

12-1-1997

## Toward Controlled Clinical Care Through Clinical Practice Guidelines: The Legal Liability For Developers and Issuers of Clinical Pathways

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### Recommended Citation

Megan L. Sheetz, *Toward Controlled Clinical Care Through Clinical Practice Guidelines: The Legal Liability For Developers and Issuers of Clinical Pathways*, 63 Brook. L. Rev. 1341 (1997).

Available at: <https://brooklynworks.brooklaw.edu/blr/vol63/iss4/8>

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# TOWARD CONTROLLED CLINICAL CARE THROUGH CLINICAL PRACTICE GUIDELINES: THE LEGAL LIABILITY FOR DEVELOPERS AND ISSUERS OF CLINICAL PATHWAYS

## INTRODUCTION

National health care reform continues to dominate the domestic political, social and economic scenes. The health care system in the United States is plagued by escalating costs and excess capacity, resulting in a fundamental shift in the way health care is administered, organized and funded.<sup>1</sup> In 1995, close to 150 million Americans received their health care through health maintenance organizations and other managed care entities, which is an increase of more than thirty percent from the ninety-two million enrollees in 1992.<sup>2</sup> The issues figuring most prominently in this reform are cost-containment, cost-effectiveness and quality treatment.<sup>3</sup> Reconciling these competing interests, quality of care versus cost-containment and effectiveness, is the major challenge facing the health care system.

As a result of these competing concerns, the health care industry has gravitated toward the use and development of clinical outcomes or clinical guidelines, generally called clinical practice guidelines ("CPGs").<sup>4</sup> Clinical practice guidelines were

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<sup>1</sup> See generally Rex O'Neal, *Safe Harbor For Health Care Cost Containment*, 43 STAN. L. REV. 399 (1991); Richard C. Reuben, *In Pursuit of Health*, A.B.A. J., Oct. 1996, at 55 (according to the United States Department of Health and Human Services, health care expenditures accounted for almost 14% of the nation's gross domestic product in 1994).

<sup>2</sup> Reuben, *supra* note 1, at 55.

<sup>3</sup> See generally Timothy Stoltzfus Jost, *Oversight of the Quality of Medical Care: Regulation, Management or the Market?*, 37 ARIZ. L. REV. 825 (1995); see also HEALTH SECURITY ACT, H.R. 3960, 103rd Cong. (1994).

<sup>4</sup> "Clinical Practice Guidelines" have various synonyms including: "clinical pathways," "critical pathways," "clinical paradigms," "practice parameters," "clinical algorithms," "treatment protocols," and "standards." The various terms are often interchangeable; however, the American Medical Association prefers the use of the

originally intended to aid in the standardization of certain aspects of health care practice.<sup>5</sup> CPGs were deemed necessary after researchers discovered that there were wide variations in the ways in which physicians treat the same illnesses, resulting in inconsistent, and often, ineffective and expensive treatments.<sup>6</sup> Moreover, studies revealed that many physicians were using methods of diagnosis and treatment that had very weak scientific support.<sup>7</sup> As a result of these findings, the guidelines have been accorded wide acceptance due to the belief that they will "improve the quality of patient care, improve patient treatment outcomes, reduce costs and generally improve patient satisfaction."<sup>8</sup>

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term "parameters," compared to "guidelines" or "standards," because the latter terms appear to invite strict adherence whereas the former suggests flexibility in application, allowing room for independent physician discretion and judgment. See Edward Hirshfeld, *Should Practice Parameters Be the Standard of Care in Malpractice Litigation?*, 266 JAMA 2886 (1991).

The distinctions between the terms used to describe "clinical practice guidelines," although seemingly subtle, should not be considered irrelevant. As discussed *infra*, there is concern over including the word "standard" when referring to CPGs because of the law's use of the word "standard" to refer to the legal duty of care. See David M. Eddy, *Designing A Practice Policy: Standards, Guidelines and Options*, 262 JAMA 3077 (1990). This differentiation is likely to be critical when practice guidelines are admitted into court in medical malpractice actions as evidence of the legal standard of care required of practitioners. The most important legal inquiry in these circumstances is likely to be whether the language of the guideline appears to specify mandatory or permissive actions by providers. "The concern is that a label such as 'standard' or 'rule' will be interpreted by the health care and legal communities as signaling a mandatory level of clinical care." See THE 1995 MEDICAL OUTCOMES AND GUIDELINES SOURCEBOOK 414 (Spencer Vibbert et al., eds., Faulkner & Gray 1995) [hereinafter MEDICAL OUTCOMES].

<sup>5</sup> See John D. Ayres, *The Use and Abuse of Medical Practice Guidelines*, 15 J. LEGAL MED. 421 (1994). Although practice guidelines have been used in the medical profession since 1930, it was not until 1980, when faced with rising costs of health care and the perception that much of the increased cost was due to inappropriate clinical practices, that the pace of development began to escalate. Experts suggested that guidelines might help physicians reduce practice variation and subsequently enhance the quality of patient care. See generally Steven H. Woolf, *Practice Guidelines: What the Family Physician Should Know*, 51 AMERICAN FAM. PHYSICIAN 1455 (1995).

<sup>6</sup> See Mark R. Chassin, et al., *Variations in the Use of Medical and Surgical Services by the Medicare Population*, 314 NEW ENG. J. MED. 285 (1986) (researchers demonstrated with overwhelming evidence that physicians' methods and practices of treating various similar conditions and illnesses vary widely for no apparent reason).

<sup>7</sup> See David M. Eddy, *Clinical Policies and the Quality of Clinical Practice*, 307 NEW ENG. J. MED. 343 (1982).

<sup>8</sup> Mark Kadzielski et al., *Peer Review and Practice Guidelines Under Health*

By making readily accessible the clinical knowledge gleaned from "outcomes research,"<sup>9</sup> CPGs are intended to "point the way toward higher quality and more cost-effective care."<sup>10</sup> Thus, the premise behind the use and development of such guidelines is that cost-effective quality health care can be provided if variation in health care is reduced.<sup>11</sup>

Although there is general agreement among physicians that the development of CPGs is likely to increase the quality of care by making more accessible the clinical knowledge obtained from outcomes research, the guidelines are a relatively new concept. Thus, continued controversy is provoked concerning certain crucial aspects of the use of the guidelines. First, many physicians, organizations and health care experts agree that greater attention is needed as regarding the processes by which guidelines are developed and disseminated. With a growing number of organizations developing various guidelines, questions arise as to: 1) the standards used to develop the guidelines; 2) the amount and type of research utilized in their development; 3) the frequency of reevaluation of guidelines in light of medical advances; and 4) the issue of choice when physicians are confronted with conflicting guidelines which are issued by different organizations.<sup>12</sup>

A second problem, which is the focus of this Note, involves the potential liability of developers and issuers of CPGs. As CPGs become more widely used and more widely sought by

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*Care Reform*, 16 WHITTIER L. REV. 157 (1995).

<sup>9</sup> Outcomes research is the study and analysis of the outcomes of various treatments administered to certain patient populations. A CPG will be more reliable and credible if the information used to develop the guideline was the result of reviewing all relevant medical literature and patient outcomes information.

See *infra* notes 34-38 and accompanying text.

<sup>10</sup> Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369 (1995).

<sup>11</sup> See generally William Roper et al., *Effectiveness in Health Care: An Initiative to Evaluate and Improve Medical Practice*, 319 NEW ENG. J. MED. 1179 (1990); Lucian L. Leape, *Practice Guidelines and Standards: An Overview*, 16 QUAL. REV. BULL. 42 (1990); Clark C. Havighurst, *Practice Guidelines for Medical Care: The Policy Rationale*, 34 ST. LOUIS U. L. REV. 777 (1990).

<sup>12</sup> Guidelines are currently being developed and issued by the federal government, physician organizations, medical specialty societies, managed care plans, insurers, hospitals, employers, quality assurance firms, state governments and private vendors. Woolf, *supra* note 5, at 1456. With hundreds of groups developing thousands of guidelines, it is easy to imagine a situation in which guidelines may conflict with respect to treating a particular illness.

physicians, hospitals, health maintenance organizations ("HMOs") and other groups, it is becoming apparent that their development, in and of itself, is a thriving business. Managed care organizations are utilizing all available cost-containment measures in an attempt to reduce the escalating health care costs. As developers begin to reap significant financial benefits from the development of CPGs, there is an increasing pressure to hold responsible and accountable those who gain financially from an activity that centers on the general public health.<sup>13</sup> A related concern is that guideline development will be viewed by a majority of managed care organizations solely as a means to contain costs, overshadowing the equally important goal of increasing the quality of health care. Because there is very little case law regarding the use of clinical pathway guidelines, the health care industry—including physicians, hospitals, and health maintenance organizations—faces legal uncertainty when considering whether the development and use of practice guidelines will heighten or reduce their liability exposure to medical malpractice claims.<sup>14</sup> This uncertainty is likely to affect the development and use of CPGs.<sup>15</sup>

This Note argues that the development of CPGs is crucial to the success of achieving both quality medical care and reduction of costs. However, because CPGs may effectively lower the cost of medical care and treatment at the expense of providing quality medical care, it may be dangerous to allow

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<sup>13</sup> Rosoff, *supra* note 10, at 390.

<sup>14</sup> A particularly sensitive subject, discussed *infra*, regards the development of CPGs by HMOs and other third party payers, who, arguably, view CPGs primarily as a cost-effective measure rather than as a way to ensure quality treatment. This tension between containing costs and providing quality care is exacerbated when the HMOs or other insurers urge their physicians, many of whom believe that the goal of CPG development should focus primarily on quality care, to abide by their developed guidelines. Critics of HMOs argue that managed care "is more about making money than saving it." Reuben, *supra* note 1, at 55. Moreover, critics contend that HMOs offer doctors powerful inducements to be conservative in their treatments, which could mean cutting back on hospital stays for patients or limiting referrals to specialists. Doctors are often put in the undesirable position of having to choose between potential malpractice for undertreatment, paying for treatment themselves when they have exhausted their "fixed fee per patient" arrangement, or being eliminated from an HMO's referral list for overutilization of treatment. Obviously this situation causes resentment among physicians for what they view as a usurpation of their medical judgment by cost-conscious, uninvolved managed care executives. *Id.*

<sup>15</sup> Rosoff, *supra* note 10, at 373.

health care management organizations and other third party payers, whose primary goal may be cost-effectiveness, to develop and issue their own guidelines. This danger may be reduced, initially, by requiring that CPGs be accredited by a neutral multi-disciplinary committee of health care experts, whose primary concern is the quality of patient care.<sup>16</sup>

Part I of this Note introduces and defines the concept of clinical pathway guidelines and traces the rise in their development and use. Part II discusses the possible bases for developers' and issuers' liability. Part III addresses the specific theories of liability which may attach when managed care organizations, such as HMOs and other managed care companies, serve as the developers and issuers of clinical guidelines. This part focuses on the tension which arises when cost-sensitive organizations are in the business of developing guidelines for quality care. It also explains the ways in which compliance with guidelines may not only shield physicians from medical malpractice liability, but may also constitute substantial evidence in lawsuits brought by physicians for indemnification against health maintenance organizations and other insurers who urged the use of the guidelines. Finally, Part IV examines the current roles of federal and state governments in institutionalizing and certifying the guidelines. This part discusses the inadequacy of the current certification process and concludes with a proposal concerning the appropriate roles of federal and state governments regarding clinical practice guidelines.

## I. BACKGROUND

### A. *What Are Clinical Practice Guidelines?*

Clinical practice guidelines are defined in various ways. The Institute of Medicine defines CPGs as "systematically developed statements to assist practitioner and patient decisions about appropriate health care from specific clinical circumstances."<sup>17</sup> The Medical Outcomes & Guidelines Sourcebook

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<sup>16</sup> To date, there is no requirement that CPGs be accredited. Similarly, there are no regulations regarding their usage or development. See Kadzielski, *supra* note 8, at 161.

<sup>17</sup> INSTITUTE OF MEDICINE: CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A

describes a CPG as "a descriptive tool or standardized specification for care of the typical patient in the typical situation; developed by a formal process that incorporates the best scientific evidence of effectiveness with expert opinion. . ."<sup>18</sup> The American Medical Association refers to guidelines as "practice parameters," in an effort to encourage both flexibility in their adoption and use of a physician's clinical judgment when it may differ from the guideline.<sup>19</sup> Most definitions are uniform in their aim: to improve physician decisionmaking by detailing appropriate indications for specific medical interventions.

The development of CPGs is complicated by the difficulty in developing a single method of guidance for highly complex and varied areas of medicine that is prescriptive, clear and unambiguous.<sup>20</sup> There are some clinical problems that are well-suited to a specific and straightforward set of guidelines that can be applied as treatment to a wide spectrum of patients.<sup>21</sup> For example, the anesthesiologist practice guideline, which was developed by the American Society of Anesthesiologists, is considered to be a successful guideline because it is "designed for a specific purpose, addresses a clinical problem that can be handled in essentially the same way for a wide spectrum of patients, and can be presented as a limited set of rules that should be followed."<sup>22</sup>

The anesthesiology guideline focuses on avoiding patient injuries caused by oxygen deprivation resulting from accidents during anesthetization.<sup>23</sup> The practice guideline identifies a set of standards that anesthesiologists should follow to avoid serious injuries which result from oxygen deprivation.<sup>24</sup> It was developed by reviewing claims made to malpractice insurance carriers after the occurrence of anesthetic accidents. The claim

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NEW PROGRAM, Washington, D.C. (National Acad. Press 1990).

<sup>18</sup> MEDICAL OUTCOMES, *supra* note 4 at 683.

<sup>19</sup> J.T. Kelly & J.C. Swartout, *Development of Practice Parameters by Physician Organizations*, 1990 QUALITY REV. BULL. 16:54-57; see also MEDICAL PRACTICE GUIDELINES, CALIFORNIA MEDICAL ASSOCIATION, THE WESTERN JOURNAL OF MEDICINE, Vol. 161 No. 1, at 39 (1995).

<sup>20</sup> Hirshfeld, *supra* note 4, at 2886.

<sup>21</sup> Hirshfeld, *supra* note 4, at 2886.

<sup>22</sup> Hirshfeld, *supra* note 4, at 2886.

<sup>23</sup> E. Pierce, *The Development of Anesthesia Guidelines and Standards*, 16 QUAL. REV. BULL. 61-64 (1990).

<sup>24</sup> *Id.*

records were analyzed to determine whether there was a common pattern to the injuries that could be resolved by initiating changes in the practices of anesthesiologists. After evaluating the records, the researchers "discovered that a high percentage of accidents might have been prevented by the use of certain types of equipment designed to measure the amount of oxygen in a patient's blood when under anesthesia and by proper maintenance and use of other anesthesia equipment."<sup>25</sup> The proposed reason why this guideline is so successful is that it is "simple and prescriptive."<sup>26</sup> Additionally, it states when equipment designed to measure blood oxygen should be used and how this equipment should be maintained. Finally, this guideline is successful because it applies to almost all patients who receive general anesthesia.<sup>27</sup>

In stark contrast to the anesthesiological guideline outlined above is the guideline for treatment of depression, developed by the Agency for Health Care Policy and Research in April, 1994, which sets forth: "The specific medication choice is based on side effects profiled, history of prior response, family

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<sup>25</sup> Hirshfeld, *supra* note 4, at 2886 (quoting E. Pierce, *The Development of Anesthesia Guidelines and Standards*, 16 QUAL. REV. BULL. 61 (1990)).

<sup>26</sup> Hirshfeld *supra* note 4, at 2886.

<sup>27</sup> Hirshfeld, *supra* note 4, at 2886. Interestingly, the guideline is designed in such a way that there is little room for clinical judgments to be made by the individual treating physicians. This guideline is also fairly limited in scope in that it does not address the medical practice of anesthesiology beyond equipment usage and maintenance.

Contrast the anesthesiology guideline with the guideline designed to aid in the decision of when to implant a pacemaker. The goal of the pacemaker guideline is different from that of the anesthesiology guideline in that the objective of the pacemaker guideline is to "reduce the provision of unnecessary medical care by providing guidance for when it is appropriate to implant a pacemaker." Hirshfeld, *supra* note 4, at 2887. Because the decision of whether and when to implant a pacemaker is considered complex, the guideline reflects this complexity in its structure. "The guideline divides patients into various categories, depending on the nature and gravity of their symptoms." Hirshfeld, *supra* note 4, at 2887. There are three distinct categories into which patients may fall: patients who are considered appropriate candidates for pacemaker implants based on specific selected criteria, patients who are considered inappropriate candidates based on certain selected criteria, and patients for whom implants are agreed to be of uncertain value. Hirshfeld, *supra* note 4, at 2887. This guideline allows for a substantial amount of uncertainty, thus allowing treating physicians to engage in more independent clinical judgments when there are patients for whom the benefits of the pacemaker implant is uncertain. There is also uncertainty as to the category in which to place a given patient when the patient's symptoms do not clearly fit into one of the guideline's categories. Hirshfeld, *supra* note 4, at 2887.



history of response, time of depression, and concurrently prescribed medications."<sup>28</sup> This guideline would be of little help to a physician because it is vague, ambiguous and provides no new information for the proper method to treat depression.<sup>29</sup> It does not provide for a division of patients into various categories reflecting various stages of depression and makes no mention of different medications and their effects on people at different stages of depression. Additionally, there is discussion about varying symptoms in the depressed patient population and how various medications may impact different symptoms. This type of guideline, which lacks specificity and direction, has no positive effect on treatment of the disorder; nor does it tend to reduce the cost of treatment, since no treatment is specified. Thus, it fulfills neither the goal of quality health care nor the goal of cost-effectiveness. Developers should, therefore, whenever possible, focus on writing guidelines which are clear, prescriptive and specific.

### B. *Who Develops Guidelines and How?*

The number of organizations responsible for developing clinical pathway guidelines has increased substantially over the past eight years. In 1990, there were twenty-six physician organizations responsible for creating more than 700 guidelines.<sup>30</sup> By 1994, it was estimated that over sixty organizations were responsible for creating more than 1,600 such guidelines.<sup>31</sup> This presents the scenario that practice guidelines are being developed by an increasingly wider range of groups and individuals, including physicians, hospital executive officers and trustees, private research organizations and third party payers.<sup>32</sup> Additionally, the federal government is becoming more involved in developing guidelines. The Agency for Health Care Policy and Research ("AHCPR"), through the Office of the Forum for Quality and Effectiveness, is responsi-

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<sup>28</sup> See Kadzielski, *supra* note 8, at 163.

<sup>29</sup> Kadzielski, *supra* note 8, at 163.

<sup>30</sup> *Medical Malpractice Guidelines*, WESTERN J. MED., July 1994, at 39.

<sup>31</sup> Ayers, *supra* note 5, at 421.

<sup>32</sup> See Karen A. Butler, R.N., *Health Care Quality Revolution: Legal Landmines For Hospitals And The Rise Of The Critical Pathway*, 58 ALB. L. REV. 843, 850 (citing JCAHO, ACCREDITATION MANUAL FOR HOSPITALS at ix (1992)).

ble for developing practice guidelines for high-cost procedures and for procedures in which significant variation in the manner of performance has been found across the country.<sup>33</sup>

The most effective practice guidelines are those that are developed through the use of outcomes research, which is research that is conducted on various methods of treatment and

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<sup>33</sup> The Omnibus Budget Reconciliation Act of 1989, Pub. L. 101-239, added Title IX to the Public Health Service Act, which established the Agency for Health Care Policy and Research to "enhance the quality, appropriateness, and effectiveness of health care services, and access to such services." See Pub. L. No. 101-239, § 6103, 103 Stat. 2189 (1989) (codified at 42 U.S.C. § 299 (Supp. V 1993)). The Agency for Health Care Policy and Research Re-authorization Act of 1992, Pub. L. 102-410, enacted on October 13, 1992, extended the authorization of the AHCPR and amended certain provisions related to the development of clinical practice guidelines.

The AHCPR, through the Office of the Forum for Quality and Effectiveness in Health Care, arranges for the development, periodic review and updating of clinically relevant guidelines that may be used by physicians, other health care practitioners, educators, and consumers. The guidelines assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated and clinically managed. The AHCPR also supports development, periodic review, and updating of medical review criteria, standards of quality, and performance measures, based on the guidelines. From 1992 through May 1994, the AHCPR has released ten clinical practice guidelines in the following areas: Acute Pain Management, Urinary Incontinence, Pressure Ulcers, Cataract Ulcers, Depression in Primary Care, Sickle Cell Disease, Evaluation and Management of Early HIV Infection, Benign Prostatic Hyperplasia, Management of Cancer Pain and Unstable Angina. Ten more guidelines are under development. MEDICAL OUTCOMES, *supra* note 4, at 171.

Arnold J. Rosoff suggests that the AHCPR's work, in many respects, "is more focused on expanding knowledge than on applying it," and states that much of their activity involves studying, developing and revising. Rosoff, *supra* note 10, at 373.

One issue, discussed *infra*, is whether the AHCPR should be responsible for being the sole official developer of clinical pathway guidelines, thereby providing credibility and consistency to an often confusing and scattered array of guidelines. The AHCPR-commissioned guidelines differ from other guidelines in that: 1) they are created by private-sector, multi-disciplinary panels of experts, including consumer representatives; 2) they are based on extensive literature reviews and reflect the best science available; 3) they are subjected to intensive scrutiny by peer reviewers and on-site clinical evaluations by potential users to assess validity, efficacy and applicability; 4) they are written for health care providers and consumers; 5) they include analysis of the use and cost of health care resources and assessment of the feasibility of implementation; and 6) they are updated to incorporate new information. MEDICAL OUTCOMES, *supra* note 4, at 168. Notably, Section 914(a) of the Public Health Service Act, 42 U.S.C. § 299b-3(a), as amended by Pub. L. No. 102-410, identifies factors to be considered in establishing priorities for guideline topics and goals which these guidelines should serve; there is no mention of cost-effectiveness as a priority in the development of clinical guidelines. MEDICAL OUTCOMES, *supra* note 4, at 171.

the subsequent outcome in the patient populations.<sup>34</sup> Outcomes research centers on two key concepts: outcomes measurement and outcomes management.<sup>35</sup> Outcomes measurement refers to the statistical evaluation of the effectiveness of particular types of clinical intervention. The outcome of one treatment is compared with the results of similar types of clinical intervention.<sup>36</sup> Outcomes management refers to the actions that providers take as a result of the above evaluations. Consequently, in the development and communication of clinical pathway guidelines, "there is a continual process of measuring and developing guidelines, applying the guidelines, and then measuring, revising, and measuring again."<sup>37</sup> Thus, outcomes research is the basis from which clinical pathway guidelines are spawned, and such on-going research is critical to maintaining the guidelines' validity.<sup>38</sup>

Although practice guidelines have been used for over fifty years to facilitate effective decisionmaking by physicians,<sup>39</sup> the rise in the number of organizations developing guidelines and the sheer number of physicians utilizing them has indicated a general shift from "unexamined reliance on professional judgment toward more structured support for, and accountability of, such judgment."<sup>40</sup> Due to the sensitivity surrounding cost-containment and cost-effective health care reforms, there is an increasing recognition of the roles that outcomes research and practice guidelines may play as cost-containment factors.

Advocates of clinical guidelines argue that such guidelines decrease physician uncertainty and lower rates of inappropriate care "by codifying knowledge in particular practice ar-

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<sup>34</sup> Kadzielski, *supra* note 8, at 161-62.

<sup>35</sup> Lowell C. Brown & Joan Procopio, *Sailing Through Uncharted Waters: Outcomes Measurement, Practice Guidelines, and the Law*, 16 WHITTIER L. REV. 1021 (1995).

<sup>36</sup> *Id.*

<sup>37</sup> *Id.*

<sup>38</sup> The Forum for Quality and Effective Health Care was created under the Omnibus Budget Reconciliation Act of 1989 with the specific mandate to preside over panels charged with the development of practice guidelines based on outcomes research. Pub. L. No. 101-239, § 901, 103 Stat. 2189 (1989) (codified as amended at 42 U.S.C. § 299 (1994)).

<sup>39</sup> Rosoff, *supra* note 10, at 373.

<sup>40</sup> Deborah W. Garnick et al., *Can Practice Guidelines Reduce the Number and Costs of Malpractice Claims?*, 266 JAMA 2860 (1991).

eas.<sup>41</sup> Additionally, they provide information that is direct, concise and easy to use. Advocates urge attorneys to advise physicians that these clinical guidelines do not trump the physician's responsibility to exercise independent judgment based on the individual patient's circumstances.<sup>42</sup> Rather, physicians are encouraged to view the practice guidelines as flexible, and they are urged to continue utilizing their independent clinical judgment—even when their judgment may conflict with the proposed guideline.<sup>43</sup>

Proponents also argue that physician acceptance and reliance on practice guidelines will reduce the number of unnecessary diagnostic tests performed on patients. Specifically, industry pressure to adhere to CPGs will prevent physicians from performing unnecessary and costly tests in an effort to insulate themselves from malpractice suits.

Although there is evidence that practice guidelines are viewed favorably by hospital executives and managed care organizations,<sup>44</sup> physicians are divided on the issue. Many physicians argue that mandating compliance with these guidelines is turning health care into "cookbook medicine," with the result that very little clinical judgment is left to the physician.<sup>45</sup> Practice guidelines also present some practical prob-

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<sup>41</sup> *Medical Practice Guidelines*, WESTERN J. MED., July 1994, at 39.

<sup>42</sup> Brown & Procopio, *supra* note 35, at 1022.

<sup>43</sup> See *infra* notes 126-33 and accompanying text. The *Wichline* court essentially held that a physician is responsible for exercising his clinical judgment even when the guideline calls for a different treatment. This may not necessarily be true in the future. It is uncertain how courts will view situations in which HMOs and other insurers have essentially strong-armed doctors into following their developed guidelines, through use of financial incentives or fear of dismissal from HMO rosters due to overutilization of treatments not recommended by the guideline. See Reuben, *supra* note 1, at 60.

<sup>44</sup> A Survey of Leading Health Care Executives Conducted by The Boston Consulting Group, *An Industry Perspective on Health Care Reform: Goals, Elements and Implications*, 1993.

<sup>45</sup> Brown & Procopio, *supra* note 35, at 1022. But see Mark A. Hall & D. Sophocles Dadakis, *Character of Guidelines Evolves, Concern Lingers Over Protection*, 13 NO. 4 MED. MALPRACTICE L. & STRATEGY 1 (1996). This article advocates for guideline developers to draft "guidelines" more as "protocols," so that they will have a greater chance of establishing a conclusive standard of care. For guidelines to be considered in the courtroom as conclusive standards of care, developers must draft the guidelines more specifically, so that the treatment decision does not lie wholly within the judgment of individual physicians. When guidelines are vague as to how a physician should treat a malady, the guideline itself will offer little protection against accusations that a physician made poor decisions. *Id.* at 2.

lems for physicians. For example, questions and complexities arise when a provider contracts with numerous health maintenance organizations or other third party payers, each of which present different guidelines for the provider to observe.<sup>46</sup>

Providers' attitudes toward CPGs have differed depending on the organization responsible for developing the guideline, their motive and the reliability of the information being used. In 1992, the most extensive survey of physician attitudes toward CPGs was conducted.<sup>47</sup> Although the survey is almost six years old, the results serve to shed light on practice guidelines' reputation among physicians. Interestingly, one of the key findings of the study showed there was a wide range of confidence in guidelines, depending on the organizations involved in their development. For example, eighty percent of physicians said they were "very confident" in guidelines prepared by the American College of Physicians, while only six percent expressed similar confidence in those developed by the Blue Cross and Blue Shield Associations.<sup>48</sup>

These findings may indicate several things. First, physicians are likely to distrust any guidelines that are developed with cost-effectiveness as the primary goal. Physicians have primarily viewed CPGs as a way to enhance the quality of patient care, not as cost-cutting measures. This conflict between the goals of individual physicians and the goals of managed care companies creates an uneasy tension, whereby the physician may come to view certain CPGs very skeptically, especially as the managed care companies more strenuously

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<sup>46</sup> Brown & Procopio, *supra* note 35, at 1023.

<sup>47</sup> Because physician support is essential to the widespread adoption and use of CPGs, a group of U.S. and Canadian researchers formed the Guidelines Appraisal Project (GAP) which was responsible for conducting the extensive study on CPGs. In order to assess physicians' attitudes toward CPGs, the GAP disseminated a lengthy questionnaire to 2,600 members of the American College of Physicians; over 1,500 responses were received. Additional findings included that: 1) most physicians are not familiar with existing guidelines, with a few notable exceptions; and 2) ambivalence characterizes physicians' attitudes toward guidelines. Although close to 70% of survey respondents believe that guidelines would improve the quality of medical care, about the same number think guidelines will be used in disciplinary actions against clinicians. MEDICAL OUTCOMES, *supra* note 4, at 73.

For a complete review of the study's results, see Sean Tunis, M.D., *Primary Care Physicians' Attitudes Toward Clinical Practice Guidelines*, CLINICAL RESEARCH (1992).

<sup>48</sup> MEDICAL OUTCOMES, *supra* note 4, at 73.

advocate for their use.<sup>49</sup> Second, physicians may believe that guidelines promulgated by a national medical organization are more respectable and indicative of the standard of care owed to a patient. Third, physicians may believe that managed care companies will force them to utilize the guideline as a requirement to remaining on the organization's roster of physicians, thus exposing the physician to medical malpractice actions based on his/her compliance with a faulty or ineffective guideline.

Physicians are hesitant to embrace practice guidelines because of their uncertain implications in the courtroom. Presently, guidelines have been used in the courtroom by both plaintiffs' attorneys and defendants' attorneys, indicating a "two-way street."<sup>50</sup> In an analysis of twenty-eight cases where guidelines were considered, plaintiffs' attorneys have used them against physicians as inculpatory evidence in twenty-two cases. Alternatively, defendants' attorneys have successfully used them as exculpatory evidence in six of the cases.<sup>51</sup> Although evidence of compliance with or deviation from the guidelines has been used by both parties, plaintiffs have tended to make substantially greater use of guidelines to their advantage,<sup>52</sup> making physicians wary as to the future implications of the use of CPGs.<sup>53</sup> If, however, CPGs are adopted as an absolute affirmative defense to patient claims of negligence, physicians would surely encourage their use. Guidelines, thus,

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<sup>49</sup> Many people supported the guidelines movement at an earlier phase when the focus was on enhancing the quality of patient care. These same people may be much less inclined to support CPGs now that the focus has changed and they are being heavily utilized by managed care companies as a way to reduce costs. See Rosoff, *supra* note 10, at 373.

<sup>50</sup> See Andrew L. Hyams, et al., *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POL. POL'Y & L. 289, 293-96 (1996).

<sup>51</sup> *Id.* at 296. Used as inculpatory evidence, a practitioner's failure to adhere to the guideline supports a finding that the practitioner deviated from the required standard of care; used as exculpatory evidence, a finding that practitioner adhered to the guideline supports a finding that he/she acted consistently with the required standard of care.

<sup>52</sup> *Id.*

<sup>53</sup> Interestingly, legislators have seen guidelines as a "one-way street," to be used only by physicians as an affirmative defense, proof that they adhered to the required standard of care. This scenario is being played out in Maine with the 1990 Maine Medical Liability Demonstration Project. To date, there has been no litigation there surrounding practice guidelines. *Id.* at 306.

would likely become more reliable and effective, because they would become more widely used, allowing for a significant basis from which to conduct outcomes research as to their ongoing effectiveness.

Critics of managed care companys' involvement with guideline development note that because HMOs and other managed care companies control the "power of the purse," physicians recognize that any independent decision made without consent of the organization could result in termination from the plan's roster. Realizing this, many physicians may begin to adhere blindly to HMO regulations and guidelines, without questioning their underlying validity. It is not unlikely, then, that when faced with the prospect of being removed from an HMO roster, physicians, especially those who work solely for the HMO, would abide by the HMO's guidelines rather than face unemployment. This highlights the strong criticism advanced by many health care experts with respect to CPGs: CPGs alter the physician's role of independent decisionmaker. The result is that doctors cease to exercise their professional judgment and, instead, adhere strictly to a prescribed set of rules.<sup>54</sup> Not only does this negatively affect patients, who may fall outside the guideline's prescriptions, it may also seriously impede medical development. When physicians adhere only to standardized rules and no longer experiment with new and potentially revolutionary treatments, the growth of medical development suffers.<sup>55</sup>

Although some practitioners, providers and other medical experts continue to be skeptical of the guidelines, both as to their implications in a court of law and their potentially chilling effect on the advancement of medicine,<sup>56</sup> physicians have noted that the following features would make guidelines more desirable: 1) greater attention to the processes by which guide-

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<sup>54</sup> See Steven H. Woolf, M.D., *Practice Guidelines: A New Reality in Medicine*, 153 ARCHIVES INTERNAL MED. 2646, 2649 (1993).

<sup>55</sup> See J. Lomas et al., *Do Practice Guidelines Guide Practice? The Effect of a Consensus Statement on the Practice of Physicians*, 321 NEW ENG. J. MED 1306 (1989); see also P.S. Appelbaum, *Practice Guidelines in Psychiatry and their Implications for Malpractice*, 43 HOSPITAL COMMUNITY PSYCHIATRY 341 (1992).

<sup>56</sup> Ironically, many physicians also view guidelines as a way to advance technology and patient care, but only when quality of care is foremost in the development of the guideline, not cost-effectiveness.

lines are developed and disseminated; 2) the comprehensive inclusion of all steps needed to be taken in a given procedure or treatment; 3) the incorporation of all factors that should be considered before the procedure is recommended; and 4) ease of comprehension and application.<sup>57</sup> Other physician research studies identified additional desirable characteristics, including wide dissemination, specificity, validity, clarity, clinical flexibility and applicability.<sup>58</sup> The Institute of Medicine suggests that guidelines should be developed by a multi-disciplinary process that includes participation by representatives of key affected groups.<sup>59</sup>

It has become clear that clinical practice guidelines are not a passing fancy. Medical specialty societies, like the American Cancer Society, the American College of Physicians and the Institute of Medicine, have all taken a leading role in developing guidelines.<sup>60</sup> In addition, the Joint Commission on the Accreditation of Health Care Organizations ("JCAHO") has asked medical specialty societies to make guideline development a priority.<sup>61</sup> Previously, organizations could establish proof of compliance with guidelines by proving that the minimum policies and procedures had been followed.<sup>62</sup> Now, the JCAHO requires that organizations complying with guidelines prove that their policies and procedures produce quality results.<sup>63</sup> One rationale for this stricter standard results from the changing and evolving use of CPGs over time. Initially, guidelines were viewed as one of the few tools that could be used "to control the volume and intensity of services offered to patients without sacrificing quality."<sup>64</sup> As the use and devel-

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<sup>57</sup> Louise Kaegi, *Foreward*, 18 QUAL. REV. BULL. 392 (1992).

<sup>58</sup> MEDICAL OUTCOMES, *supra* note 4, at 415-16.

<sup>59</sup> NATIONAL ACAD. PRESS, INSTITUTE OF MEDICINE: CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM (1990). See also A Survey of Leading Health Care Executives Conducted by The Boston Consulting Group, *An Industry Perspective on Health Care Reform: Goals, Elements and Implications*, at 58 (1993) (finding that defining what should be measured and how accurate metrics can be collected are critical issues needing resolution. "Some type of federal board to set standards combined with a method of localization appears to be a popular approach.") For a full discussion, see *supra* Part IV. See also Leape, *supra* note 11, at 42.

<sup>60</sup> *Medical Malpractice Guidelines*, WESTERN J. OF MED, July 1994, at 39.

<sup>61</sup> *Id.*

<sup>62</sup> Brown & Procopio, *supra* note 35, at 1021-22.

<sup>63</sup> Brown & Procopio, *supra* note 35, at 1021-22.

<sup>64</sup> *Medical Practice Guidelines*, WESTERN J. OF MED., July 1994, at 39. Of



opment of these guidelines has grown and many more organizations are involved in their proliferation, there are growing concerns that the goal of cost-effective treatment could or may be overshadowing the development of quality care guidelines.

Since there is no governmental regulation of the development, issuance and usage of practice guidelines, many physicians' groups, managed care companies and other organizations have become involved. Such groups had little to fear in the way of liability because there has not been a lawsuit alleging negligence (or any other legal theory) in guideline development. As a consequence of the many groups and individuals involved in promulgating guidelines, there are also many methods being used. For example, the federal legislation which created the Agency for Health Care Policy and Research expressly granted to the body the power to appoint panels of physician experts and consumer representatives to carefully direct the development of CPGs. Such guidelines are to be based "to the fullest extent possible, on the findings of treatment outcomes and effectiveness research."<sup>65</sup> Alternatively, there are many locally developed guidelines that are being advanced by institutional providers, like local hospitals and other health systems. Additionally, there are individual physicians and health care executives who are involved in development. As one can imagine, the methods used by such varied individuals and entities can vary drastically, causing inconsistency and ineffectiveness.<sup>66</sup> As will be discussed in Part IV,

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course, this view that guidelines do not sacrifice quality for cost-effectiveness is being continually challenged and is a central concern when health maintenance organizations and managed care systems are the bodies developing the guidelines.

<sup>65</sup> 42 U.S.C.A. § 299(b) (1994).

<sup>66</sup> Kadzielski, *supra* note 8, at 161. Kadzielski argues that:

[T]he issue which is central to the whole debate of whether guidelines have any utility in the courtroom [as a sword for plaintiffs or as a shield for physicians] is that there exists good guidelines which are valid and have potential use, as well as bad guidelines which may be equated with 'junk science.' It is important to realize that what we are dealing with in respect to these varying quality of guidelines is like making a comparison between apples and oranges. It is necessary to differentiate between the two to determine whether guidelines have any role at all in clinical practice *and* in courts of law.

Kadzielski, *supra* note 8, at 161 (emphasis added).

this potential result is a strong incentive to add some type of regulation or certification into the mixture of development and usage.

Clinical practice guidelines will only become more entrenched in the United States health care system as the federal government tries to provide all residents with medical coverage.<sup>67</sup> Health care outcomes reporting and practice guideline development were included as important elements of federal health reform proposals. In 1993, President Clinton proposed, in the Health Security Act,<sup>68</sup> the creation of a National Quality Management Council to establish national measures of quality performance. In the Health Care Reform Bill, passed by Congress in 1996, there are numerous references to the importance of the development and use of CPGs as one of the most effective ways to contain costs and increase quality simultaneously.<sup>69</sup> Prior to passage of this bill, it was unclear how much of a role, or what kind of a role, practice guidelines would play in federal health care reform measures. Clearly, the federal government finds the use of practice guidelines critical to the goal of providing cost-effective, quality health care.

## II. THE BASES OF DEVELOPERS' AND ISSUERS' LIABILITY

Because clinical practice guidelines are a relatively recent phenomenon, there is little case or statutory law regarding their legal implications. There has, however, been much scholarly work concerning the potential legal issues surrounding such guidelines.<sup>70</sup> One outstanding issue is the potential for liability of the guideline developers and issuers. To date, there

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<sup>67</sup> State governments have not been as active as the federal government in developing guidelines, although a number of guidelines have been developed at the state level. The future of state-developed guidelines will depend on the degree of health care reform at the state rather than federal level. See *Medical Malpractice Guidelines*, WESTERN J. MED., July 1994 at 39.

<sup>68</sup> H.R. 3600, 103rd Cong., § 1757 (1993).

<sup>69</sup> This law became the Health Insurance Portability and Accountability Act of 1996 ("HIPPA"), Pub. L. No. 104-191, 110 Stat. 1936 (codified in scattered sections of 42 U.S.C.)

<sup>70</sup> See generally Rosoff, *supra* note 10, at 369; see also Butler, *supra* note 32, at 843. Much of the scholarly work in this area has focused on the effect of guidelines on medical malpractice and decisionmaking.

have not been any reported cases which focus solely on the issue of guideline development liability, despite the magnitude of guideline use by physicians, health maintenance organizations, and hospitals.<sup>71</sup> Most scholarly work on guideline liability has focused on the situation in which proof of a physician's compliance with the appropriate guideline may shield the physician from malpractice liability.<sup>72</sup>

Since the number of organizations and individuals developing guidelines has tripled since 1990,<sup>73</sup> and the number of actual guidelines has doubled,<sup>74</sup> there is a growing concern that guidelines are being developed under less than adequate empirical conditions.<sup>75</sup> Additionally, even though the federal government has assigned to the AHCPR direct responsibility for sponsoring the development of certain clinical practice guidelines,<sup>76</sup> there are currently no national standards or requirements which must be followed by developers and issuers.

In addressing the potential liability of a guideline developer, the initial inquiry must focus on the relationship between the developer and the plaintiff, since liability will attach only if

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<sup>71</sup> Although there have been no cases which deal directly with the liability of practice guideline developers, there have been several cases, discussed at length in Part III, which address the liability of utilization management review techniques. Utilization management review involves prospective treatment decisions made by managed care companies with the goal of reducing the cost of "unnecessary" medical treatment. See *Wickline v. State of Cal.*, 239 Cal. Rptr. 810 (Cal. Ct. App. 1986); see also *Wilson v. Blue Cross of S. Cal.*, 271 Cal. Rptr. 876 (Cal. Ct. App. 1990).

<sup>72</sup> Maine has been the first state to recognize compliance with clinical practice guidelines as an affirmative defense in medical malpractice cases. One of the most controversial issues detailed in Maine's Medical Liability Demonstration Project is the provision allowing physicians who follow the guidelines to use this compliance as an affirmative defense in a malpractice action. The stated intent of this legislation is to "develop practice standards, consistent with appropriate standards of care, which will avoid malpractice claims and increase the defensibility of malpractice claims." Butler, *supra* note 32, at 856. (citing ME. REV. STAT. ANN. tit. 24, §§ 2971, 2979 (West Supp. 1994)).

Similarly, in Minnesota, if a doctor complies with the practice guideline, it is considered an absolute defense. See *Brown & Procopio, supra* note 35, at 1024. The authors also raise an interesting point when they question the difficulty in having a system in which a physician can use compliance with guidelines as a defense, yet still act outside those guidelines.

<sup>73</sup> See generally Rosoff, *supra* note 10.

<sup>74</sup> See generally Rosoff, *supra* note 10.

<sup>75</sup> See generally Rosoff, *supra* note 10.

<sup>76</sup> Omnibus Budget Reconciliation Act of 1989, § 6103 (codified at 42 U.S.C. § 299 (1994)).

the developer owed a duty of care to the plaintiff. Clearly, if a plaintiff was harmed by a practice guideline that was developed and disseminated by an HMO, there is no duty problem, because the organization has an absolute duty with respect to its participants, especially if the HMO is "forcing" its physicians to utilize the guideline.<sup>77</sup> If, however, the issuer is the American Medical Association, there may be disagreement as to whether that type of organization had a duty with respect to a harmed individual. Certainly, the AMA could not possibly owe a duty to every individual in the country.

Aside from the duty problem associated with suing an organization such as the AMA, it and other similarly situated medical associations, unlike managed care organizations, are unlikely to face liability for developing practice guidelines for an additional reason. Medical associations stress that practice guidelines are parameters; they are not rigid, mandatory standards which must be followed in all situations.<sup>78</sup> The AMA urges all physicians to use their professional judgment in each and every treatment decision, utilizing a practice guideline only if it is found suitable for the situation.<sup>79</sup>

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<sup>77</sup> HMOs may "force" physicians to abide by a certain practice guideline through the use of financial incentives and disincentives. For example, an HMO may provide bonuses to those doctors who abide by the guidelines, while those physicians who do not meet certain compliance rates may see their number of patients decreasing or they may be removed altogether from the HMO's list of preferred providers. See Thomas W. Malone & Deborah H. Thaler, *Managed Health Care: A Plaintiff's Perspective*, 32 TORT & INS. L. J. 123, 128 (Fall 1996) (describing the use of financial incentives and disincentives by managed care companies as a way to maintain costs).

<sup>78</sup> See, e.g., *Schachar v. American Academy of Ophthalmology*, 870 F.2d 397 (7th Cir. 1989). This case involved a statement made by the Academy of Ophthalmology, suggesting that radial keratotomy was experimental and should be used only with caution. The academy was sued by aggrieved ophthalmologists for acting in a concerted fashion and restraining trade. The court concluded that there could be no sense of restraint because the society had in no way threatened to discipline or expel its members who performed radial keratotomy. This case highlights the potential dangers involved when medical organizations coerce their members into adhering to rigid guidelines.

<sup>79</sup> See Edward 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) (stating the position of the AMA: "[o]ut 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.").

In contrast, many HMOs and other managed care organizations often regard CPGs as standards to be adhered to under all reasonable circumstances. The essential difference between the AMA as developer and the managed care company as developer stems from their respective philosophical positions regarding the nature and the goals of CPGs. This underlying difference is clearly demonstrated in their attitudes toward cost-containment. The AMA is primarily concerned with developing guidelines which improve the quality of care; cost considerations are not a central issue in their formulation,<sup>80</sup> as such organizations do not reap financial gain from promulgating guidelines that are developed to contain costs. Alternatively, a managed care company is more likely to view cost-effective treatment as the primary concern when developing guidelines, which may result in the development of less scientifically-based guidelines. Moreover, HMOs and managed care organizations may pressure physicians through financial incentives or disincentives to abide by the guidelines' prescribed treatments.<sup>81</sup>

There are several possible bases for a developer's liability. The first and most obvious basis could be negligence in the analysis of the outcomes measurement data or negligence in translating such data into clinical recommendations.<sup>82</sup> A second basis for liability could be negligence in constructing the specifics of outcomes measurement studies, or using data that the developer knew or should have known was inaccurate or insufficient,<sup>83</sup> or consciously omitting from the study a possible effective treatment. A court may also find liability on behalf of a developer if it can be proven that there was a lack of good faith on the part of the developer.<sup>84</sup>

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<sup>80</sup> Even though the AMA and other similar organizations may not view cost-effectiveness as a primary goal in guideline development, this will not shield them completely from liability, especially if there is proof that the guideline was negligently developed or not adequately maintained. If a plaintiff's attorney could hurdle the question of duty, then the AMA should be held to the same standard of care as any other organization in the development arena.

<sup>81</sup> Practice guidelines cannot possibly benefit managed care companies unless they are adopted into practice by the physicians. It will be interesting to see what devices these companies will employ to increase compliance rates and how their "encouragement" may play out in a court of law.

<sup>82</sup> Rosoff, *supra* note 10, at 362.

<sup>83</sup> Rosoff, *supra* note 10, at 362.

<sup>84</sup> See *Wilson v. Blue Cross of S. Cal.*, 271 Cal. Rptr. 2d 876 (1990) in which

A fourth basis for liability could be the developer's failure to update and maintain its guidelines. With rapid advances in medical technology and treatments, the developer would have a unique obligation to maintain the efficacy of the guidelines. Questions abound as to the frequency of guideline updates and reviews and whether information that a guideline may be near obsolescence must be disseminated by the developer.<sup>85</sup> Additionally, if a developer advertises that its guidelines are on the cutting edge of the industry, this could constitute a contractual claim that binds the developer. The potential for liability may require that the developer not only stay abreast of medical advances and developments, but also actively continue to research the guidelines' outcomes, especially after the guidelines are disseminated and used in a wide range of circumstances.<sup>86</sup> The developer is in the ideal position to collect outcomes research and effectiveness data regarding their guide

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plaintiffs attempted to show that the insurer and utilization management company, which had allegedly authorized the premature discharge of a psychiatric patient who committed suicide, had breached the legal obligation for a good faith investigation of claims. For a fuller discussion, see *infra* Part III.

There will likely be many issues regarding good faith liability due to the increasing number of managed care and health maintenance organizations that are involved in guideline development. One can imagine scenarios in which managed care companies may consciously omit research on certain types of expensive, experimental treatments because of the fear that these expensive treatments may be found to be extremely effective, thereby requiring the company to cover these procedures. This type of liability goes beyond negligence because it would involve the maligned intent of the company. Pharmaceutical companies are another type of organization conducting outcomes research. These companies also have great incentives to "prove" that their product is the best one on the market for "X" disease. These types of conflicting interests cause concern and doubt as to the true effectiveness of certain practice guidelines. See *infra* Part III.

An interesting and related issue which has not been addressed by the court system, and is beyond the scope of this Note, involves what type of obligation the developers owe to the public to study and research certain types of highly experimental treatments that are very costly yet very effective.

<sup>85</sup> In *Washington v. Washington Hosp. Ctr.*, 579 A.3d 177 (D.C. 1990), the court required that providers adopt new devices to keep pace with the rapidly advancing state of technology. In *Burton v. Brooklyn Doctors Hosp.*, 88 A.D.2d 217, 452 N.Y.S.2d 875 (1982) the court held a hospital and its physicians liable for not following new treatment studies that contravened conventional wisdom.

<sup>86</sup> See Rosoff, *supra* note 10, at 392 (speculating that those groups or individuals with special access to critical information may well have a corresponding obligation to make effective use of that information).

lines. It is precisely this type of information that helps to create reliable and valid practice guidelines which can be utilized on a widespread basis.<sup>87</sup>

### III. LIABILITY OF HEALTH MAINTENANCE ORGANIZATIONS AND MANAGED CARE COMPANIES AS DEVELOPERS AND ISSUERS OF CLINICAL PRACTICE GUIDELINES

Although the development of clinical practice guidelines may originally have been spurred by a desire to more effectively treat illnesses and consequently improve the quality of health care,<sup>88</sup> their concurrent effect of maintaining and cutting costs did not go unnoticed. Because the use of CPGs results in cost-effective medical care by eliminating unnecessary care, the guidelines are finding their greatest use in managed care settings, including health maintenance organizations and

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<sup>87</sup> Guideline developers owe a duty to the public to maintain their guidelines and continue to research their outcomes. For practice guidelines to have a positive effect on quality treatment, rather than simply cost-effective treatment, physicians must find them credible and reliable. It is essential that developers do their part to ensure that if a guideline is widely adopted and becomes a statement of customary practice, that the developer is reaping critical information from the outcomes of these physicians' data. See *infra* Part IV.

<sup>88</sup> This statement is still being debated. Some health care experts contend that quality care was always the driving force behind the guidelines, while other experts argue that cost-containment played an equally significant if not more significant role in guideline development. For example, the Agency for Health Care Policy and Research, the federal organization responsible for developing certain national guidelines, makes no mention of cost-effectiveness or cost-containment as a goal or an issue with respect to the development of guidelines.

See also Troyen A. Brennan, *Practice Guidelines and Malpractice Litigation: Collision or Cohesion?*, 16 JOURNAL OF HEALTH POL., POL'Y & L. 67, 70 (1991). Brennan differentiates between "appropriateness" guidelines and "standard-of-care" guidelines. "Appropriateness" guidelines are intended to reduce care that is unnecessary or inefficient in cost; cost-effectiveness is usually the driving force behind development of these types of guidelines. "Standard-of-care" guidelines emphasize outcomes, not cost-efficiency. These guidelines define the standard of practice, "presumably as a result of implicit or explicit assessment of outcomes," and are not motivated by cost-efficiency. *Id.* at 70. Finally, there are experts who contend that it was a combination of several factors, including the rising costs of health care, the perception that much of the cost was due to inappropriate clinical practices, and the belief that guidelines might help physicians reduce practice variation and enhance the quality of patient care, that led to the escalation in guideline development. Woolf, *supra* note 5, at 1456 (citing Annual Report to Congress: Physician Payment Review Commission, Washington, D.C. 1989 at 219); see also Brennan, *supra*, at 67.

other managed care organizations ("MCOs").<sup>89</sup> Because such organizations have a considerable stake in containing costs, profit-motivated decisionmaking is likely to increase both the risks and liabilities associated with the delivery of health care.<sup>90</sup>

*A. Extending Liability to HMOs: Consumers Suing HMOs for Faulty Development of CPGs.*<sup>91</sup>

The term "managed care" generally refers to "a system that, in varying degrees, integrates the financing and delivery of health care through contracts with selected physicians and hospitals that provide comprehensive health care services to enrolled members for a predetermined . . . premium."<sup>92</sup> Managed care organizations are all similar in at least one respect: they involve an attempt to control costs by modifying the manner in which patients utilize the health care system.<sup>93</sup> The term "managed care" encompasses several different types of

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<sup>89</sup> Three-quarters of all health maintenance organizations have practice guidelines in place, more than 70% conduct outcomes research of common clinical conditions and almost all have utilization review protocols in place. Marsha R. Gold et al., *A National Survey of the Arrangements Managed Care Plans Make With Physicians*, 333 NEW ENG. J. MED. 1678, 1680-1 (1995); see also Phil Douglas, *Medicine's Brave New World*, PHYS. PRAC. DIG., Fall 1995 at 12 (indicating that some reports estimate that 65% of insured people in the United States receive medical care through managed care arrangements).

<sup>90</sup> See Robert J. Conrad, Jr. & Patrick D. Seiter, *Health Plan Liability in the Age of Managed Care*, 62 DEFENSE COUNS. J. 191 (1995) (warning that because cost-containment mechanisms may directly affect the medical care received by health plan patients, they increase the liability potential for the plan providers, administrators, insurers and sponsors).

<sup>91</sup> This section is specifically separated from Part II, which discusses theories of liability in general. Because plaintiffs historically have had a difficult time successfully suing managed care companies for treatment decisions, a fuller discussion is required as to the theories of liability that may successfully get plaintiffs past some of the barriers inherent in suing insurers. It is only after addressing this that the discussion in Part II will be relevant, because there are enormous differences in potential liability depending on who is developing the guideline.

<sup>92</sup> Malone & Thaler, *supra* note 77, at 125 (quoting John K. Inglehart, *Health Policy Report: Physicians and the Growth of Managed Care*, 331 NEW ENG. J. MED. 1167 (1994)).

<sup>93</sup> Malone & Thaler, *supra* note 77, at 126.



health care organizations, including health maintenance organizations,<sup>94</sup> preferred provider organizations ("PPOs")<sup>95</sup> and point of service plans.<sup>96</sup>

The active involvement of HMOs and other managed care companies in the development of CPGs has interesting and uncertain complications for both the companies and the physicians who work for them.<sup>97</sup> Historically, managed care companies were able to avoid liability when their physicians were sued for medical malpractice, under the "corporate practice of medicine" doctrine.<sup>98</sup> This doctrine forbids a licensed physician from accepting instructions in diagnosing or treating illnesses from a corporation or an individual who is not licensed to practice medicine.<sup>99</sup> The purpose of the doctrine was to fos-

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<sup>94</sup> In a health maintenance organization physicians are under contract to provide medical care at a lower price than their customary fee. There are three major HMO models which need to be defined in order to fully understand the types of liability that attach to each: 1) under a staff model HMO, the HMO employs staff physicians directly and compensates them as salaried employees, placing them in a traditional employer-employee type relationship. Usually, staff model physicians work together in a centralized facility owned or leased by the HMO; 2) under a group model, the HMO contracts with a group of physicians rather than with the physicians individually. The HMOs' claim that the physicians are independent contractors, not employees. Physicians receive payment on the capitation system, meaning a fixed monthly fee per member, regardless of the amount of service actually rendered; 3) under the independent practice association model (IPA), the most common form of managed care organization, the HMO contracts with an independent practice association. The association then contracts directly with each independent physician with regard to terms and conditions of employment and method of payment. Generally, IPAs do not work exclusively or even primarily for the HMO. Malone & Thaler, *supra* note 77, at 128.

<sup>95</sup> A PPO is an organized group of providers offering services at a discount. PPOs compete with HMOs in that both are organized to provide discounted medical services. The PPO often resembles a traditional direct payment insurance plan in that the subscriber pays the PPO directly and the PPO then reimburses the doctors and the hospital. PPO members can choose their own physician whether or not they are a part of the plan. Although PPOs discourage patients from going outside of the plan, they differ from an HMO in that fee-for-service physicians do not have financial incentives to voluntarily minimize patient hospitalization stays.

<sup>96</sup> A point of service plan is a hybrid of an HMO and a PPO.

<sup>97</sup> For a complete discussion of managed care companies and emerging theories of liability, see Richard A. Hinden & Douglas L. Elden, *Liability Issues for Managed Care Entities*, 14 SETON HALL LEGIS. J. 1 (1990).

<sup>98</sup> See Butler, *supra* note 32, at 863; see also Reuben, *supra* note 1, at 55.

<sup>99</sup> Reuben, *supra* note 1, at 56. The "corporate practice of medicine doctrine" essentially barred "direct malpractice lawsuits against most types of HMOs and managed-care entities on the theory that they are not corporations formed to practice medicine; rather they are formed like insurance companies just to pay for the treatments." *Id.*

ter physician autonomy by preventing physicians who were working for corporations from being controlled by those corporations. Practically, the doctrine has worked to shield managed-care entities from liability on the theory that "they are not corporations formed to practice medicine; rather, they are formed like insurance companies just to pay for the treatments."<sup>100</sup>

However, with managed care organizations in the business of developing guidelines, they are somewhat curiously in the business of practicing medicine. Therefore, it seems unlikely that in the future a managed care company will be able to rely solely on this doctrine as a shield from liability. It will be difficult for a company to convince a court that it was not in the business of practicing medicine, especially when "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."<sup>101</sup> The public is likely to be sympathetic to physicians and the precarious position in which they are placed by managed care companies. Physicians face tremendous pressures to adhere to their managed care companies' myriad regulations. Previously, many such regulations were not viewed as directly affecting patient health. Today, however, managed care organizations' involvement with developing and mandating compliance with practice guidelines is one example of techniques available in the health care industry to strong-arm physicians and patients.

Physicians reluctantly recognize that failure to abide by promulgated practice guidelines set forth by their managed care company could result in harsh consequences. For example, physicians who exercise independent clinical judgment and determine that a certain guideline is not applicable to their patient's situation risk not being reimbursed by the health care company for that procedure. The doctor is then faced with mounting out-of-pocket expenses as a result of his or her decision to deviate from the guideline. Many physicians may also face termination from the health care company if it is found that they have not been abiding by prescribed guidelines. Man-

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<sup>100</sup> Reuben, *supra* note 1, at 56. (stating that this doctrine is often an early battleground in litigation).

<sup>101</sup> Rosoff, *supra* note 10, at 373.

aged care companies exert this type of control over physicians by conducting regular inquiries into the physician's history of treatment, keeping careful watch on a physician's utilization of treatments. Similarly, physicians not working directly for a particular managed care organization may face elimination from the rosters of health care providers so that new patients will not be given their name as a prospective provider. When faced with these consequences, it is not hard to see how physicians can be influenced to treat patients precisely the way the managed care company dictates.<sup>102</sup> It seems that the more that HMOs and other managed care companies exercise control over their participating physicians, the more their exposure to liability for the torts of the doctors will continue to increase.<sup>103</sup>

Because plaintiffs' attorneys have in the past had a difficult time getting past the "corporate practice of medicine" threshold defense in medical malpractice suits against specific third party payers and hospitals, they may rely on several additional theories: vicarious liability, simple and corporate negligence, and contractual liability.<sup>104</sup> These theories may also prove to be viable in the inevitable lawsuits which will arise from faulty development or maintenance of clinical practice guidelines.

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<sup>102</sup> In an effort to protect consumers against these types of problems, some state legislation is proposing that managed care organizations disclose the following information: any financial incentives offered to physicians who are frugal in providing services, information about grievance procedures, utilization review quality assurance programs and ownership interests. This information is taking the label of "report card," and is being used to educate individual consumers about the various plans. See Marc A. Rodwin, *Managed Care and Consumer Protection: What Are The Issues?*, 26 SETON HALL L. REV. 1007, 1017 (1996). But see Jason Ross Penzer, *Grading The Report Card: Lessons From Cognitive Psychology, Marketing, and the Law of Information Disclosure For Quality Assessment in Health Care Reform*, 12 YALE J. ON REG. 207 (1995) (discussing "the drawbacks of relying on health care report cards as a quality assurance system" and concluding that "report cards cannot currently assure quality, given limitations in the state of the art of quality measurement and an inadequate understanding of how consumers would process disclosed information." *Id.*

<sup>103</sup> See Reuben, *supra* note 1, at 56 (quoting Domenick C. DiCicco Jr., a litigator handling matters for insurance companies, who calls the liability issue "a disaster waiting to happen.")

<sup>104</sup> See David D. Griner, *Paying the Piper: Third-Party Payor Liability For Medical Treatment Decisions*, 25 GA. L. REV. 861 (1990); see also Reuben, *supra* note 1, at 56.

## 1. Vicarious Liability

Traditionally, a hospital would not be held vicariously liable for negligent acts of its medical staff which occurred during treatment of patients. This is because a hospital, as an institution, could not be licensed to practice medicine. Under this theory, physicians were considered to be independent contractors over which the hospitals exerted no control.<sup>105</sup> However, over the past three decades, courts have gradually eroded this rule by recognizing the applicability of respondeat superior to salaried physicians.<sup>106</sup> Although courts today appear increasingly likely to find hospitals responsible for controlling the actions of their physicians, it remains to be decided whether courts will extend the notion of respondeat superior to the relationship between physicians and third party payers, such as HMOs and MCOs.<sup>107</sup>

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<sup>105</sup> Griner, *supra* note 104, at 892.

<sup>106</sup> See *Bing v. Thunig*, 2 N.Y.2d 656, 143 N.E.2d 3, 163 N.Y.S.2d 3 (1957). Under the doctrine of respondeat superior, an employer is liable for the negligent acts of an employee committed within the scope of employment. See RESTATEMENT (SECOND) OF AGENCY § 219 (1958); see also Griner, *supra* note 104, at 891-92. (under the doctrine of respondeat superior, hospitals have always been liable for the negligence of their employees; however, medical staff in the performance of medical acts were not traditionally considered employees of the hospitals).

<sup>107</sup> See Griner, *supra* note 104, at 892. In 1990, when Griner wrote this article, clinical pathway guideline development was in its infancy. This author speculated, without addressing the issue of clinical pathway guidelines, that the doctrine of respondeat superior would certainly be applicable to direct-service plans, such as a staff model HMO where the physician is an actual employee of the health organization. However, he found it increasingly more problematic to extend the doctrine to other model HMO situations or other private insurance situations in which the third party payer does not limit subscriber access to providers and the providers are usually independent contractors rather than actual employees. In 1990, the percentage of people subscribing to a staff model HMO where the patient must choose the provider from the third party payer's list of accepted physicians, was much lower than it is today.

Additionally, the Restatement of Agency § 8 and § 159 recognize an exception to respondeat superior. RESTATEMENT (SECOND) OF AGENCY, §§ 8, 159 (1958). This exception, often referred to as apparent authority or ostensible agency, can also be applied to a third party payer in limited circumstances. Under this theory, a third party payer could be responsible for the negligence of an independent physician if the third party payer represented to the patient, or gave the appearance that the physician was an employee. Again, David Griner finds this application of apparent authority limited to third party payers that offer a closed panel of providers, "like some HMOs" which can give the appearance that an agency relationship exists by virtue of their control over the medical care delivery system. Griner, *supra* note 104, at 894. Again, however, when this article was written, the conventional insur-

The determination of whether a physician is actually an independent contractor will be crucial in extending liability to a corporate managed care organization.<sup>108</sup> For example, if the physician is a member of a staff model HMO, courts appear more likely to find the HMO answerable for the decision to utilize one practice guideline over another because the physician is viewed as a direct employee of the HMO. Because a staff model HMO physician has significantly less autonomy than would an independent physician, is paid directly by the HMO, and most often conducts his/her business in an HMO-owned facility, courts are more likely to find liability attaching to the HMO under the theories of vicarious liability or ostensible/apparent agency.<sup>109</sup>

A staff model physician depends solely on the HMO for his or her livelihood, making its control over the physician's decisions almost complete. If, however, the treating physician is an independent practitioner who treats only a few HMO patients and whose bulk of patients stems from private insurance, courts appear more likely to hold the treating physician solely responsible because of the lesser level of control over the independent practitioner's decisions.<sup>110</sup> This type of physician would not be considered an employee of the HMO because he is not paid directly by the HMO, nor is he working from an HMO-owned or leased facility, making it unlikely the courts would find liability under either vicarious liability or the ostensible/apparent agency theories.<sup>111</sup> In *Allrid v. Emory University*,<sup>112</sup> the court stated that "[t]he true test of whether the relationship is one of employer-employee or employer-independent contractor is whether the employer . . . assumes the right

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ance plan, where patients typically have a free choice of physicians, was much more widely subscribed to than other third party payer situations, like the health maintenance organization. Thus, with the rise in subscription to health maintenance organizations, we may see a substantial increase in this type of liability.

<sup>108</sup> Malone & Thaler, *supra* note 77, at 131.

<sup>109</sup> Malone & Thaler, *supra* note 77, at 131.

<sup>110</sup> Malone & Thaler, *supra* note 77, at 131.

<sup>111</sup> The doctrine of ostensible or apparent agency, an offshoot of vicarious liability, can be used to impose liability when the evidence shows that: 1) the apparent principal represented or held out the apparent agent; and 2) justifiable reliance upon the representation led to the injury. RESTATEMENT (SECOND) OF AGENCY § 267 (1958); RESTATEMENT (SECOND) OF TORTS § 429 (1958).

<sup>112</sup> 285 S.E.2d 521 (Ga. 1982).

to control the time, manner and method of executing the work, as distinguished from the right merely to require certain definite results in conformity to the contract."<sup>113</sup>

Clearly, if a staff model physician is abiding by prescribed HMO practice guidelines, liability for reliance on a faulty guideline should attach to the HMO, because they are clearly the employer in such a relationship and the physician is clearly the employee. While it would be more difficult to attach liability to the HMO if the physician were not a staff member of the organization, an argument could be made that, although the physician is not technically an employee of the organization, the HMO, through its insistence on compliance with guidelines, exerts sufficient control over manner and method of treatment.<sup>114</sup> Although managed care companies may defend on the ground that the physician is an independent contractor, this defense seems weak after showing that the managed care company is in the business of developing and promulgating practice guidelines, thus engaging in treatment decisions.<sup>115</sup>

Another basis of liability which has been used to hold hospitals liable for the acts of their physicians has been apparent or ostensible agency.<sup>116</sup> This doctrine differs from respondeat superior in that liability will only attach if the apparent principal represented or held out the physician as the apparent agent, and there was justifiable reliance upon the representation which led to the injury. This theory may result in increased liability against a managed care company because the

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<sup>113</sup> *Id.* at 525-6.

<sup>114</sup> Some cases have suggested that vicarious liability will attach merely when the employer exerts control over time or salary without control over manner or method. *See Newton County Hosp. v. Nickolson*, 207 S.E.2d 659 (Ga. Ct. App. 1974). This may suggest that control over manner or method may also suffice to find vicarious liability on behalf of the employer.

<sup>115</sup> Thomas W. Malone argues that even though managed care companies may claim as a defense the fact that the physician is an independent contractor, there are other factors which may support a finding of an employer-employee relationship. Malone states that:

These include requirements by HMOs and [other managed care companies] of pre-authorization of elective hospital admissions and other procedures, concurrent review of length of stays, charge fees set by the HMO, and failure to abide by the managed care organization's regulations as cause for the corporation to remove the physician from its provider list.

Malone & Thaler, *supra* note 77, at 133.

<sup>116</sup> *See supra* note 111 and accompanying text.

physician is not required to be an employee of the company. Conceivably, a managed care company could be liable for the actions of an independent contractor physician if the patient justifiably relied on the skill of the physician in the belief that the physician was an employee of the managed care company.<sup>117</sup>

In determining whether apparent agency exists, courts engage in an extensive, fact-intensive inquiry into whether the HMO or other managed care company held the physician out to be the agent of the HMO. In *Boyd v. Albert Einstein Medical Center*,<sup>118</sup> the plaintiff alleged negligent oversight and failure to furnish adequate care on behalf of the HMO. The court found the HMO liable under the apparent agency theory, highlighting that: 1) the patient's fees were paid directly to the HMO, not the individual doctor; 2) subscribers were required to choose their primary care physicians from a limited list; 3) the physician list was screened by the HMO and physicians were required to follow HMO rules and regulations; and 4) the promotional materials distributed by the HMO stated that the HMO would provide health care services and benefits to its members in order "to protect and promote their health."<sup>119</sup> Liability under this theory would almost certainly attach to staff model and group model HMOs.

Interestingly, liability may also attach to physicians who are not employed by the managed care organization. For example, in *Dunn v. Praiss*,<sup>120</sup> the court found that an agency relationship existed where the HMO exercised considerable control over the independent physicians by controlling the patients they see and by paying on a per capita basis.<sup>121</sup> When HMOs force physicians to abide by their practice guidelines, courts should find that this is tantamount to exerting considerable, legally-significant control over independent physicians. By threatening HMOs with this type of liability, we may see a fundamental change in the way HMOs and other managed

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<sup>117</sup> The apparent/ostensible agency theory relies on appearances. The actual contractual arrangements between the managed care company and the provider may prove irrelevant. See Malone & Thaler, *supra* note 77, at 135.

<sup>118</sup> 547 A.2d 1229 (Pa. Super. Ct. 1988).

<sup>119</sup> See Malone & Thaler, *supra* note 77, at 135.

<sup>120</sup> 606 A.2d 1053 (N.J. Super. Ct. App. Div. 1992).

<sup>121</sup> See Malone & Thaler, *supra* note 77, at 136-7.

care companies engage in medical decisionmaking. HMOs may find it too costly to play the liability game with respect to practice guidelines, with the result that physicians may begin to enjoy some essential autonomy in clinical decisionmaking.

## 2. Corporate Negligence

The theory of corporate negligence has been relied upon in medical malpractice suits against third party payers.<sup>122</sup> This doctrine espouses that HMOs owe a duty to patients to exercise reasonable care to ensure the competence of physicians and staff they hire.<sup>123</sup> More generally, this theory focuses on the overall independent duty of the organization to protect the patient from harm. Thus, a plaintiff's attorney could potentially show that the HMO or other third party payer involved in guideline development was legally negligent in construction of the guideline which the physician followed. Presumably, this would be a costly and fact-intensive approach as it would essentially involve a thorough review of all the evidence, medical research, and criteria used to create the guideline. It would also involve an analysis as to whether the physician should have blindly followed the purported guideline or should have independently engaged in the above-mentioned inquiry.

## 3. Third Party Payer Negligence

A plaintiff's attorney could also rely on a simple negligence theory to prove that the HMO or other third party payer was negligent in guideline construction or negligent in relying on or issuing to their staff physicians practice guidelines promulgated by other sources which were inadequate, incorrect or unreliable. It is conceivable that managed care companies could choose to adopt guidelines from outside sources and advocate their use among its own plan physicians. If, however, the company did not adequately consider or assess the reliabil-

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<sup>122</sup> Griner, *supra* note 104, at 895 (noting that most courts have refused to follow this theory).

<sup>123</sup> The corporate negligence theory has been applied to hospitals since the mid-1960s. It was extended to HMOs in the late 1980s. See Harrell v. Total Health Care, Inc., 781 S.W.2d 58 (Mo. 1989); see also Reuben, *supra* note 1, at 57.



ity and accuracy of the guidelines prior to their complete adoption and required usage, the company could be faced with liability.

Similarly, there have been some cases dealing with third party payer liability for medically inappropriate decisions made through the implementation of cost-controlling decisionmaking. Utilization management review,<sup>124</sup> a cost-controlling mechanism which may be considered a precursor to CPGs, was featured in *Wickline v. State of California*,<sup>125</sup> the first major case to deal directly with the liability of third party payers for improper use of cost-containment procedures. In *Wickline*, the plaintiff, a hospital patient, sued the state alleging a negligent recommendation derived from utilization review by California's medical assistance program ("Medi-Cal"). The plaintiff was hospitalized with leg and back pain that required surgery. After the plaintiff experienced some postsurgical complications, her physicians requested that Medi-Cal authorize an additional eight days of hospitalization.<sup>126</sup> The Medi-Cal reviewers refused to approve the request for an eight-day extension, but did authorize a four-day extension.

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<sup>124</sup> Generally, utilization review refers to "external evaluations that are based on established clinical criteria and are conducted by third party payers, purchasers, or health care organizers to evaluate the appropriateness of an episode, or series of episodes, of medical care." John D. Blum, *An Analysis of Legal Liability in Health Care Utilization Review and Case Management*, 26 HOUS. L. REV. 191, 192-3 (citing CONOR, ET AL., DYNAMICS OF UTILIZATION MANAGEMENT, AMERICAN HOSPITAL ASSOCIATION (1983)).

<sup>125</sup> 239 Cal. Rptr. 810 (Cal. Ct. App. 1986). Utilization review is widely used in both public and private sectors as a cost-containment strategy with its principle focus to prevent overutilization and maximize revenues by increasing the amount of service provided and to insure that patients were not unnecessarily exposed to risks as a result of unnecessary surgery and/or hospitalization.

A crucial question regarding utilization management is how much variation among reviewer clinical judgments should be allowed for the same situation, and what considerations this variation should be based upon. The parallels to practice guideline proliferation is obvious. It may be helpful to think of utilization review as the precursor to CPGs—as a basis for the more fine-tuned development of clinical practice guideline development. Utilization review and practice guideline use differ in that utilization review decisions are made by consultants/employees of the third party payer, and they are often not physicians. With clinical guidelines, it is the physicians themselves who are following the guideline, the only middleman being the guideline itself.

<sup>126</sup> *Wickline*, 239 Cal. Rptr. at 817.

The plaintiff was released and consequently suffered severe clotting and infection, which resulted in the eventual amputation of her leg.<sup>127</sup>

At trial, the jury found that Medi-Cal had been negligent and awarded plaintiff \$500,000. On appeal, the decision was reversed.<sup>128</sup> Although the appeals court held that Medi-Cal was not responsible for the patient injury resulting from the utilization review decision because the decision to release the plaintiff was not a negligent one and was in accord with the then existing statutory law,<sup>129</sup> the court issued a strong statement regarding future claims of this type:

[T]he patient who requires treatment and who is harmed when care which should have been provided is not provided should recover for the injuries suffered from all those responsible for the deprivation of such care, including, when appropriate, health care payers. *Third party payors of health care services can be held legally accountable when medically inappropriate decisions result from defects in the design or implementation of cost containment mechanisms as, for example when appeals made on a patient's behalf for medical or hospital care are arbitrarily ignored or overridden.*<sup>130</sup>

With this statement, the court made it clear that although Medi-Cal was not liable in this situation, that court would not hesitate to find liability in the proper circumstances.<sup>131</sup>

Many parallels can be drawn between the utilization management review processes in *Wickline* and the process of making treatment decisions based on a practice guideline set forth by a managed care company. Both can be viewed as primarily cost-containing mechanisms which enjoy widespread use in health care. They also share the common denominator that the

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<sup>127</sup> *Id.*

<sup>128</sup> Griner, *supra* note 104, at 887 (discussing the jury decision in *Wickline*).

<sup>129</sup> See Griner, *supra* note 104, at 887.

<sup>130</sup> *Wickline*, 239 Cal. Rptr. at 819 (emphasis added).

<sup>131</sup> Notwithstanding the court's dicta, the *Wickline* decision sent a clear message to practitioners and providers that anyone involved in or affected by utilization management decisions should diligently seek appeal of these determinations or face sole liability.

A significant barrier to an action of this type is presented by the Employee Retirement Income Security Act (ERISA), 29 U.S.C. §§ 1001-1361 (1982 & Supp. IV 1986), which severely limits the availability of state tort actions in the context of health benefits plans falling under the statute. This Note does not address the implications of ERISA, but a careful analysis of this statute must be completed as to any potential action to determine whether it may be preempted.

treating physician is often not the individual making the utilization review decision nor deciding on which guideline to follow.

Interestingly, third party payers' insistence that physicians abide by their developed guidelines offers a much stronger basis for liability than an insurer's utilization review decision. This is so because in the past, utilization review decisions have been viewed primarily as "benefits" decisions, rather than "medical decisions."<sup>132</sup> The distinction between benefits decisions and medical decisions is crucial to overcoming the corporate practice of medicine barrier faced by many plaintiffs' lawyers. If a utilization review company can persuade a court that they were engaging in a type of benefits decision and not an actual medical decision, the company is more likely to avoid liability on the basis that it is not licensed to practice medicine; therefore, it cannot be seen to make medical decisions. Alternatively, a managed care company engaging in the design and implementation of clinical practice guidelines is clearly "practicing medicine," and should certainly be held accountable if it is determined that the company pressured its physicians into adhering to their guidelines.<sup>133</sup>

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<sup>132</sup> In *Wickline*, the court held it was the treating physician's direct responsibility to decide the course of treatment medically necessary to treat the plaintiff's ailment. 239 Cal. Rptr. at 819. The court distinguished between decisions made by Medi-Cal and decisions made by the treating physician by stating that Medi-Cal was not viewed as a party to the medical decision which released plaintiff from the hospital. The court stated that:

while Medi-Cal played a part in the scenario before us in that it was the resource for the funds to pay for the treatment sought, and its input regarding the nature and length of hospital care to be provided was of paramount importance, Medi-Cal did not override the medical judgment of Wickline's treating physicians at the time of her discharge.

*Id.* See also Blum, *supra* note 124, at 199 (stating that the heart of *Wickline* is its holding that the Medi-Cal program cannot be held liable for negligently discharging a patient because that decision is a medical one and falls outside the purview of third party utilization management).

Arguably, the landscape is changing with respect to how much independent clinical judgment by physicians will be accepted by managed care companies. Courts are likely to recognize the pressures placed on physicians, realizing that physicians are often not "free" to act on their own judgment. Hence, a court may be more likely to find liability on behalf of the managed care companies.

<sup>133</sup> The individual physician, however, may also risk liability if he or she relies on faulty guidelines. Physicians, along with managed care companies, will be vulnerable to malpractice actions and should expect to be held legally accountable if their actions are not in the best interests of patients.

In a follow-up case to *Wickliffe*, *Wilson v. Blue Cross of Southern California*,<sup>134</sup> the plaintiffs attempted to show that the insurer and the utilization review company had breached the legal obligation of a good faith investigation of claims. In *Wilson*, a utilization review decision allegedly authorized premature release of a psychiatric patient. After release based on the utilization review recommendation, the patient committed suicide. Despite the defendants' argument that *Wickliffe* had established that liability rested ultimately with the treating physician, who had acted in response to the utilization review recommendation, the court found substantial evidence that the utilization review decision not to authorize continued hospitalization was a critical factor in the patient's death.<sup>135</sup> Ultimately, a jury found that the utilization review company had breached three of the four elements of bad faith, but not the fourth; thus, no liability was found against the defendants. Nevertheless, *Wilson* supports the proposition that insurers, utilization management companies, HMOs and other managed care companies can be held liable for the consequences of their decisions.<sup>136</sup>

#### 4. Contractual Liability

Managed care organizations and other third party insurers involved in developing practice guidelines may also be liable under the contractual theory that the organization breached its covenant of good faith. Most legal decisions that have addressed this type of liability are based upon the reckless denial of coverage.<sup>137</sup> However, an argument can be made that when managed care companies contract with patients and then require physicians to abide by medical treatment decisions that they have decided upon, the company has a continuing responsibility to its participants to conduct good faith investigations into the adequacy and reliability of the practice guidelines being used. The breach of good faith inquiry would focus on the efforts of the organization to assure the reliability and validity

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<sup>134</sup> 271 Cal. Rptr. 876 (Cal. Ct. App. 1990).

<sup>135</sup> *Id.* at 883.

<sup>136</sup> See Alice G. Gosfield, *Utilization Management Law and Policy: Emerging Liability Trends*, 9 NO. 11 HEALTHSPAN 3, 5 (Dec. 1992).

<sup>137</sup> See Malone & Thaler, *supra* note 77, at 140.

of their proffered guidelines. This theory may be particularly pertinent to situations involving negligent maintenance of practice guidelines and may be used when it can be proven that managed care companies purposefully and knowingly disregarded essential data or outcomes research that should have been incorporated into the guideline. This egregious behavior would lend itself to claims of breach of good faith where the omitted data was found highly effective but had cost-effective draw-backs for the company.<sup>138</sup>

### *B. Physicians Suing HMOs: Indemnification for Forced Compliance*

A potentially explosive new area of litigation centers around physicians suing HMOs and other MCOs for essentially forcing the physician to discount his or her professional judgment in treating a patient who is a member of the health care organization. The problem with this type of suit is that courts have traditionally viewed the treating physician as primarily responsible for a patient's treatment.<sup>139</sup> However, with the proliferation of practice guidelines, especially within the MCO communities, courts may have to recognize a new defense set forth by physicians facing medical malpractice actions: the "HMO made me do it" defense.<sup>140</sup> This potential defense would rest on the notion that if a treatment decision is not made in good faith and is made primarily to contain costs rather than provide quality treatment, there should be some relief available to the physician.

Currently, though, these physicians are "plaintiffs in search of a theory."<sup>141</sup> Because most provider/third party payer contracts allow either party to terminate the relationship without cause, it is difficult for a physician to prove he/she was

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<sup>138</sup> It is essential to remember that this discussion is only speculative. Very few states have explicitly permitted a suit based on a utilization review decision about medical care and to date, no state has directly addressed the liability for development of practice guidelines.

<sup>139</sup> See *Wickline v. California*, 239 Cal. Rptr. 810 (Cal. Ct. App. 1986). In *Wickline*, the court held that primary responsibility for the patient's treatment decisions rested with the physician, not the HMO. See *supra* notes 126-32 and accompanying text.

<sup>140</sup> See Reuben, *supra* note 1, at 60.

<sup>141</sup> Reuben, *supra* note 1, at 60.

compelled into a treatment decision against better judgment or that they terminated the physician because he/she did not follow mandatory guidelines laid out by the MCO and not for other reasons. One possible theory for terminated physicians is based in contract: the idea that the termination of a physician violates the implied covenant of good faith and fair dealing traditionally read into contracts.<sup>142</sup> This defense has not been recognized in any court of law to date; however, with the number of cases expected to center around MCOs' utilization review decisions and clinical practice guideline development and implementation, one may expect to see this defense recognized.<sup>143</sup>

This is a volatile area of litigation because the relied-upon providers may be placing the public health at risk by being compelled by large managed care companies into certain methods of treatment which may be inadequate, incorrect or with which they may strongly disagree. Additionally, litigation may flourish because there is no ERISA preemption problem, no state limits on punitive damages and no arbitration clauses in physician contracts.<sup>144</sup>

#### IV. A PROPOSAL FOR THE FUTURE

There is an increasing probability of lawsuits being initiated against developers and issuers of clinical pathway guidelines. This is a positive thing, on the one hand, because it should force developers to conduct comprehensive and proper analyses of outcomes research data that will result in highly credible and effective treatment protocols. On the other hand, the potential for liability may have a chilling effect on the development of clinical practice guidelines. This would be a troublesome and detrimental result, because CPGs potentially

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<sup>142</sup> Reuben, *supra* note 1, at 60. (citing to *Harper v. Healthsource N.H.*, 674 A.2d 962 (N.H. 1996) (finding that refusal to reappoint a surgeon to a panel after ten years with the HMO could violate public policy and allowing the surgeon to challenge the decision on the ground that the termination violated the implied covenant of good faith and fair dealing)).

<sup>143</sup> Ironically, the result the physician is trying to avoid, termination of his/her employment, would be expected if such a suit was brought against a managed care company.

<sup>144</sup> See Reuben, *supra* note 1, at 60.

provide sound, scientific underpinnings necessary to reduce uncertainties in health care decisionmaking. Fearing exposure to liability, many organizations are likely to find it too risky to be involved in this type of medical development. The potential decline in guideline development would certainly adversely affect the medical community, as CPGs are a sound way to optimize quality care, eliminate waste and avoid unnecessary procedures. However, because of their potential to contain costs they may be abused by influential organizations, and the developers must be held accountable for ineffective health care due to compulsory applications and faulty, inadequate and unreliable guidelines, which could expose patients to unnecessary risks.

One seemingly effective way to remedy this unfortunate situation is to require that any proposed practice guidelines be certified, or "blessed" as it is often called, before they are approved.<sup>145</sup> This type of quality control review most likely would be done by a governmental body, at either the state or federal level. The most likely candidate is the Agency for Health Care Policy and Research.<sup>146</sup>

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<sup>145</sup> See Rosoff, *supra* note 10, at 373, 383. Rosoff addresses whether or not the AHCPR should be the sole official generator of CPGs, a government facilitator to foster their development by others, or the official body for reviewing and certifying CPGs.

See also Kadzielski, *supra* note 8, at 161. The author parallels the need for practice guideline certification to the solidly established approval process of new drugs by the Food and Drug Administration (FDA). Before any new drug is introduced to the public, the FDA requires assurances that the drug is safe and effective. Practice guidelines affect the public health in the same way that drugs do; therefore, why should a practice guideline be introduced immediately into the public domain prior to tests for safety and efficacy of the guideline? By failing to have a certification process, the area is and will continue to be ripe for abuse, because there is currently no legal responsibility for faulty guidelines.

<sup>146</sup> This Note is not arguing that the federally funded AHCPR should be the sole generator of guidelines, only that they would be a well-qualified organization to engage in certification. The AHCPR has earned widespread respect as a guideline developer for several reasons: first, AHCPR guidelines are created by private-sector, multi-disciplinary panels of experts; second, the guidelines are based on extensive literature reviews and reflect the best scientific evidence available; third, the guidelines are subjected to intensive scrutiny by peer reviewers and on-site clinical evaluations by potential users to assess validity, efficacy and applicability; fourth, they include analysis of the use and cost of health care resources and assessment of the feasibility of implementation; and finally, they are regularly updated to incorporate new information. MEDICAL OUTCOMES, *supra* note 4, at 168.

This requirement of certification or accreditation would serve several important functions. First, if a neutral body is responsible for conducting efficacy tests on developing guidelines as well as maintaining responsibility for their continual updating, there will be greater safeguards against inadequate and faulty CPGs. This will result in a reduction in the number of health care risks and medical malpractice suits brought against developers. Furthermore, if a governmental agency is chosen as a neutral body to collect CPGs from varied sources, certify and disseminate them under its own auspices, the agency would almost certainly enjoy immunity for their development.<sup>147</sup> Additionally, the government agency responsible for certification would not face the same competing interests which confront the managed care companies: effective health care would not be overshadowed by the mandate to contain costs, because the agency would have no incentive to place cost savings above appropriate medical care. Moreover, the body certifying the guidelines would be certain to stress that they are always voluntary and do not define the approach to every case, reminding and permitting many providers to exercise their professional judgment in each case.

Second, by continuing to allow all individuals and organizations to remain involved in guideline development by adding the certification requirement rather than unduly narrowing the field of development to one body charged with creating CPGs, innovation in clinical practice will not be impeded. While there are genuine concerns regarding managed care companies which create practice guidelines, it cannot be denied that these types of organizations are often the most well-equipped to engage in CPG development because of the vast amount of information and resources available to them. Having hundreds of patients and doctors on their rosters and plans, managed care companies are often in the best position to conduct outcomes research and develop guidelines based upon that research.

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<sup>147</sup> A problem arises, however, concerning the accountability for CPG maintenance. Certification of a CPG upon issuance is only one step in the legitimization of the CPG. Equally important is the CPG being continually updated as new evidence is uncovered which bears on the effectiveness of the treatment approach set forth in the CPG. See Rosoff, *supra* note 10, at 385.



Finally, requiring guideline certification would remove much of the public concern over the credibility of guidelines developed by organizations, like HMOs and other managed care companies, which have obvious competing interests. The medical community would be more likely to respect a practice that they know has been carefully considered and found acceptable by various members of their profession. Furthermore, it is more likely that CPGs would be recognized in a court of law as the legal standard if it is obvious that the medical profession has accepted and adopted the CPG as authoritative.<sup>148</sup> The certification requirement will likely foster a much needed sense of trustworthiness and validity in the proffered practice guidelines.

*Megan L. Sheetz*

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<sup>148</sup> See Rosoff, *supra* note 10, at 380. (finding that "[t]he 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."). Currently, the American Medical Association opposes the adoption of CPGs as a legal standard, preferring instead that CPGs be used only as evidence of the customarily observed professional standard until the CPGs become widely accepted and relied upon among the medical community. See Rosoff, *supra*, note 10, at 383.