under such conditions. Moreover, even if there were no significant legal system advantages to be gained from expanding the use of CPGs, the health care system advantages are sufficiently great to justify the quest for the best way to incorporate CPGs into the law.

VII. POTENTIAL LIABILITY OF GUIDELINES DEVELOPERS AND ISSUERS

Among the many issues raised by the practice guidelines movement, there is another that deserves mention here, although it is outside the focus of this Article. It is the potential for liability of the guideline developers and issuers. The ques-
tion has intrigued both scholars and practitioners, and it will certainly affect the zeal with which various parties participate in the development and sponsorship of CPGs.

As guidelines take on greater importance in health care policy and practice and their development becomes big business, the pressure will grow to hold accountable those who reap large gains from an activity that bears strongly on the public health. One obvious basis for liability would be negligence in analyzing the outcomes research data or translating it into clinical recommendations. Another would be using data that the developer knew, or should have known, were inaccurate or insufficient. Beyond mere negligence, a court might find a lack of good faith, supporting the award of punitive damages, in representing that a given test or procedure can safely be omitted when the data and analysis do not adequately support that conclusion. This result would be most likely and most justified when the guideline's developer was an organization, such as an HMO or managed care company, that would stand to gain directly by an unJustifiably parsimonious or corner-cutting standard. As important as cost-containment may be, the safety and well-being of patients must be the prime objective in guidelines development.

Another basis for negligence liability could be the CPG developer's failure to keep its guidelines continually updated and replace obsolete standards as technology and knowledge move forward. This ground is particularly appropriate for at least two reasons. First, since the function of guidelines is to synthesize and disseminate the state of the medical art, their issuers have a special obligation to stay abreast of new developments. Indeed, if they market their services as being on the "cutting edge" of medical knowledge, or as advancing the state of the art, such claims could easily be taken for a contractual undertaking, or warranty, to constantly reassess, and revise where necessary, their informational product. Second, once a guideline is issued and substantial numbers of providers start

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66. Some recent cases, e.g., Washington v. Washington Hosp. Center, 579 A.2d 177 (D.C. 1990), have required providers to adopt new devices rapidly to keep pace with the advancing state of technology. Presumably, adoption of new knowledge would be pushed even more aggressively, since no capital investment is required. See Burton v. Brooklyn Doctors Hosp., 88 A.D.2d 217, 223 (N.Y. App. Div. 1982) (holding a hospital and physicians liable for not following new treatment studies that contravened conventional wisdom).
following it, much more data will become available on the
clinical experience under its recommended treatment approach.
The disseminator of the guideline then will have a unique abil-
ity to follow up and assess the validity of the guideline. With
special access to critical information might well come the cor-
responding obligation to make effective use of that information.
Legal recognition of this special obligation would assure the
creation and operation of mechanisms for using this new data
to validate, or invalidate, the guideline.

But liability is not a certainty. In his 1991 article, Brennan offers four main reasons why there is little like-
lihood of a successful suit against those who issue guidelines.
First, courts tend to place primary responsibility for the care of
the patient on the physician rather than on others involved in a
less direct way with treatment decisions. Second, recognizing
that guideline developers are undertaking a complex pioneering
activity for the benefit of the public, courts would not want to
chill their activity. Third, when guidelines are essentially a
compilation of existing literature, they would provide only nar-
row grounds for a suit. Brennan notes that he is not aware of
any suits against the author of a review article on the ground
that she or he failed to consider all aspects of a particular ques-
tion. However, he acknowledges that the situation may be dif-
ferent when “the guidelines represent new data derived from an
explicit consensus-building effort within a group of experts.”
Finally, when the guideline developer is a governmental body, a
sovereign immunity might apply.

68. Id. at 78. Although it was dictum in the specific context of that case, the court in Wickline v. California, 239 Cal. Rptr. 810 (Cal. Ct. App. 1986), expressed a broadly held
sentiment:

[T]he physician who complies without protest with the limitations imposed by a
third party payor, when his medical judgment dictates otherwise, cannot avoid his
ultimate responsibility for his patient's care. He cannot point to the health care
payor as the liability scapegoat when the consequences of his own determinative
medical decisions go sour.

Id. at 819.
69. Brennan, supra note 3, at 79.
This Article has attempted just an overview, not a comprehensive exposition, of the legal issues surrounding the Clinical Practice Guidelines movement. Much more exploration could and should be applied to each of the issues raised above. Absent such in-depth analysis, it is arguably inappropriate to draw conclusions or make policy pronouncements; but, in the interest of provoking further debate and inquiry, I would like to close by proposing some guiding principles and a set of specific recommendations.

Further development of the Clinical Practice Guidelines movement holds great promise for improving the nation’s health care system, with regard both to cost and quality. I favor CPGs and would like to see their use and authority continue to grow. In supporting this growth, the following four essential principles should be observed. First, private sector initiatives should be relied upon to the fullest extent practicable; government involvement in setting standards for medical practice should not be increased beyond what is necessary to assure the safe and sensible development and application of CPGs. Second, guidelines must not be allowed to freeze, or even chill, the advance of medical knowledge and practice. There must be ample latitude for the introduction of new technologies and clinical approaches. By the same token, there must be room for the development of new guidelines and provision for the continual updating and revision of existing guidelines. Third, malpractice litigation processes should be streamlined and simplified to the greatest extent practicable through the adoption of CPGs. At the least, CPGs should be added to the legal landscape in a way that causes no disruption of judicial processes or escalation of their complexity. Finally, parties to medical malpractice litigation should be treated fairly and even-handedly. CPGs should not be used in a way that gives either plaintiffs or defendants undue advantage.

Working from a belief that the development and use of CPGs offers substantial benefits and should be encouraged at the national level, and consistent with the general principles articulated above, I propose the following specific elements for a national program to foster the development and widespread use of clinical practice guidelines.
A pluralistic system should be adopted; that is, all interested and qualified parties should be allowed to develop and promote the use of their CPGs. However, a clear legal distinction should be drawn between certified and uncertified CPGs, creating an incentive for voluntary compliance with a federal program of quality assurance for guidelines development and use.

A federal agency, either AHCPR or another appropriate sub-unit of the DHHS, should be designated by congressional legislation as the sole agency to certify ("bless") CPGs. The reasonable costs of initial certification and periodic recertification should be borne by the entity issuing the CPG. General costs related to AHCPR's activities as the certifying agency should be borne by the HHS budget.

To be certified, a CPG must be developed: (1) through solid, scientific outcomes research, using an appropriate and adequately large clinical practice data base; (2) using appropriate methodology, as defined by DHHS regulations; (3) with input from qualified medical professionals, and (4) with provision for prompt, periodic updating to incorporate experience gained through clinical practice under the CPG.

The legislation establishing the certification process also should direct federal and state courts to recognize a CPG as establishing an "acceptable standard" of health care only if the CPG has been certified by the designated government agency and its requirements for periodic updating and ongoing recertification of the CPG have been met.

CPGs should be available equally to plaintiffs and defendants for use in malpractice litigation. While the substantive rules of liability for medical negligence may make CPGs more useful to one party than the other, there should be no inequality of treatment under procedural or evidentiary rules. The principle of equal treatment would not preclude a rule that compliance with a recognized guideline creates a rebuttable presumption that the health care provider used reasonable care in the treatment of the patient.

An issuer of a CPG should be immune from civil liability for harms caused by the adoption and use of the CPG if the initial and ongoing federal certification requirements have been met. Liability protection for the certifying body itself (presumably AHCPR) would be through sovereign immunity.

If the above general principles can be observed and a national framework of federal and state laws developed along the
specific lines proposed, the use of clinical practice guidelines will bring substantial benefits to our health care system. While there will always be a need and a place for professional medical judgment, it is wise to make maximum use of available empirical evidence of what works and does not work, synthesizing those data into carefully analyzed, widely disseminated guidelines to assist physicians in the application of their judgment. Benefits to the legal system will flow from this as well, making possible more accurate, efficient, timely, and affordable resolution of disputes about the quality and appropriateness of health care provided.