

## **Hospital Peer Review Standards and Due Process: Moving from Tort Doctrine Toward Contract Principles Based on Clinical Practice Guidelines**

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## I. INTRODUCTION

Over five years ago, the Institute of Medicine issued its report on medical errors entitled *To Err Is Human*.<sup>1</sup> This report documented the fact that between 44,000 and 98,000 patients die each year in

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<sup>1</sup> INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM* (Linda T. Kohn et al. eds., 1999).

hospitals due to medical mistakes.<sup>2</sup> These figures are equal to the number of casualties that would occur if one jumbo jet crashed in this country every day for a whole year.<sup>3</sup> Five years after the *To Err Is Human* report, the medical profession has made some progress in the reduction of medical errors, but this progress has been insufficient.<sup>4</sup> According to one expert,

[s]tronger regulation has helped, as have some early improvements in information technology and in workforce organization and training. Error-reporting systems have had little impact, and *scant progress has been made in improving accountability*. Five years after the [*To Err Is Human*] report's publication, we appear to be at "the end of the beginning."<sup>5</sup>

The medical malpractice system is one of the major vehicles of accountability for medical errors. Physicians, lawyers and politicians debate the merits of the medical malpractice system generally,<sup>6</sup> but its overall impact on patient safety, both positive and negative, is overstated.<sup>7</sup> Peer review systems are less discussed, but have more potential significance in improving quality of care.<sup>8</sup> 'Peer review' refers to

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<sup>2</sup> *Id.* at 1.

<sup>3</sup> Robert M. Wachter, *The End of the Beginning: Patient Safety Five Years After 'To Err Is Human'*, HEALTH AFFAIRS, Nov. 30, 2004, at 534, <http://content.healthaffairs.org/webexclusives/index.dtl?year=2004>; see also Troyen A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I*, 324 NEW ENG. J. MED. 370, 370 (1991) (noting that among 2,671,863 patients discharged from New York hospitals in 1984, there were 98,609 adverse events, 27,179 of which involved negligence); Lucian L. Leape et al., *The Nature of Adverse Events in Hospitalized Patients: Results of the Harvard Medical Practice Study II*, 324 NEW ENG. J. MED. 377, 377 (1991) (stating that investigation of patients admitted into New York hospitals in 1984 revealed that 3.7 percent suffered injuries and twenty-eight percent of those injuries were due to negligence).

<sup>4</sup> Wachter, *supra* note 3, at 535.

<sup>5</sup> *Id.* at 534 (emphasis added).

<sup>6</sup> See, e.g., *id.* at 540; HARVARD MED. PRACTICE STUDY, PATIENTS, DOCTORS, AND LAWYERS: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION IN NEW YORK (1990) [hereinafter HARVARD STUDY] (Harvard University study of the feasibility of a statewide no-fault system for injuries from medical care pursuant to a contract with the Department of Health of the State of New York); MAXWELL J. MEHLMAN, THE HARVARD NO-FAULT PROJECT: A CRITIQUE i-iv, 58-59 (1989) (asserting that a no-fault system would decrease patient compensation, eliminate deterrence, dramatically increase costs, reduce physician morale and create a bureaucratic nightmare); see generally MAXWELL J. MEHLMAN, SAYING "NO" TO NO-FAULT: WHAT THE HARVARD MALPRACTICE STUDY MEANS FOR MEDICAL MALPRACTICE REFORM (1991) (pointing out bias and design flaws in the Harvard Malpractice Study). See also *infra* notes 182-98 and accompanying text.

<sup>7</sup> Wachter, *supra* note 3, at 540. See generally HARVARD STUDY, *supra* note 6.

<sup>8</sup> Wachter, *supra* note 3, at 540-41:

In contrast to malpractice . . . the lack of accountability for poor performance does harm patient safety. . . . [T]here are some bad doc-

the evaluation of the performance of a physician by other physicians to ensure the quality of patient care given in an institution.<sup>9</sup> In 1995, Congress determined that peer review held the promise of enhancing the quality of medical care through the deterrence of medical malpractice and the identification of incompetent physicians.<sup>10</sup> However, individual institutions, such as hospitals,<sup>11</sup> and professional associations, such as the American Medical Association and state licensing boards,<sup>12</sup> have been struggling with how to implement systems of accountability to deal with incompetent physicians, with little success.

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tors and nurses, and our system of accountability (at the level of individual institutions, professional associations, and state licensing boards) does not know how to deal with them. . . .

. . . [W]e have made virtually no progress in tackling these exceptionally thorny questions in the past five years.

<sup>9</sup> See SLEE'S HEALTHCARE TERMS 474 (4th ed. 2001) [hereinafter SLEE'S].

<sup>10</sup> See 42 U.S.C. § 11101(1)–(3) (2000) (congressional findings acknowledging that peer review is a factor in the resolution of the national issue of medical malpractice).

<sup>11</sup> See Wachter, *supra* note 3, at 540–41. See also John H. Colteaux, Note, *Hospital Staff Privileges: The Need For Legislation*, 17 STAN. L. REV. 900, 901–02 (1965):

The need for hospital professional discipline has developed primarily because of the failure of other forms of restraint. A state medical license is no assurance that a doctor can competently perform every procedure known at the time he obtains the state's permission to practice. Furthermore, although his license legally permits a physician to attempt the most sophisticated procedures then known or later developed, licensing boards do not conduct postlicensing competency checks. . . . Voluntary professional associations, . . . [such as the American Medical Association], attempt to influence practice by statements on proper standards and procedures and by the threat of expulsion. As a practical matter, however, their effectiveness is limited. First, membership in professional associations is not required for practice, and nonmembers cannot be disciplined. Second, these associations can effectively discipline members only after the fact and in the most flagrant cases of malpractice because a physician's colleagues are loathe publicly to question his qualifications prior to his making a major mistake, and even then fear of defamation actions may stifle criticism. Third, even where a member is expelled—which is rare—the action has no legal effect and may have little practical effect on the doctor's ability to practice as he sees fit. . . .

In short, the physician outside the hospital is largely responsible only to himself for the type of procedures he undertakes. The hospitals, however, can provide an effective restraint on unqualified medical and surgical practitioners.

*Id.* (footnotes omitted).

<sup>12</sup> “At this point, confidence that medical licensure boards are capable of systematically identifying incompetent practitioners, and that board interventions can address the problems caused by such practitioners, are [sic] probably misplaced.” Timothy S. Jost et al., *Consumers, Complaints, and Professional Discipline: A Look At Medical Licensure Boards*, 3 HEALTH MATRIX 309, 336 (1993) (describing the results of a study analyzing complaints closed by the Ohio State Medical Board in 1990).

Thus, the potential that peer review holds to enhance the quality of patient care has yet to be fulfilled.

One reason for this failure may be attributed to the standards which are being used to measure the competence of physicians in hospital peer review proceedings.<sup>13</sup> Hospitals across the country are relying on a variety of extraordinarily vague standards as measures of clinical competence.<sup>14</sup> These standards appear to fall into three basic categories: those which vest absolute discretion in the hospital to terminate the staff privileges of physicians for ‘the good of the hospital;’<sup>15</sup> those which rely on customary care as practiced in the hospital or some broader medical community;<sup>16</sup> and, those which import tort standard of care doctrines that equate a negligence inquiry with an incompetence evaluation.<sup>17</sup>

The use of these standards has negative implications for all of the stakeholders in the peer review process: patients, hospitals and physicians. Many of these vague standards bring with them a whole bag of rules and premises, both legal and evidentiary, that are inappropriate in the context of peer review. Attempts to apply these legal and evidentiary doctrines may confuse and burden the peer review process, raising its attendant transaction costs to a prohibitive level. These doctrines also raise the level of outcome uncertainty. In light of both the high level of cost and uncertainty, a hospital may be reluctant to initiate the peer review process, placing patient safety at risk. In short, the application of these vague standard of care measurements in peer review proceedings may be one of the reasons that, seven years after the *To Err Is Human* report, peer review has failed to meet expectations as a vehicle of accountability.

When the hospital staff does engage in the formal peer review process, the validity of the process may be jeopardized by employing vague and ambiguous standard of care rules ex post facto.<sup>18</sup> Employing these vague standard of care measurements runs directly contrary to rule of law principles grounded in due process/fundamental fair-

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<sup>13</sup> The source for the information regarding the standards that are being relied upon by hospitals in peer review is a broad sampling of the reported cases dealing with the appeal of peer review decisions to the courts. Thus, this Article is analogous to a case study. Further empirical research which gathers data directly from the hospitals themselves is necessary to confirm that this sample is an accurate reflection of the standards in use in all hospitals across the country.

<sup>14</sup> See *infra* Part VI.

<sup>15</sup> See *infra* Part VI.A.

<sup>16</sup> See *infra* Part VI.B.

<sup>17</sup> See *infra* Part VI.C.

<sup>18</sup> See *infra* notes 150–52 and accompanying text.

ness concerns. The end result may be that a physician's ability to practice medicine is unfairly impacted, without the compensating opportunity for any meaningful judicial review. Finally, if the peer review participants are sued individually by a physician dissatisfied with a peer review hearing result based on due process concerns, all of these participants are at risk of losing the immunity normally provided by the Health Care Quality Improvement Act ("HCQIA").<sup>19</sup>

Numerous courts opine that there is no good solution to this vagueness problem. They doubt whether the establishment of clear, objective criteria is possible.<sup>20</sup> Over and above this issue, these courts express concern regarding the feasibility of making timely revision of objective criteria to reflect the rapid pace of scientific advancements.<sup>21</sup> This quick rate of obsolescence raises the specter that judgments regarding physician competence could be based on bad data. Thus, standards based on objective criteria, while being less vague, may nevertheless be arbitrary. In addition, although no court has pointed out this parallel, it could be argued that many of the same vague standards that are used in peer review have survived vagueness challenges in the context of medical malpractice litigation and medical licensure proceedings.

Perhaps for these reasons, the vast majority of the case and statutory law gives scant attention to peer review standards, instead focusing considerable efforts on enforcing an extensive set of mechanical process protections in the attempt to protect due process.<sup>22</sup> However, this list of process protections are all empty formalities if, after the proceedings are completed, the decision-makers can decide to take whatever actions their personal inclinations dictate. This concern becomes evident when examining the differences between the decision-makers in peer review and the decision-makers in medical malpractice and medical licensure proceedings.<sup>23</sup> The decision-makers in medical malpractice litigation and medical licensure hearings are judges, juries and administrative officials who are unlikely to have had prior dealings or involvement with the targeted physician. They are disinterested third parties. In contrast, peer review is generally handled entirely in-house. It is highly likely that both the decision-makers and the other participants in the process have had, or continue to have, personal and economic dealings with the targeted phy-

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<sup>19</sup> See *infra* note 84 and accompanying text.

<sup>20</sup> See *infra* note 157 and accompanying text.

<sup>21</sup> See *infra* note 158 and accompanying text.

<sup>22</sup> See *infra* Parts III-IV.

<sup>23</sup> See *infra* note 157.

sician.<sup>24</sup> Moreover, peer review decision-makers may feel pressure to bow to the wishes of the executive committee (or other powerful members of the hospital staff) to terminate the targeted physician. While vagueness concerns are important in all of these proceedings, the risks to a fair process are greater in peer review, requiring much greater clarity in the standards used.

This Article proposes a solution to the problems associated with the current use of vague standards in peer review. This Article will examine the proposal that medical staffs switch from ad hoc judicial decision-making to rule-making. This switch will allow medical staffs to abandon the troublesome practice of applying vague 'standard of care' measures ex post facto. In its stead, express contractual terminology could be adopted, such as 'expectations of performance,' which incorporates specifically chosen and uniquely tailored clinical practice guidelines ("CPGs") directly into the medical staff by-laws. Describing the expectations of physician performance in express contractual terms enables physicians to conform to appropriate institutional norms ex ante, which, this Article argues, enhances patient safety. In addition, providing physicians with clear notice of the conduct that could trigger the formal peer review process deters conduct that places patient safety at risk. This choice also decreases the risk of caprice and discrimination and permits a more meaningful judicial review of hospital peer review actions. This Article also proposes a mechanism to avoid CPG obsolescence to ensure that decisions are based on good outcomes data (evidence-based medicine), and not past practice (eminence-based medicine). This proposed mechanism is similar to that which is currently being used by hospital Institutional Review Boards to keep abreast of scientific developments and avoid duplication of efforts, delays and expense.

Adopting this strategy may also avoid many of the pitfalls that are attendant to the use of the current vague standards and could minimize the temptation to import inappropriate and destructive legal and evidentiary doctrines into the peer review process. This may result in a more equitable balancing of the public's quality of care concerns with the interests of the physician in a fair process of formal peer review. This shift to contract principles could streamline the formal peer review process making a hospital less reluctant to engage in peer review, providing a greater assurance of patient confidential-

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<sup>24</sup> See generally John D. Blum, *Beyond the Bylaws: Hospital-Physician Relationships, Economics, and Conflicting Agendas*, 53 BUFF. L. REV. 459, 470-74 (2005) (explaining how credentialing includes economic considerations blurring the line between business and quality judgments).

ity and enhancing the certainty of HCQIA protections for all involved in the process. These clear expectations of performance meet rule of law principles as they provide clearly articulated standards that satisfy due process/fairness concerns. Finally, a switch from ad hoc judicial decision-making to rule-making carries with it the benefits of allowing a conscious choice between competing social values inherent in our complex health care system.

Part II of this Article provides a history of the oversight of the quality of care in hospitals. Part III furnishes a brief summary of how the formal peer review process is conducted. Part IV explains the Health Care Quality Improvement Act. Part V outlines the current schism in the courts over the appropriateness of the standards currently being used to evaluate physician competence in peer review. Part VI describes the problems inherent in the various vague categories of standards currently being used to evaluate physician competence. In Part VII, several potential solutions are evaluated. While not a perfect short term solution, this Article concludes that, ultimately, the use of CPGs to measure competency is a far superior approach in light of the myriad problems associated with the current system.

## II. HISTORY OF THE OVERSIGHT OF QUALITY OF CARE IN HOSPITALS

Until the early 1900s, the vast majority of patient care was performed in either the physician's office or in the patient's home.<sup>25</sup> Hospitals were considered to be charitable institutions which provided free care for the poor.<sup>26</sup> Popular opinion at the time was that hospitals in general were so poorly run as to bring "discredit upon the medical profession."<sup>27</sup> Physicians avoided sending their patients to hospitals as "the hospital had no special advantages over the home, and the infections that periodically swept through hospital wards made physicians cautious about sending patients there."<sup>28</sup> Even complicated surgeries were conducted "in the home, often in the

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<sup>25</sup> See Eleanor D. Kinney, *Private Accreditation as a Substitute for Direct Government Regulation in Public Health Insurance Programs: When is it Appropriate?*, LAW & CONTEMP. PROBS., Autumn 1994, at 47, 50 ("Until the twentieth century, most health care was provided at home.").

<sup>26</sup> *Id.*; see also Craig W. Dallan, *Understanding Judicial Review of Hospitals' Physician Credentialing and Peer Review Decisions*, 73 TEMP. L. REV. 597, 599-604 (2000) (providing an excellent summary of the history of the hospital-physician relationship and the organization of medical staffs).

<sup>27</sup> LOYAL DAVIS, FELLOWSHIP OF SURGEONS: A HISTORY OF THE AMERICAN COLLEGE OF SURGEONS 63 (Am. Coll. of Surgeons 1973) (1960).

<sup>28</sup> PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 157 (1982).



kitchen.”<sup>29</sup> One estimate suggests that only two percent of physicians had hospital privileges.<sup>30</sup>

With medical advances, physicians began to rely more on the “diagnostic and therapeutic facilities which only a hospital could provide.”<sup>31</sup> Hospital appointments increased in value as hospitals became “indispensable for surgical practice and specialization.”<sup>32</sup> Between 1870 and 1910, hospitals evolved “[f]rom refuges mainly for the homeless poor and insane . . . into doctors’ workshops for all types and classes of patients.”<sup>33</sup> In this same period of time, “[t]he number of hospitals increased from 178 in 1873 to 4359 in 1909.”<sup>34</sup> By 1930, the number of hospitals had increased to 6719.<sup>35</sup>

In 1913, the American College of Surgeons (“ACS”) was organized<sup>36</sup> to facilitate the standardization of hospital care through the implementation of minimum safety and performance requirements.<sup>37</sup> Shortly thereafter, the voluntary “Minimum Standard” was established by the ACS, followed by the creation of the Hospital Standardization Program (“HSP”).<sup>38</sup> The goal of the HSP was to study and monitor hospitals in order to refine and expand upon the Minimum Standard.<sup>39</sup> One of the steps advocated by the Minimum Standard was self-regulation through an organized medical staff.<sup>40</sup> For example, the Minimum Standard required “[t]hat physicians and surgeons privileged to practice in the hospital be organized as a definite medical staff” and “[t]hat the medical staff initiate and, with the approval of the governing board of the hospital, adopt rules, regula-

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<sup>29</sup> Morris J. Vogel, *The Transformation of the American Hospital, 1850–1920*, in *HEALTH CARE IN AMERICA: ESSAYS IN SOCIAL HISTORY* 105, 105–06 (Susan Reverby & David Rosner eds., 1979).

<sup>30</sup> STARR, *supra* note 28, at 162.

<sup>31</sup> MILTON I. ROEMER & JAY W. FRIEDMAN, *DOCTORS IN HOSPITALS: MEDICAL STAFF ORGANIZATION AND HOSPITAL PERFORMANCE* 35 (1971).

<sup>32</sup> STARR, *supra* note 28, at 163.

<sup>33</sup> *Id.* at 146.

<sup>34</sup> Timothy Stoltzfus Jost, *The Joint Commission on Accreditation of Hospitals: Private Regulation of Health Care and the Public Interest*, 24 B.C. L. REV. 835, 846 (1983).

<sup>35</sup> *Id.*

<sup>36</sup> ROEMER & FRIEDMAN, *supra* note 31, at 35.

<sup>37</sup> See Jost, *supra* note 34, at 847; DAVIS, *supra* note 27, at 63, 70–71.

<sup>38</sup> Jost, *supra* note 34, at 848.

<sup>39</sup> *Id.* (“[T]he HSP sought regularly to analyze and audit hospital progress toward compliance with the minimum HSP standards. Like the earlier ACS standards, HSP standards focused on the organization and suitability of the hospitals for physicians.” (footnote omitted)).

<sup>40</sup> Dallon, *supra* note 26, at 602 (citing MALCOLM T. MACÉACHERN, *HOSPITAL ORGANIZATION AND MANAGEMENT* 669–70 (3d ed. 1957)).

tions, and policies governing the professional work of the hospital.”<sup>41</sup> Prior to this time, many ‘open staff’ hospitals allowed any physician, regardless of qualifications, to admit and care for patients in the hospital.<sup>42</sup> Others allowed physicians onto the medical staff based on “favoritism rather than skill.”<sup>43</sup> Hospital standardization operated to protect the public by “preventing hospitals from being imposed upon by incompetent physicians,”<sup>44</sup> by prescribing requirements for membership on the medical staff, and by fostering “collective responsibility for standards among the ‘open staff’ itself.”<sup>45</sup>

By 1935, ninety percent of the hospitals surveyed by HSP had organized medical staffs.<sup>46</sup> In 1951, the ACS, the American Hospital Association, the American Medical Association, the American College of Physicians and the Canadian Medical Association created the Joint Commission on Accreditation of Hospitals (“JCAH”).<sup>47</sup> In 1952, the ACS transferred the HSP to the JCAH.<sup>48</sup> The JCAH was later renamed the Joint Commission on Accreditation of Healthcare Organizations (“JCAHO”).<sup>49</sup> Today, JCAHO continues to require that the independent, self-governing medical staff have “overall responsibility for the quality of the professional services provided by individuals with clinical privileges, as well as the responsibility of accounting therefore to the governing body.”<sup>50</sup> JCAHO is a private, non-profit organization and hospitals are not required to follow its guidelines.<sup>51</sup> However, most hospitals work diligently to maintain JCAHO compliance because JCAHO accreditation is required in order to qualify for state Medicare payments and to meet many state licensure requirements.

<sup>41</sup> *Id.* (alterations in original) (quoting MACEACHERN, *supra* note 40, at 669–70).

<sup>42</sup> See Jost, *supra* note 34, at 847.

<sup>43</sup> ROSEMARY STEVENS, IN SICKNESS AND IN WEALTH: AMERICAN HOSPITALS IN THE TWENTIETH CENTURY 53 (1989).

<sup>44</sup> See *Harris v. Thomas*, 217 S.W. 1068, 1072 (Tex. App. 1920).

<sup>45</sup> STEVENS, *supra* note 43, at 53.

<sup>46</sup> See Jost, *supra* note 34, at 848–49.

<sup>47</sup> See AMA (AMA History) 1941 to 1960, <http://www.ama-assn.org/ama/pub/category/1926.html> (last visited Apr. 28, 2006).

<sup>48</sup> Jost, *supra* note 34, at 850–51.

<sup>49</sup> The Joint Commission on Accreditation of Hospitals was renamed the Joint Commission on Accreditation of Healthcare Organizations in 1987. Kinney, *supra* note 25, at 52 n.25.

<sup>50</sup> JOINT COMM’N ON ACCREDITATION OF HEALTHCARE ORGS., COMPREHENSIVE ACCREDITATION MANUAL FOR HOSPITALS: THE OFFICIAL HANDBOOK ¶ MS.1, at MS-2 (1999) [hereinafter CAMH].

<sup>51</sup> Timothy Stoltzfus Jost, *Medicare and the Joint Commission on Accreditation of Health Care Organizations: A Healthy Relationship?*, LAW & CONTEMP. PROBS., Autumn 1994, at 15, 15.

In addition to the role that the medical staff has in assuring the quality of patient care, medical staff members also have a role in the operation of the hospital. “The medical staff is an organized, self-governing collective that develops and adopts its own bylaws, rules, and regulations.”<sup>52</sup>

The bylaws establish, among other things: (1) a medical staff executive committee and define its functions; (2) “[f]air-hearing and appellate review mechanisms for medical staff members and other individuals holding clinical privileges”; (3) “[m]echanisms for corrective action, including indications and procedures for automatic and summary suspension of an individual’s medical staff membership or clinical privileges”; (4) “the medical staff’s organization, including categories of medical staff membership”; (5) “[a] mechanism designed to provide for effective communication among the medical staff, hospital administration, and governing body”; and (6) “[m]edical staff representation and participation in any hospital deliberation affecting the discharge of medical staff responsibilities.”<sup>53</sup>

Membership on the medical staff of a hospital is an essential precondition to the ability to admit patients into that hospital for treatment.<sup>54</sup> The scope of the services the physician may provide at the hospital is defined by the “clinical privileges” that the hospital grants the physician.<sup>55</sup> Membership on the medical staff does not guarantee a grant of clinical privileges<sup>56</sup> which is dependent on the particular physician’s education, license, experience, training, competence, judgment and health.<sup>57</sup>

### III. THE PEER REVIEW PROCESS

It is the hospital medical staff’s obligation to bear “the overall responsibility for the quality of the professional services provided by individuals with clinical privileges . . . .”<sup>58</sup> While the term ‘peer review’ can be used in the context of other professions, the usual use of the term refers to the evaluation of the performance of a physician by

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<sup>52</sup> Dallon, *supra* note 26, at 609.

<sup>53</sup> *Id.* (alterations in original) (citing CAMH, *supra* note 50, ¶¶ MS.2.3 to MS.2.3.8, at MS-3 to MS-4).

<sup>54</sup> See CAMH, *supra* note 50, ¶ MS 6.5.1, at MS-12.

<sup>55</sup> *Id.* ¶ MS.1.1.2, at MS-2, ¶ MS.6.4 at MS-12.

<sup>56</sup> David J. Behinfar, *Exclusive Contracting Between Hospitals and Physicians and the Use of Economic Credentialing*, 1 DEPAUL J. HEALTH CARE L. 71, 78 (1996).

<sup>57</sup> See CAMH, *supra* note 50, ¶ MS.1 n.\*, at MS-2; see also *id.* ¶ MS.6.4, at MS-12.

<sup>58</sup> *Id.* ¶ MS.1, at MS-2.

other physicians pursuant to this obligation.<sup>59</sup> In a hospital setting, the term ‘peer review’ describes several distinct activities which are generally performed by a hospital medical staff committee, all with the goal of maintaining or improving quality of patient care. One such activity involves the assembly and assessment of information regarding the competence and professional conduct of those physicians seeking hospital staff privileges for the first time or applying for the renewal of those privileges.<sup>60</sup> This process is referred to as the credentialing process.<sup>61</sup>

Another activity involves the ongoing collection and evaluation of data regarding the professionalism and competence of each physician who is a current member of the hospital staff.<sup>62</sup> If this evaluative process reveals a physician who is found lacking, informal or formal punitive or restrictive measures may be imposed to bring about improvement in the subject physician’s performance. Informal measures include self-correction, assistance by colleagues, supervisory oversight and guidance with later re-assessment.<sup>63</sup> Informal measures are usually undertaken by the subject physician’s department chair and the chief of staff. If informal measures are either ineffectual or deemed to be inadequate from the onset, what this Article will refer to as the formal peer review process will be initiated. Formal peer review could result in a suspension of staff privileges until corrective measures are taken by the physician or further education is received by the physician, restrictions on the scope of practice the physician

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<sup>59</sup> SLEE’S, *supra* note 9, at 474.

<sup>60</sup> CREDENTIALING AND PEER REVIEW PRACTICE GROUP OF THE AM. HEALTH LAWYER’S ASS’N, PEER REVIEW GUIDEBOOK (3d ed. 2003) [hereinafter PEER REVIEW GUIDEBOOK].

<sup>61</sup> CAMH, *supra* note 50, at MS-7. While information gathering and analysis usually lies in the hands of a credentialing committee, the medical staff executive committee ultimately reviews the qualifications of applicants and makes recommendations that are acted on by the governing body. *Id.* at MS-4. The governing body, commonly a board of directors, is often made up of lay persons who tend to accept the medical judgments of the medical executive committee. Colteaux, *supra* note 11, at 907.

<sup>62</sup> CAMH, *supra* note 50, ¶¶ MS.8 to MS.8.4, at MS-13 to MS-14. CAMH requires that the medical staff of hospitals participate in “performance improvement activities” and implement a properly designed peer review process as part of continued accreditation. *Id.* Medicare’s Conditions of Participation for Hospitals also require peer review by mandating that hospitals conduct ongoing periodic evaluations of its physicians as part of “an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. . . . [that] involves all hospital departments and services,” and that “track[s] medical errors and adverse patient events, analyze[s] their causes, and implement[s] preventative actions and mechanisms . . . .” 42 C.F.R. § 482.21 (2005).

<sup>63</sup> PEER REVIEW GUIDEBOOK, *supra* note 60, at 2–3.

may engage in within the hospital, or termination of staff privileges altogether.<sup>64</sup>

There are several general categories of conduct that could trigger the imposition of formal sanctions. Examples include inadequate clinical competence, physical and mental impairment, disruptive behavior, loss of license or malpractice insurance, or repeated violations of medical staff by-laws. This Article focuses on the standards which are used to evaluate clinical competence. This evaluation can occur in situations when a physician is either denied staff privileges in the first instance based on clinical competence concerns, or when staff privileges are curtailed, terminated, or not renewed as a result of allegations of clinical incompetence.

When a physician is an active member of the medical staff, the formal peer review process is commonly triggered by the report of an event or a series of events that raises questions about a physician's clinical competence.<sup>65</sup> The exact process to be followed is unique to each individual hospital and is described in that institution's medical staff by-laws. However, there are many features of the process that are common to most hospitals. First, as a general rule, medical staff by-laws are enforceable contracts between the hospital and the members of the medical staff.<sup>66</sup> Generally, the by-laws will designate those

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<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at 22. Another point at which a physician could effectively have staff privileges terminated is at the very start of his or her career. Most hospitals place newly accepted staff members on a one to two year probationary period. At the end of the probationary period, the physician's records are reviewed by the medical executive committee which then recommends promotion to full medical staff status, termination or an extension of the probationary period. *See, e.g.,* Chessick v. Sherman Hosp. Ass'n, 546 N.E.2d 1153, 1155-56 (Ill. App. Ct. 1989) (restrictions placed on advancement from probationary status to full staff based on 'substandard' care). Termination can also arise in the form of non-renewal of privileges. A physician's appointment to the medical staff is generally for only one to two years, creating an annual or bi-annual need to reapply. It is common for an investigation into the level of a physician's competence to coincide with this renewal period. *See, e.g.,* Duby v. Jordan Hosp., 341 N.E.2d 876, 878-79 (Mass. 1976) (attempted termination of physician's privileges failed as the necessary two-thirds vote under the by-law for termination not obtained; physician's privileges were not renewed as a result of the same charges based on a less rigorous provision of the by-laws dealing with renewal that only required a simple majority); Dayan v. Wood River Twp. Hosp., 152 N.E.2d 205, 206 (Ill. App. Ct. 1958). As a result of the timing, the investigation could lead the board of directors to deny the renewal of the physician's staff privileges. In this circumstance, under some by-laws, the appeal of the denial of renewal is made directly to the board of directors. In this fashion, the board of directors could perform the roles of investigator, prosecutor, jury, and appellate body.

<sup>66</sup> *See* MICHAEL A. CASSIDY, IMMUNITY FOR CREDENTIALING DECISIONS UNDER FEDERAL AND STATE LAW 38 (2003). Some courts do not view the act of adopting medical staff by-laws as creating a contract, but have found consideration to support

individuals who, or bodies which, can make a request to institute an investigation, referred to either as a complaint or as a request for corrective action. The by-laws will also identify the individuals who, or body which, can make the decision on whether to authorize an investigation.<sup>67</sup> Normally, decisions that are not time-sensitive are made by the medical staff executive committee.<sup>68</sup> In a situation requiring a rapid response, the decision is commonly made jointly by the physician's department chair and the chief of staff.<sup>69</sup> When the situation poses 'immediate danger' to patients warranting immediate summary suspension of the physician's staff privileges, one individual can be designated as the decision-maker, commonly the chief of staff, or the decision can be made by the executive committee.<sup>70</sup>

If a decision is made to investigate a complaint, usually the physician is notified immediately,<sup>71</sup> although this is not always the case.<sup>72</sup>

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finding a contract in subsequent acts. *See, e.g.,* Virmani v. Presbyterian Health Servs., 488 S.E.2d 284, 287-88 (N.C. Ct. App. 1997) (enactment of by-laws pursuant to pre-existing duty does not create a contract; but offering staff privileges is sufficient consideration to create same). *See also* Sadler v. Dimensions Health Corp., 787 A.2d 807 (Md. Ct. Spec. App. 2001), *rev'd and remanded*, 836 A.2d 655 (2003). *Cf.* Monroe v. AMI Hosps. of Tex., Inc., 877 F. Supp. 1022, 1029 n.5 (S.D. Tex. 1994) (by-laws do not constitute contract as they are adopted pursuant to preexisting duty).

<sup>67</sup> PEER REVIEW GUIDEBOOK, *supra* note 60, at 23.

<sup>68</sup> *Id.*

<sup>69</sup> *Id.*

<sup>70</sup> *Id.* In *Pulido v. St. Joseph Memorial Hospital*, 547 N.E.2d 1383 (Ill. App. Ct. 1989), the court granted summary judgment against a physician who complained that the four-member executive committee first made the initial decision that summary suspension of staff privileges was warranted. Then, when the physician requested a hearing, the same four-member executive committee conducted the hearing on the merits of its own decision where it upheld the summary suspension. *Id.* at 1387-88. The hospital board of trustees held an appellate review and affirmed. *Id.*

<sup>71</sup> The PEER REVIEW GUIDEBOOK advocates giving the physician the full details of the complaint:

Although applicable case law may not require notice to the physician prior to the decision to investigate, it would be hard to imagine a situation in which the sense of urgency would outweigh the benefits of at least an informal discussion with the affected physician before the decision is made. Because the affected physician's ability to respond will depend on understanding the nature of the complaint, counsel should consider giving him or her the full details of the complaint. Some medical staffs wrestle with the balance between giving the affected physician all of the information relevant to the complaint and the desire to protect the complainant(s). One way to strike that balance is to provide the affected physician with all of the information relevant to the complaint, along with a warning regarding the serious consequences of unapproved contact with or retaliation against the complainant(s).

PEER REVIEW GUIDEBOOK, *supra* note 60, at 23. *See, e.g.,* Campbell v. St. Mary's Hosp., 252 N.W.2d 581, 584 (Minn. 1977) (physician notified of investigation).

Either the executive committee will conduct the investigation itself, or an ad hoc committee made up of members of the general medical staff will be appointed to conduct the investigation. The physician may or may not be interviewed in this investigation phase. Beyond this interview, the physician has no role in the investigation phase.

The steps that are taken once the investigation is complete depend upon whether an ad hoc committee of the medical staff or the medical executive committee has conducted the investigation. If the investigation has been undertaken by an ad hoc committee, this committee will then draft a set of charges and make recommendations for corrective actions based upon those charges, referred to commonly as the recommended corrective action.<sup>73</sup> Typically, the recommended corrective action of the ad hoc committee is sent directly to the physician who may then appeal it to the executive committee. The executive committee will then conduct a hearing and reach a judgment. This judgment can then be appealed by the physician to the governing body of the hospital. The appeal is based on the record created by the hearing in front of the executive committee.<sup>74</sup> It is common for the board of directors to be made up of lay

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<sup>72</sup> *Islami v. Covenant Med. Ctr.*, 822 F. Supp. 1361, 1365 (N.D. Iowa 1992) (physician was not informed of investigation).

<sup>73</sup> Alternatively, it is also common for the ad hoc committee to send the recommended corrective action to the executive committee for approval. The executive committee may accept, revise, or reject any portion of the recommended action. The recommended action, as adopted, is provided to the physician who may appeal it to the governing body of the hospital, commonly a board of directors or board of managers. After a hearing on the matter, the decision of the board of directors then constitutes a final action of the hospital that the physician can appeal to a trial court.

<sup>74</sup> However, if the executive committee has conducted the investigation, a different set of routes is possible. The executive committee will draft the recommended action which will then be provided to the physician. PEER REVIEW GUIDEBOOK, *supra* note 60, at 28. If the physician exercises the right to appeal, a hearing will be held to determine the validity of the charges contained in the recommended action. If the executive committee has conducted the investigation, this hearing will either be conducted directly by the hospital board of directors, or an ad hoc committee of the medical staff will be constituted as the hearing panel, with the board of directors hearing any appeal of this ad hoc committee's decision. In *Carson v. Northwest Community Hospital*, 548 N.E.2d 579 (Ill. App. Ct. 1989), the executive committee both conducted the investigation and recommended that the physician be summarily suspended. *Id.* at 580. The physician requested a hearing before the executive committee. After the hearing, the executive committee issued a decision sustaining the suspension based on its finding that the physician provided 'inadequate care.' *Id.* The physician appealed and an ad hoc panel of five physicians convened nine times over six months to hear the case. *Id.* The panel found that the summary suspension should be lifted, conditioned on completion of training and one year probationary status. *Id.* The hospital board of directors rejected the panel's recommendation and reinstated the summary suspension. *Id.*

persons who tend to accept the medical judgments of the medical executive committee.<sup>75</sup> As explained in the next section, if this hearing process is fundamentally fair, the participants in the process will be granted immunity from suit by the physician under the Health Care Quality Improvement Act of 1986.<sup>76</sup>

#### IV. THE HEALTH CARE QUALITY IMPROVEMENT ACT

The interests of the public, the physician, and the hospital in the peer review process have been recognized by Congress<sup>77</sup> by the passage of the Health Care Quality Improvement Act ("HCQIA").<sup>78</sup> HCQIA was designed both to encourage the peer review<sup>79</sup> of physicians and to ensure that this process is fair. Prior to HCQIA, participants in the peer review process risked being sued by physicians seeking monetary damages from adverse actions. Creative lawyering engendered claims such as breach of contract for violating medical staff by-laws, tortious interference with business relations, violation of the Uniform Deceptive Trade Practices Act, breach of confidential relationship, conspiracy, defamation, deprivation of the right to practice a profession,<sup>80</sup> intentional infliction of emotional distress and antitrust violations.<sup>81</sup> With the passage of HCQIA, Congress specifically concluded that the quality of medical care would be enhanced by peer review through the deterrence of medical malpractice<sup>82</sup> and the identification of incompetent physicians.<sup>83</sup> Acting on this belief, Congress passed HCQIA, which grants qualified immunity<sup>84</sup> from suit

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<sup>75</sup> Colteaux, *supra* note 11, at 907.

<sup>76</sup> See *infra* note 84 and accompanying text.

<sup>77</sup> Dallan, *supra* note 26, at 625.

<sup>78</sup> 42 U.S.C. §§ 11101–52 (2000).

<sup>79</sup> Under HCQIA, formal sanction proceedings are referred to as 'professional review' actions. *Id.* at § 11151(9).

<sup>80</sup> Patton v. St. Francis Hosp., 581 S.E.2d 551, 554 (Ga. Ct. App. 2003).

<sup>81</sup> For a listing of the cases in which each of these theories was asserted, see PEER REVIEW GUIDEBOOK, *supra* note 60, at 9.

<sup>82</sup> 42 U.S.C. § 11101(3) (2000) (peer review is a factor in the resolution of the national issue of medical malpractice).

<sup>83</sup> Congress explained that "[t]he purpose of this legislation is to improve the quality of medical care by encouraging physicians to identify and discipline other physicians who are incompetent or who engage in unprofessional behavior." U.S. HOUSE OF REPRESENTATIVES ENERGY & COMMERCE COMM., HEALTH CARE QUALITY IMPROVEMENT ACT OF 1986, H.R. REP. NO. 99-903, pt. 1, at 2 (1986), as reprinted in 1986 U.S.C.C.A.N. 6384, 6384; Goldsmith v. Harding Hosp., Inc., 762 F. Supp. 187, 188–89 (S.D. Ohio 1991).

<sup>84</sup> HCQIA provides a qualified immunity from liability "in damages under any law of the United States or of any state . . . with respect to [a professional peer review] action," 42 U.S.C. § 11111(a)(1) (2000), when "adequate notice and hearing proce-



for those who participate in the peer review process, while at the same time conditioning this immunity upon the provision of adequate notice and fair process to the physician.<sup>85</sup> This immunity deprives physicians of full access to the judicial system and is only warranted if, in fact, peer review is being used to enhance the quality of patient care.

There are four basic conditions which must be met in order to obtain HCQIA immunity for the imposition of formal sanctions. These sanctions must have been imposed:

- (1) in the reasonable belief that the action was in the furtherance of quality health care,
- (2) after a reasonable effort to obtain the facts of the matter,
- (3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and
- (4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement of paragraph (3).<sup>86</sup>

A plaintiff physician who wishes to avoid HCQIA immunity and sue those who participated in the peer review process carries the burden of establishing by a preponderance of the evidence that one of these four criteria has not been fulfilled.<sup>87</sup> This allocation of the burden of proof creates a rebuttable presumption that all four of the criteria have been fulfilled. The question of whether the formal sanction was reasonable is an objective one<sup>88</sup> and the subjective good faith of the

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dures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances . . . ." *Id.* § 11112(a)(3).

<sup>85</sup> See, e.g., *Singh v. Blue Cross/Blue Shield of Mass., Inc.*, 308 F.3d 25, 35 (1st Cir. 2002); *Imperial v. Suburban Hosp. Ass'n, Inc.*, 37 F.3d 1026, 1031 (4th Cir. 1994), *aff'd*, No. 96-1978, 1998 U.S. App. LEXIS 893 (4th Cir. Jan. 22, 1998); *Patrick v. Floyd Med. Ctr.*, 565 S.E. 2d 491, 495 (Ga. Ct. App. 2002), *cert. denied*, No. S02C1457, 2002 Ga. LEXIS 713 (Ga. Sept. 6, 2002); *Peyton v. Johnson City Med. Ctr.*, No. E2001-02477-COA-R3-CV, 2002 Tenn. App. LEXIS 770, \*3 (Tenn. Ct. App. Oct. 29, 2002).

<sup>86</sup> 42 U.S.C. § 11112(a) (2000). The question of what the phrase "or after such other procedures as are fair to the physician under the circumstances" means was addressed in *Islami v. Covenant Medical Center*, 822 F. Supp. 1361, 1374 (N.D. Iowa 1992). In *Islami*, the court found that this same language contained in the hospital by-laws was written to capture the general rule that hospitals are not required to comply with the by-laws in every technical aspect. *Id.* This language from the hospital's by-laws was modeled directly upon § 11112(a). *Id.* at 1377. The court found that both this language and the 'substantial compliance' inquiry are directed toward a determination of whether the procedures provided to the physician were fundamentally fair. *Id.* at 1374.

<sup>87</sup> 42 U.S.C. § 11112(a) (2000).

<sup>88</sup> *Freilich v. Upper Chesapeake Health, Inc.*, 313 F.3d 205, 212 (4th Cir. 2002); *Mathews v. Lancaster Gen. Hosp.*, 87 F.3d 624, 635 (3d Cir. 1996); *Austin v. McNamara*

hospital is not relevant.<sup>89</sup> The issue of the qualification for HCQIA immunity is a question that is answered by the court as a matter of law.<sup>90</sup>

HCQIA lists a number of suggested<sup>91</sup> procedures that a hospital may utilize to provide adequate notice and a fair hearing. The statute expressly states that declining to follow these suggestions does not equate to a failure to provide an adequate notice or a fair hearing when other adequate processes are in place.<sup>92</sup> With regard to notice, it is suggested that a physician be provided a notice that includes the following information:

- (1) that a professional review action has been proposed to be taken against the physician,
- (2) [the] reasons for the proposed action,
- (3) that the physician has the right to request a hearing on the proposed action,
- (4) any time limit (of not less than 30 days) within which to request such a hearing, and
- (5) a summary of the [physician's hearing] rights . . . .<sup>93</sup>

With regard to the actual hearing, it is suggested that the physician be given the right:

- (1) to representation by an attorney or other person of the physician's choice,
- (2) to have a record made of the proceedings, . . .
- (3) to call, examine, and cross-examine witnesses,

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mara, 979 F.2d 728, 734 (9th Cir. 1992); *Egan v. Athol Mem'l Hosp.*, 971 F. Supp. 37, 42 (D. Mass. 1997), *aff'd per curiam*, 134 F.3d 361 (1st Cir. 1998), *cert. denied*, 525 U.S. 964 (1998); *Monroe v. AMI Hosps. of Texas, Inc.*, 877 F. Supp. 1022, 1028 (S.D. Tex. 1994); *Doctor's Med. Clinic v. City of Jackson*, 569 N.W.2d 231, 236 (Minn. Ct. App. 1997), *aff'd in part, rev'd in part*, 581 N.W.2d 30 (Minn. 1998); *Schilling v. Moore*, 545 N.W.2d 442, 444 (Neb. 1996).

<sup>89</sup> *Brader v. Allegheny Gen. Hosp.*, 167 F.3d 832, 840 (3d Cir. 1999); *Davenport v. Ne. Ga. Med. Ctr.*, 542 S.E.2d 525, 530 (Ga. App. Ct. 2000); *Goodwich v. Sinai Hosp. of Baltimore, Inc.*, 680 A.2d 1067, 1079 (Md. 1996); *Manzetti v. Mercy Hosp. of Pittsburgh*, 776 A.2d 938, 946 (Pa. 2001).

<sup>90</sup> *Bryan v. James E. Holmes Reg'l Med. Ctr.*, 33 F.3d 1318, 1321 (11th Cir. 1994), *cert. denied*, 514 U.S. 1019 (1995).

<sup>91</sup> While these procedures are suggested, they are not required for good reason. For example, if a patient's health is in 'imminent danger' unless immediate action is taken, it may not be practical to provide the above procedural protections to the physician prior to summary suspension. 42 U.S.C. § 11112(c)(2) (2000). As long as the post-deprivation hearing is fundamentally fair, HCQIA immunity will attach.

<sup>92</sup> *Egan*, 971 F. Supp. at 42; *Mathews*, 883 F. Supp. at 1016; *Monroe*, 877 F. Supp. at 1028; *Goldsmith v. Harding Hosp. Inc.*, 762 F. Supp. 187 (S.D. Ohio 1991); *Gill v. Mercy Hosp.*, 245 Cal. Rptr. 304 (Ct. App. 1988), *cert. denied*, 488 U.S. 892 (1988).

<sup>93</sup> 42 U.S.C. § 11112(b)(1) (2000).

- (4) to present evidence determined to be relevant by the hearing officer, regardless of its admissibility in a court of law, and
- (5) to submit a written statement at the close of the hearing.<sup>94</sup>

Finally, regardless of compliance with HCQIA, it is important to note that a physician may still sue for injunctive and other types of equitable relief. For example, a physician can still bring an action for injunctive relief to bar the imposition of any corrective action alleging that either the due process guaranteed by the Constitution or common law, or the fair process granted by the medical staff by-laws, has not been provided.<sup>95</sup>

The desire to earn HCQIA immunity supplies a strong motivation to provide a formal peer review process in keeping with HCQIA's criteria for what kind and amount of notice is sufficient to be 'adequate notice' and what rights granted to a physician will be enough for the proceedings to be considered 'fair.' If the HCQIA criteria are met, the physician will be barred from pursuing an action in damages against those who participated in the process. Thus, even in those states that have heretofore found that due process fairness concerns are inapplicable to the formal peer review process undertaken by private hospitals, HCQIA creates a notice and fairness floor for peer review participants who wish to avoid suit for damages.<sup>96</sup>

## V. FAIR PROCESS

What is a fair process? A fair process is a process which weighs the interests of the stakeholders in the process, balances them and properly protects those interests accordingly.<sup>97</sup> In the context of peer review, a fair process is one which employs both the process protections and the standards necessary to safeguard the relative interests of

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<sup>94</sup> *Id.* § 11112(b)(3)(C).

<sup>95</sup> *See, e.g.*, *Singh v. Blue Cross/Blue Shield of Mass., Inc.*, 308 F.3d 25, 35 (1st Cir. 2002); *Imperial v. Suburban Hosp. Ass'n, Inc.*, 37 F.3d 1026, 1031 (4th Cir. 1994), *aff'd by*, No. 96-1978, 1998 U.S. App. LEXIS 893 (4th Cir. 1998); *Patrick v. Floyd Med. Ctr.*, 565 S.E.2d 491, 495 (Ga. Ct. App. 2002), *cert. denied*, No. S02C1457, 2002 Ga. LEXIS 713 (Ga. Sept. 6, 2002); *Peyton v. Johnson City Med. Ctr.*, No. E2001-02477-COA-R3-CV, 2002 Tenn. App. LEXIS 770, \*3 (Tenn. Ct. App. Oct. 29, 2002).

<sup>96</sup> Many state statutes provide a much broader immunity for both the individual participants in the peer review process and the hospital. *See generally* Susan O. Scheutzow, *State Medical Peer Review: High Cost But No Benefit—Is It Time For A Change?*, 25 AM. J.L. & MED. 7 (1999) (suggesting that peer review protection statutes do not encourage peer review). Unlike HCQIA, in most cases, the state immunity provisions will not provide immunity from federal antitrust liability. *See Islami v. Covenant Med. Ctr.*, 822 F. Supp. 1361, 1379–80 (N.D. Iowa 1992).

<sup>97</sup> *See infra* note 163 and accompanying text.

the stakeholders. Following the passage of HCQIA, it appears that most hospitals are utilizing adequate process protections in peer review hearings. On the other hand, based at least on a survey of the peer review cases being appealed to the courts, the substantive standards being used to measure physician competence in peer review do not properly protect the interests of all of the stakeholders, rendering the process fundamentally unfair. This lack of fundamental fairness places all of the participants in the peer review process at risk of losing HCQIA immunity.

A. *Stakeholders in Peer Review*

There are many competing interests at stake in the judicial review of a negative peer review outcome. The physician who pursues the appeal has an interest in the ability to practice his or her profession.<sup>98</sup> The hospital has an interest in maintaining its autonomy in staffing decisions, the provision of quality patient care and the avoidance of liability for negligent credentialing and negligent provision of care by its physicians.<sup>99</sup> The public has a foot in both camps; it has an interest in both the availability of quality medical care and in the ability of individuals to choose their own health care providers.<sup>100</sup>

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<sup>98</sup> Sheree Lynn McCall, *A Hospital's Liability for Denying, Suspending and Granting Staff Privileges*, 32 BAYLOR L. REV. 175, 175 (1980).

<sup>99</sup> See generally John D. Hodson, Annotation, *Liability of Hospital or Sanitarium for Negligence of Physician or Surgeon*, 51 A.L.R. 4th 235 (1987) (detailing rejection of charitable immunity for hospitals); see generally also BARRY R. FURROW ET AL., HEALTH LAW § 7-1, at 378-79 (2d ed. 2000) [hereinafter FURROW ET AL., HEALTH LAW] (discussing erosion of governmental immunity); Kenneth S. Abraham & Paul C. Weiler, *Enterprise Medical Liability and the Evolution of the American Health Care System*, 108 HARV. L. REV. 381, 388 (1998) (discussing the enterprise liability doctrine); Daniel L. Icenogle, Annotation, *Hospital Liability as to Diagnosis and Care of Patients in Emergency Room*, 58 A.L.R. 5th 613 (1988); Martin C. Williams, Jr. & Hamilton E. Russell, III, *Hospital Liability for Torts of Independent Contractor Physicians*, 47 S.C. L. REV. 431, 445-57 (1996) (discussing non-delegable duty doctrine).

<sup>100</sup> "[T]he power to select a medical staff is a fiduciary power to be exercised reasonably and for the public good." *Kiracofe v. Reid Mem'l Hosp.*, 461 N.E.2d 1134, 1142 (Ind. Ct. App. 1984) (Ratliff, J., concurring) (citing *Greisman v. Newcomb Hosp.*, 192 A.2d 817 (N.J. 1963)).

A non-profit private hospital serving the public generally is a quasi-public institution whose obligation to serve the public is the linchpin of its public trust and the fiduciary relationship which arises out of the management of that trust. . . . When a hospital's board of trustees or directors is in the process of determining whether a doctor should be admitted to its staff, the hospital's public trust is directly involved in view of the public's interest in the quality and availability of medical service. The board, of course, has an interest in preserving its autonomy and in maintaining control over the quality of its staff. Additionally, doctors, particularly surgeons, have a substantial interest in favor-

The extent of the impact of the peer review process on the interests of the hospital and the public is fairly obvious. On the other hand, the extent of the impact that the peer review process can have on the interests of a physician is less apparent. The termination of staff privileges<sup>101</sup> has major implications for a physician's ability to practice medicine.<sup>102</sup> The clearest example of this impact is when there is only one hospital facility in the community.<sup>103</sup> Termination of

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able responses to their applications for staff membership, for their ability to pursue their profession may depend on the availability of necessary hospital facilities.

Garrow v. Elizabeth Gen. Hosp. & Dispensary, 401 A.2d 533, 537 (N.J. 1979).

<sup>101</sup> In many states, the general rule is that a physician's staff privileges constitute a property interest protected by the Due Process Clause of the Fourteenth Amendment. *See, e.g.*, Darlak v. Bobear, 814 F.2d 1055, 1061 (5th Cir. 1987) ("Where medical staff privileges have been held to constitute an interest protected by the fourteenth amendment, it has been because there was an explicit or implicit agreement providing for no termination of the privileges without cause and a hearing, or because denial of staff privileges 'might effectively foreclose . . . practicing in the area because of harm to [a] professional reputation and because of the lack of other [comparable] facilities.'" (alterations in original) (quoting Daly v. Sprague, 675 F.2d 716, 727 (5th Cir. 1982)); Lew v. Kona Hosp., 754 F.2d 1420, 1424 (9th Cir. 1984) ("The state of Hawaii has recognized a licensed doctor's property right in employment as a probationary hospital staff member."); Anton v. San Antonio Cmty. Hosp., 567 P.2d 1162, 1174 (Cal. 1977) ("[T]he essential nature of a qualified physician's right to use the facilities of a hospital is a property interest which directly relates to the pursuit of his livelihood.' This interest is clearly fundamental . . .").

<sup>102</sup> FURROW ET AL., HEALTH LAW, *supra* note 99, § 7-1, at 378 (explaining that pre-condition to the practice of medicine is access to hospitals); McCall, *supra* note 98, at 175 ("A physician's livelihood is dependent on acquiring and maintaining hospital staff privileges. The access to hospital facilities is necessary for most physicians to adequately treat and care for patients, to maintain their medical practice, and to pursue their medical career."); Note, *The Physician's Right to Hospital Staff Membership: The Public-Private Dichotomy*, 1966 WASH. U. L.Q. 485, 510-11 (a successful doctor must have access to hospitals).

<sup>103</sup> *Kiracofe*, 461 N.E.2d at 1142 (noting that when a hospital is the only one in a community, "its economic impact is great, and the denial of hospital privileges, in many cases, is tantamount to denying a physician the opportunity to practice his or her chosen profession"). In *Greisman*, 192 A.2d at 824-25, the court described the situation as follows:

The Newcomb Hospital is the only hospital in the Vineland metropolitan area and it is publicly dedicated, primarily to the care of the sick and injured of Vineland and its vicinity . . . Doctors need hospital facilities and a physician practicing in the metropolitan Vineland area will understandably seek them at the Newcomb Hospital. Furthermore, every patient of his will want the Newcomb Hospital facilities to be readily available. It hardly suffices to say that the patient could enter the hospital under the care of a member of the existing staff, for his personal physician would have no opportunity of participating in his treatment; nor does it suffice to say that there are other hospitals outside the metropolitan Vineland area, for they may be too distant or unsuitable to his needs and desires. All this indicates very pointedly that,

clinical privileges at that one hospital means that the physician will be barred from the practice of medicine in that community.<sup>104</sup> Even for a physician who practices in a very large community with multiple hospitals, an adverse peer review outcome can have the same disastrous result. Physicians are required by hospitals to disclose adverse actions at other hospitals when either renewing privileges or applying for privileges at a new hospital. Hospitals do not rely solely on a physician's obligation to disclose, but also inquire into a physician's history with state licensing boards and the National Federation of State Medical Boards Physician Disciplinary Data Bank.<sup>105</sup> In addition, in the 1980s, HCQIA<sup>106</sup> set up a National Practitioner Data Bank ("NPDB") which compiles data on physicians who have either had their hospital privileges limited in some manner or have had some other adverse action taken against them, have had adverse actions taken against them as a result of proceedings instituted by a state under its licensure authority or have had a judgment entered against them in a malpractice action.<sup>107</sup> The NPDB supplies hospitals with information on physicians applying for staff privileges.<sup>108</sup> This central information storehouse inhibits physicians with suspect practice backgrounds from moving from state to state without disclosing their practice histories. HCQIA mandates that all health care entities<sup>109</sup> report any formal sanctions to the state licensure board which, in turn, must send the report to the NPDB.<sup>110</sup> This reporting activity is also

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while the managing officials may have discretionary powers in the selection of the medical staff, those powers are deeply imbedded in public aspects, and are rightly viewed, for policy reasons . . . as fiduciary powers to be exercised reasonably and for the public good.

*Id.* at 824.

<sup>104</sup> *Kiracofe*, 461 N.E.2d at 1142; *Greisman*, 192 A.2d at 824-25.

<sup>105</sup> CAMH, *supra* note 50, ¶ MS.5.4.3.2, at MS-8.

<sup>106</sup> 42 U.S.C. § 11101 (2000).

<sup>107</sup> *Id.* § 11133.

<sup>108</sup> If a hospital fails to inquire into a physician's history with the NPDB first upon an initial credentialing request, and again every two years after the request is granted, then a presumption arises that the hospital is aware of the information contained in the files. *Id.* § 11135(b). This creates the specter of direct liability for negligent credentialing if the physician injures a hospital's patient.

<sup>109</sup> *Id.* § 11151(4). If a report is not filed, any HCQIA immunity is lost. The non-complying entity is listed in the Federal Register, and any peer review proceedings leading to formal sanctions that are commenced in the three year period of time starting thirty days after the publication are barred from HCQIA immunity. *Id.* § 11111(b).

<sup>110</sup> *Id.* § 11133. Other entities that report to the NPDB include insurance companies, doctors and hospitals that settle or pay judgments in malpractice actions, and state licensure boards that sanction physicians.

insulated from liability if the report is made without knowledge of any false information contained in the report.<sup>111</sup>

*B. Judicial Review of the Fairness of Hospital Peer Review Proceedings*

The courts have struck a balance between the interests of the physician, the hospital, and the public decidedly in favor of the interests of the public and the hospital by providing a high level of deference to hospital staffing decisions in judicial review of adverse peer review actions:

Human lives are at stake, and the governing board must be given discretion in its selection so that it can have confidence in the competence and moral commitment of its staff. The evaluation of professional proficiency of doctors is best left to the specialized expertise of their peers, subject only to limited judicial surveillance.<sup>112</sup>

On the other hand, most courts do provide limited protections for the interests of physicians in pursuing their profession, acknowledging that “[b]oth doctors and their patients can suffer if otherwise qualified doctors are wrongly denied staff privileges.”<sup>113</sup> While recognizing their limitations with regard to factual evaluations of medical competence, courts are in agreement that they are “equipped to determine whether a hospital governing body has followed its bylaws and whether a decision regarding an application for privileges was made in accordance with basic principles of fairness and due process of law.”<sup>114</sup> Thus, most courts claim that they “require that the procedures employed by the hospital are fair, that the standards set by the hospital are reasonable, and that they have been applied without arbitrariness and capriciousness.”<sup>115</sup> Therefore, under differing theories,<sup>116</sup> it appears on the face of it that, at a minimum, courts review an adverse peer review outcome to ensure that the hospital provided the

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<sup>111</sup> 42 U.S.C. § 11137(c) (2000).

<sup>112</sup> *Sosa v. Bd. of Managers of the Val Verde Mem'l Hosp.*, 437 F.2d 173, 177 (5th Cir. 1971); *see also* *Dallon*, *supra* note 26, at 624.

<sup>113</sup> *Balkissoon v. Capitol Hill Hosp.*, 558 A.2d 304, 308 (D.C. 1989) (quoting *Nanavati v. Burdette Tomlin Mem'l Hosp.*, 526 A.2d 697, 701 (N.J. 1987)).

<sup>114</sup> *Kiester v. Humana Hosp. Alaska, Inc.*, 843 P.2d 1219, 1223 (Alaska 1992).

<sup>115</sup> *Laje v. R.E. Thomason Gen. Hosp.*, 564 F.2d 1159, 1162 (5th Cir. 1977), *cert. denied*, 437 U.S. 905 (1978). *See also* *Sokol v. Akron Gen. Med. Ctr.*, 173 F.3d 1026, 1030 (6th Cir. 1999) (In a restriction of clinical privileges appeal, the court held that “hospitals must provide ‘procedural due process . . . in adopting and applying’ ‘reasonable, nondiscriminatory criteria for the privilege of practicing’ surgery in the hospital.” (alteration in original) (quoting *Khan v. Suburban Cmty. Hosp.*, 538 N.E.2d 113, 114 (Ohio 1999))).

<sup>116</sup> *See* *Dallon*, *supra* note 26, at 626–38.

physician with what amounts to fundamental fairness and procedural due process.<sup>117</sup> For governmental institutions, this protection has its basis in the Constitution.<sup>118</sup> For private hospitals, “the due process review is based on contract (the bylaws), fiduciary duty, common law fairness, or statute.”<sup>119</sup> While “foundational factual findings must be sustained if supported by substantial evidence,”<sup>120</sup> the question of “whether the administrative proceedings were fundamentally fair is a question of law to be decided on appeal.”<sup>121</sup>

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<sup>117</sup> In addition, fairness principles call for *revealed* procedures and for the application of the clearly articulated, known standards. “*Revealed* procedures—procedures seen and comprehended—are essential to an individual’s effective and comfortable participation in the agency’s application of its standards to her.” ALFRED C. AMAN, JR. & WILLIAM T. MAYTON, ADMINISTRATIVE LAW § 7.6.1, at 171 (2d ed. 2001).

<sup>118</sup> Dallan, *supra* note 26, at 678.

<sup>119</sup> *Id.* Courts have often distinguished between public and private hospitals in explaining the basis of judicial review. See McCall, *supra* note 98, at 175–90. See also *Kiester*, 843 P.2d at 1223 (“We note a growing trend which affords judicial review to ensure that no hospital, whether public or private, establishes rules governing admission which permit exclusion on an arbitrary or irrational basis, or which are unreasonably susceptible to arbitrary or discriminatory application.” (citing *Miller v. Eisenhower Med. Ctr.*, 614 P.2d 258 (Cal. 1980))); *Sosa v. Bd. of Managers of the Val Verde Mem’l Hosp.*, 437 F.2d 173, 174 (5th Cir. 1971) (as state funds are used to construct, maintain and operate private hospitals, their acts are state acts and must comport with the provisions of the Fourteenth Amendment); *Storrs v. Lutheran Hosps. & Homes Soc’y of Am., Inc.*, 609 P.2d 24, 28 (Alaska 1980) (Due process standards apply in a private hospital as it “is a quasi-public hospital because it is the only hospital serving the community, the construction of the hospital was funded in significant part by state and federal grants, and over twenty-five per cent of the funds received for hospital services comes from governmental sources.”). See also *Anton v. San Antonio Cmty. Hosp.*, 567 P.2d 1162, 1168 (Cal. 1977); *Silver v. Castle Mem’l Hosp.*, 497 P.2d 564, 571 (Haw. 1972), *cert. denied*, 409 U.S. 1131 (1973); *Greisman v. Newcomb Hosp.*, 192 A.2d 817, 818–19 (N.J. 1963); *Peterson v. Tucson Gen. Hosp., Inc.*, 559 P.2d 186, 189 (Ariz. Ct. App. 1976).

There are some jurisdictions that have given mere lip service to the concept that the physician is owed a fair and reasonable process in private hospitals. For example, in *Yashon v. Hunt*, 825 F.2d 1016 (6th Cir. 1987), the court held that a physician’s due process, fair hearing rights were not violated when he was barred from representation by a lawyer, was not presented with an opportunity to produce witnesses on his behalf, was charged with conduct when the same conduct had been part of prior hearings where he was exonerated, and was not presented with a written decision setting forth the findings of the peer review panel, all under a process with no written guidelines or standards. *Id.* at 1017–18. As a practical matter, the cases that give such a narrow reading to the amount of process due a physician no longer have much influence on the formal peer review process. As explained in the prior section, the desire to earn HCQIA immunity supplies a strong motivation to provide a formal peer review process more in keeping with the ideals described by the court in *Kiester*.

<sup>120</sup> *Rosenblit v. Superior Court of Orange County*, 282 Cal. Rptr. 819, 824 (Ct. App. 1991).

<sup>121</sup> *Id.*



### 1. Fairness of Process Protections

In the context of formal peer review, most lower courts are in accord on many of the procedural due process protections that should be offered a physician.<sup>122</sup> These include the right to representation by an attorney or other person of a physician's choice; the right to have a record made of the proceedings; the right to call, examine and cross-examine witnesses; and, the right to present evidence determined to be relevant by the hearing officer.<sup>123</sup> These are basically the same rights as those enumerated in HCQIA.<sup>124</sup> This Article refers to these rights as 'process protections.'

### 2. Principles Governing Fairness of Standards in General

The lower courts also all appear to agree that the standards used to evaluate physician competency must be fair and not subject to arbitrary or capricious application.<sup>125</sup> Under general due process doctrine, for a standard to be fair, it must not be impermissibly vague.

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<sup>122</sup> See *supra* notes 84–92.

<sup>123</sup> The question of how to decide what procedural protections are due was answered in *Mathews v. Eldridge*, 424 U.S. 319 (1976). The Court in *Mathews* explained that

identification of the specific dictates of due process generally requires consideration of three distinct factors: First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.

*Id.* at 335.

<sup>124</sup> See *supra* notes 86–94 and accompanying text.

<sup>125</sup> See *supra* notes 112–21 and accompanying text. Some states hold that "the exclusion of a physician from staff privileges at a private hospital is a matter which will ordinarily rest within the discretion of the hospital's administrative authorities and is not subject to judicial review." *Scappatura v. Baptist Hosp. of Phoenix*, 584 P.2d 1195, 1199 (Ariz. 1978); see also *Edson v. Griffin Hosp.*, 144 A.2d 341, 343–44 (Conn. Super. Ct. 1958). For other cases, see also Kathleen M. Dorr, Annotation, *Exclusion of or Discrimination Against Physician or Surgeon by Hospital*, 28 A.L.R. 5th 107 (1995). However, these hospitals commonly limit their own discretion by stating in either their constitution, by-laws, rules, or regulations that the hospital may not act in an arbitrary or capricious fashion. Thus, even in these hospitals, the standard used to evaluate physician competence must be fair and not subject to arbitrary or capricious application. See, e.g., *Scappatura*, 584 P.2d at 1199 (judicial review to determine if hospital rule was reasonable and not arbitrary). On the other hand, "California courts have long recognized a common law right to fair procedure protecting individuals from arbitrary exclusion or expulsion from private organizations which control important economic interests." Such a private organization's actions must be both substantively rational and procedurally fair." *Rosenblit*, 282 Cal. Rptr. at 825 (citations omitted).

While acquiescing in principle to subscribe to due process/fundamental fairness protections, the lower courts are split on their willingness to strike down remarkably vague standards that clearly fail both to provide adequate notice to physicians and to restrict the discretion of the administrative decision-makers.

Under the vagueness doctrine, it has long been recognized that “a statute which either forbids or requires the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application violates the first essential of due process of law.”<sup>126</sup> In the context of a medical administrative proceeding like peer review,<sup>127</sup> the vagueness doctrine is not

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<sup>126</sup> *Connally v. Gen. Constr. Co.*, 269 U.S. 385, 391 (1926); see also *Kolender v. Lawson*, 461 U.S. 352, 357–58 (1983). While more commonly seen in the areas of arbitrary encroachments on fundamental liberty interests or First Amendment rights, this basic precept is equally applicable to the civil enforcement of regulations of economic and professional activity. *Whisenhunt v. Spradlin*, 464 U.S. 965, 970 (1983) (Brennan, J., dissenting) (citing *Kolender*, 461 U.S. at 357–58; *Parker v. Levy*, 417 U.S. 733, 756 (1974); *Smith v. Goguen*, 415 U.S. 566, 573 n.10 (1974); *Winters v. New York*, 333 U.S. 507, 515 (1948)). “As the Court held long ago, the requirement of fair warning does not prohibit particular types of penalties but rather ‘exaction of obedience to a rule or standard which [is] so vague and indefinite as really to be no rule or standard at all.’” *Whisenhunt*, 464 U.S. at 970 (alteration in original) (quoting *A.B. Small Co. v. Am. Sugar Ref. Co.*, 267 U.S. 233, 239 (1925)).

<sup>127</sup> In the context of public hospitals, counties, cities, or towns are commonly given the authority by state statute to establish and regulate hospitals. 26 AM. JUR. *Hospitals and Asylums* §§ 3–5, at 588–90 (1952). See, e.g., *Koelling v. Bd. of Trs. of Mary Francis Skiff Mem’l Hosp.*, 146 N.W.2d 284 (Iowa 1966). Those same statutes provide that the county, city, or town may, by ordinance, provide for the election of hospital trustees and the transfer of the responsibility for the operation of a city or town hospital to this board of trustees. *Id.* at 287–88; 26 AM. JUR. *Hospitals and Asylums*, *supra*, §8, at 592. “The board then becomes the local body charged with the responsibility of legislating on this local issue.” *Koelling*, 146 N.W.2d at 288. The board may then prescribe reasonable rules that govern staff privileges. *Id.* at 290. As the board is a state administrative agency, the policies and procedures of general administrative law apply to the board of trustees as it acts in both its rule-making and adjudicative roles. See, e.g., *Lew v. Kona Hosp.*, 754 F.2d 1420, 1424 (9th Cir. 1984) (referring to peer review in state hospital as an administrative hearing); *Branch v. Hempstead County Mem’l Hosp.*, 539 F. Supp. 908, 910 (W.D. Ark. 1982) (a peer review hearing at a county hospital was governed by the same rules and statutes governing administrative proceedings). In the context of private hospitals, courts have treated peer review as an administrative proceeding. In *Balkissoon v. Capitol Hill Hospital*, 558 A.2d 304 (D.C. 1989), the court explained that:

The actions of hospitals in regard to staff privileges can be analogized to administrative agencies. “[B]oth the administrative agency and the hospital board of trustees do exercise discretion and bring expertise to their respective tasks. Both must also pay due respect to procedural safeguards whether because of constitutional due process or fundamental fairness.”

*Id.* at 308 n.8 (alteration in original) (citing *Garrow v. Elizabeth Gen. Hosp. & Dispensary*, 401 A.2d 533, 537–38 (N.J. 1979)). See also *Storrs v. Lutheran Hosps. &*

being used to challenge an ill-defined statute; instead, the challenge is against the hospital “for its failure to render a vague [standard] more specific by implementing it through rules.”<sup>128</sup> Thus, fairness in this civil context refers to actions taken “according to known standards that are impartially applied through revealed procedures.”<sup>129</sup>

In administrative law, clearly articulated ‘standing rules’ are an essential ingredient of fair notice as “[k]nown standards allow a person to better understand what . . . [is] expect[ed] of her, so that she can plan her life in some forehanded way.”<sup>130</sup> And, of equal importance, “[k]nown standards also limit the allocation choices of . . . officials. They require that choices be made according to principle rather than the preference of the official.”<sup>131</sup> The absence of clearly articulated standards that are capable of objective application creates an unacceptable risk of arbitrary and capricious decision-making. As Justice Brennan explained:

By demanding that government articulate its aims with a reasonable degree of clarity, the Due Process Clause ensures that state power will be exercised only on behalf of policies reflecting a conscious choice among competing social values; reduces the danger of caprice and discrimination in the administration of the laws; and permits meaningful judicial review of state actions.<sup>132</sup>

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Homes Soc’y of Am., Inc., 609 P.2d 24, 28 (Alaska 1980) (via stipulation of the parties, the decision made pursuant to the peer review process “should be treated as an administrative decision and . . . the review of that decision should be treated as a review of an administrative proceeding”).

<sup>128</sup> AMAN & MAYTON, *supra* note 117, § 3.3, at 72.

<sup>129</sup> *Id.*, § 7.6.1, at 170.

<sup>130</sup> *Id.* See also *White v. Roughton*, 530 F.2d 750, 754 (7th Cir. 1976) (“The requirements of due process include a determination of the issues according to articulated standards.”); *Mayer v. Wing*, 922 F. Supp. 902, 910–12 (S.D.N.Y. 1996) (a regulation that allowed for termination of in-home health care benefits when it was ‘inappropriate’ allowed for arbitrary decision-making in violation of procedural due process as “[d]ue process demands that decisions regarding entitlements to government benefits be made according to ‘ascertainable standards’”); *Harnett v. Bd. of Zoning, Subdivision, and Building Appeals*, 350 F. Supp. 1159, 1161 (D.V.I. 1972) (“There is a tendency for regulatory systems which operate without clearly enunciated standards to be inherently irrational and arbitrary.”).

<sup>131</sup> AMAN & MAYTON, *supra* note 117, § 7.6.1, at 170–71. As Professor Lon Fuller observed, “[t]he first desideratum of a system for subjecting human conduct to the governance of rules is an obvious one: there must be rules.” LON L. FULLER, *THE MORALITY OF LAW* 46 (rev. ed. 1969) (1964).

<sup>132</sup> *Whisenhunt v. Spradlin*, 464 U.S. 965, 969 (1983) (Brennan, J., dissenting). Professors Aman and Mayton expand on this explanation with the following:

Using a due-process based prescription of standing rules, the courts, along with trying to assure evenhandedness, have also tried to assure a measure of stability in agency action. They have required agencies to develop, codify, and publish rules so that the private sector is informed

For these reasons, courts have rejected assertions that “a discretion to proceed by *ad hoc* orders rather than by rules is necessary to permit an agency to make decisions finely tuned to the facts and circumstances of an individual case.”<sup>133</sup> For example, in *Soglin v. Kauffman*,<sup>134</sup> several students were expelled by the administration of the University of Wisconsin which applied a ‘misconduct’ standard. In finding that this standard was unconstitutionally vague, the court stated:

No one disputes the power of the University to protect itself by means of disciplinary action against disruptive students. Power to punish and the rules defining the exercise of that power are not, however, identical. Power alone does not supply the standards needed to determine its application to types of behavior or specific instances of ‘misconduct.’<sup>135</sup>

Clearly, “[p]rocedures and hearings offer little protection without such rules and standards as might give content to the hearings.”<sup>136</sup> Or, as the Fifth Circuit has so succinctly stated, “[t]he idea of a hearing is fine. But what is to be heard?”<sup>137</sup>

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of what it can expect from government and manage its affairs accordingly. In this context, a requirement of rules has been described and applied as an aspect of a vagueness doctrine.

But unlike the usual vagueness doctrine case, the claim is not against the statute itself. Rather, the claim is against an agency, for its failure to render a vague statute more specific by implementing it through rules.

AMAN & MAYTON, *supra* note 117, § 3.3, at 72 (footnote omitted).

<sup>133</sup> AMAN & MAYTON, *supra* note 117, § 3.3, at 73. In *Dixon v. Love*, 431 U.S. 105, 114 (1977), the United States Supreme Court maintained that the ability of an agency to suspend a driver’s license by using a subjective decision-making, case-by-case process that turned upon an “ordinary and reasonable care” standard, rather than objective rules, would reduce the fairness of the system. The Court stated that “[t]he decision to use objective rules in this case provides drivers with more precise notice of what conduct will be sanctioned and promotes equality of treatment among similarly situated drivers.” *Id.* at 115.

<sup>134</sup> 418 F.2d 163 (7th Cir. 1969).

<sup>135</sup> *Id.* at 167.

<sup>136</sup> AMAN & MAYTON, *supra* note 117, § 3.3, at 73.

<sup>137</sup> *Block v. Thompson*, 472 F.2d 587, 588 (5th Cir. 1973) (per curiam) (In the absence of specific objective criteria, after a hearing on the pros and cons of granting or denying a privilege, the decision-makers can “take a show of hands and then adapt its decision to this momentary plebiscite.”). This query was echoed by the Seventh Circuit when it stated that “[t]he requirements of due process include a determination of the issues according to articulated standards. The lack of such standards in this case deprives any hearing, whether before an agency or a court, of its meaning and value as an opportunity for the plaintiffs to prove their qualifications for assistance.” *White v. Roughton*, 530 F.2d 750, 754 (7th Cir. 1976); *see also Raper v. Lucey*, 488 F.2d 748 (1st Cir. 1973).

### 3. Fairness of Standards in Peer Review

The lower courts disagree over their ability to enforce this fairness prescription in the context of medical peer review. One group of courts found that specific criteria that can be objectively applied in measuring physician competence are achievable,<sup>138</sup> while another found that such a task is ‘impossible.’<sup>139</sup>

#### a. Fair Notice

The courts’ opinions in *Kiester v. Humana Hospital Alaska, Inc.*<sup>140</sup> and *Wyatt v. Tahoe Forest Hospital District*<sup>141</sup> exemplify the position that clearly articulated standards are possible.<sup>142</sup> The Supreme Court of Alaska in *Kiester* focused on the requirement that a physician be given fair notice of the charges and a meaningful opportunity to refute

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<sup>138</sup> See, e.g., *Kiester v. Humana Hosp. Alaska, Inc.*, 843 P.2d 1219, 1225–26 (Alaska 1992). See also, e.g., *Williams v. Kleaveland*, 534 F. Supp. 912, 917 (W.D. Mich. 1981) (holding that rules established by hospitals to regulate the conduct of doctors must be capable of objective application); *Miller v. Eisenhower Med. Ctr.*, 614 P.2d 258, 265 (Cal. 1980) (finding that rules governing the admission of physicians cannot stand if the standard is “unreasonably susceptible of arbitrary or discriminatory application”); *Martino v. Concord Cmty. Hosp. Dist.*, 43 Cal. Rptr. 255, 258 (Ct. App. 1965) (stating a hospital must set up standards which are clear, not vague, ambiguous or uncertain); *Wyatt v. Tahoe Forest Hosp. Dist.*, 345 P.2d 93, 97 (Cal. Ct. App. 1959) (noting that the standard set up was so vague and uncertain “that admission to the staff can depend on the whim and caprice of the directors”).

<sup>139</sup> See *infra* note 157.

<sup>140</sup> 843 P.2d 1219 (Alaska 1992).

<sup>141</sup> 345 P.2d 93 (Cal. Ct. App. 1959).

<sup>142</sup> Another example is the situation in *Martino v. Concord Community Hospital District*, 43 Cal. Rptr. 255, 259 (Ct. App. 1965). In *Martino*, only those physicians who were competent to provide “the best possible care and professional skill” to patients were permitted on the hospital staff. The hospital committee charged with making this evaluation was given the authority to conduct a hearing and give “such tests, oral and written, as the Credentials Committee shall in its discretion determine.” *Id.* at 256. The court found that this authority gave the committee “a broad and virtually unfettered discretion to subject an applicant to written and oral tests designed to explore every phase of his professional ability, training and experience” and “authorize[d] the credentials committee to require that an applicant take tests covering far more than his competence in his own particular field of medicine.” *Id.* at 259–60. “In determining what tests to require of an applicant and, again, in determining whether an applicant has successfully passed whatever tests it may have required, the credentials committee has no standards to guide it except that it shall admit to staff membership physicians who will provide patients with ‘the best possible care and professional skill’ . . . .” *Id.* at 259–60. The court held that this “vague and ambiguous language” did not furnish the committee with adequate standards. *Id.* at 260. The *Martino* court cited *Rosner v. Eden Township Hospital District*, 375 P.2d 431 (Cal. 1962), for the proposition that a hospital district should not be permitted to adopt standards for the exclusion of doctors from the use of its hospital that are “so vague and ambiguous as to provide a substantial danger of arbitrary discrimination in its application.” *Martino*, 43 Cal. Rptr. at 260 (citing *Rosner*, 375 P.2d at 435).

them. In *Kiester*, the hospital based its decision to deny staff privileges on oral evaluations of the physician's medical competence that concluded that the physician "lacked sufficient medical knowledge."<sup>143</sup> On appeal, the court explained that the "basic principles of due process of law require that criteria established for granting or denying privileges not be vague and ambiguous, and that as established, they be applied objectively."<sup>144</sup> The court went on to hold that "basic principles of due process of law require that when a hospital denies an application for privileges, it notifies the applicant of the specific criteria which were determinative in the denial and how the applicant failed to meet the hospital's expectations with regard to the criteria."<sup>145</sup> The court held that the oral examinations violated due process in that

none of the evaluations establish the level of [medical] knowledge which would be of "sufficient adequacy" or the criteria used to evaluate sufficiency. . . . nor does it attempt to quantify in any way the extent to which an applicant must answer in a satisfactory manner in order to meet standards of training and education or demonstrated competence. Absent such notice, it is impossible for any reviewing body to objectively and independently determine if an applicant has established "competence."<sup>146</sup>

Consequently, according to the *Kiester* view, in order to establish adequate notice, the hospital must identify both the objective criteria that the physician has violated and the manner in which the physician violated the criteria.<sup>147</sup> Both the criteria used to judge competency and the violations should be identified with sufficient clarity to allow the physician to prepare a full and fair defense against the claims of the hospital.<sup>148</sup>

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<sup>143</sup> *Kiester*, 843 P.2d at 1226.

<sup>144</sup> *Id.* at 1225.

<sup>145</sup> *Id.*

<sup>146</sup> *Id.* at 1226 (footnote omitted). See also *Martino*, 43 Cal. Rptr. at 259-60.

<sup>147</sup> *Kiester*, 843 P.2d at 1225. See also *Garrow v. Elizabeth Gen. Hosp. & Dispensary*, 401 A.2d 533 (N.J. 1979):

Fundamental fairness dictates that the hospital apprise the physician of the specific charges and that the applicant be afforded the opportunity to appear and present witnesses and material in support of his position and to contradict or explain the bases asserted for the proposed denial. Such hearings in addition to affording the doctor an opportunity to respond to charges enable a hospital to make "an intelligent and reasonable judgment in good faith upon all the facts presented."

*Id.* at 541 (quoting *Sussman v. Overlook Hosp. Ass'n*, 231 A.2d 389, 393 (N.J. Super. 1967)).

<sup>148</sup> *Christenson v Mount Carmel Health*, 678 N.E.2d 255, 262-63 (Ohio Ct. App. 1996); but see *Yashon v. Hunt*, 825 F.2d 1016, 1017-18 (6th Cir. 1987) (physician was

Under HCQIA, in order for the participants in the peer review process to be granted immunity, the physician must have received adequate notice. Specifically, HCQIA requires that the physician be told the “reasons for the proposed action.”<sup>149</sup> Applying the *Kiester* rationale that describes the key elements of fundamentally fair proceedings, when the hospital supplies the “reasons for the proposed action” under HCQIA, the hospital must identify both the objective criteria that the physician has violated and the manner in which the physician violated the criteria. Absent these clearly articulated, objective criteria, all of the participants in the peer review process will be denied HCQIA immunity.

b. Arbitrary and Capricious Application

Alternatively, the California Court of Appeal in *Wyatt* focused on the failure of a standard to provide any restrictions on the discretion of the hospital’s directors. In *Wyatt*, only physicians and surgeons who, in the judgment of the board, would provide the “best possible care and professional skill” were granted staff privileges.<sup>150</sup> The court quizzically asked: “What is the best possible care and professional skill? Would it limit the practice of medicine in the Tahoe District Hospital to physicians and surgeons who are recognized authorities in their respective fields?”<sup>151</sup> The court concluded:

The standard set up is such that admission to the staff can depend on the whim and caprice of the directors. A hospital district in the exercise of its duty to prescribe reasonable rules and regulations must set up standards or qualifications for those who wish to serve in the hospital which are general but not arbitrary or discriminatory. . . . The rule enacted by the board of directors of respondent hospital does not meet this test and as such may not be used to exclude appellant.<sup>152</sup>

While concluding that the standards used in the peer review proceedings by the hospitals in *Kiester* and *Wyatt* were impermissibly vague, these courts did not give any guidance on how to create clearly articu-

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barred from representation by a lawyer, was not presented with an opportunity to produce witnesses on his behalf, was charged with conduct when the same conduct had been part of prior hearings where he was exonerated and was not presented with a written decision setting forth the findings of the peer review panel, all under a process with no written guidelines or standards).

<sup>149</sup> 42 U.S.C. §11112(b)(1) (2000).

<sup>150</sup> *Wyatt v. Tahoe Forest Hosp. Dist.*, 345 P.2d 93, 97 (Cal. Ct. App. 1959).

<sup>151</sup> *Id.*

<sup>152</sup> *Id.* (citation omitted).

lated standards. Is the creation of such standards possible? Many courts answer this question in the negative.<sup>153</sup>

c. Feasibility of Clearly Articulated Standards

Representative of those courts which take the position that it is not possible, or desirable, to create clearly articulated standards to evaluate physician competence is the case of *Jackson v. Fulton-DeKalb Hospital Authority*.<sup>154</sup> In *Jackson*, a physician appealed the suspension of his surgical privileges which were found by the hospital to be “detrimental to the maintenance of *proper standards* of medical care.”<sup>155</sup> The United States District Court for the Northern District of Georgia upheld the suspension in the face of a challenge that the standard was “impermissibly vague and arbitrary.”<sup>156</sup> In doing so, the court threw up its hands in defeat, thereby abdicating its obligation to ensure that the peer review process conforms to basic principles of fairness:

“[I]n the area of personal fitness for medical staff privileges precise standards are difficult if not impossible to articulate. . . . The subjectives of selection simply cannot be minutely codified. The governing board of a hospital must therefore be given great latitude in prescribing the necessary qualifications for potential applicants.”<sup>157</sup>

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<sup>153</sup> See *infra* notes 154–60 and accompanying text.

<sup>154</sup> 423 F. Supp. 1000 (N.D. Ga. 1976); see also *Klinge v. Lutheran Charities Ass’n*, 523 F.2d 56, 59–60 (8th Cir. 1975) (hearing panel terminated staff privileges finding that the surgeon failed to exercise the degree of care and skill that a reasonably careful and skilled surgeon would have exercised and failed to possess the degree of care and skill ordinarily possessed by reasonably skilled surgeons).

<sup>155</sup> *Jackson*, 423 F. Supp. at 1005 (emphasis added); see also *Koelling v. Bd. of Trs. of Mary Francis Skiff Mem’l Hosp.*, 146 N.W.2d 284 (Iowa 1966) (failure to provide “adequate medical care” as judged by an in-house standard).

<sup>156</sup> *Jackson*, 423 F. Supp. at 1005; see also *Miller v. Indiana Hosp.*, 419 A.2d 1191, 1192–94 (Pa. Super. Ct. 1980) (finding, in peer review matter where physician’s staff privileges were terminated for providing “inadequate care” or care that fell “below that which should be acceptable in any hospital,” that notice to the physician was not vague as the charges were sufficiently precise).

<sup>157</sup> *Jackson*, 423 F. Supp. at 1005 (quoting *Sosa v. Bd. of Managers of the Val Verde Mem’l Hosp.*, 437 F.2d 173, 176 (5th Cir. 1971)). It is interesting that the *Jackson* court took this quote directly from the Fifth Circuit’s opinion in *Sosa*. In *Sosa*, a physician was denied privileges based on his character. The hospital’s position was that the physician had an inability to work well with others and had questionable ethics. 437 F.2d at 175. In this context, the court of appeals stated that “standards such as ‘character qualifications and standing’ are very general, but this court recognizes that *in the area of personal fitness* for medical staff privileges precise standards are difficult if not impossible to articulate.” *Id.* at 176 (emphasis added). This finding, made in the context of personal character fitness, was then grafted into subsequent court opinions, such as the one in *Jackson*, dealing with the measure of competency of the



The court went on to explain this relinquishment, maintaining that broad standards are preferable in that a “[d]etailed description of prohibited conduct is concededly impossible, perhaps even undesirable, in view of rapidly shifting standards of medical excellence and the fact that a human life may be and quite often is involved in the ultimate decision of the board.”<sup>158</sup>

The reasoning of the *Jackson* opinion illustrates the perspective of courts which generally acknowledge the inherent unfairness of ap-

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medical care for patients. None of the reasoning of the courts in this line of cases accounts for the leap in application of this ‘impossibility’ conclusion from character fitness situations to the measurement of competence in the provision of medical care.

<sup>158</sup> *Jackson*, 423 F. Supp. at 1005–06 (quoting *N. Broward Hosp. Dist. v. Mizell*, 148 So. 2d 1, 5 (Fla. 1962)). In *North Broward*, the hospital’s Board of Commissioners terminated staff privileges under a by-law giving it “the right to remove any member of the medical staff or to deprive any physician or surgeon of the privileges of the hospital whenever in their sole judgment the good of the hospital or the patients therein may demand it.” *North Broward*, 148 So. 2d. at 2. The court found that this broad discretion was warranted, stating that “[a]n exception from the strict requirements of legislative prescription is often recognized in the area of determination of personal fitness.” *Id.* at 5.

Another line of cases dealing with medical licensure arguably follows this rationale. For example, in *Braun v. Board of Dental Examiners*, 702 A.2d 124 (Vt. 1997), the Vermont Supreme Court upheld a vagueness challenge by a dentist who was disciplined under a Vermont statute for a “gross failure to uphold the standard of care.” *Id.* at 129. The conduct at issue was the delegation of the diagnosis of a patient’s condition to a dental assistant by the dentist. *Id.* at 126. The court explained its position by stating that:

[I]t is not necessary, or possible, for a statute that regulates a professional field to detail each and every act that is prohibited.

[A]ny board or body whose duty it is to pass upon the qualifications of licenses of the various professions . . . must do so by applying some broad and necessarily general standards.

*Id.* at 129 (second and third alterations in original) (citations omitted). However, in *Braun*, the broad “gross failure” licensure standard was saved by the fact that it was given definition by a separate state standard of care statute that expressly prohibited the delegation of diagnosis to a dental assistant. *Id.* at 127.

The licensure situation can be distinguished from peer review. In comparison to peer review, in cases involving licensure, the risk to fairness is posed more by notice problems than by arbitrary and capricious decision-making. In peer review, the risk to fairness is posed by both of these vagueness concerns equally. For example, the decision-makers in licensure cases are administrative officials who are most likely to have had little to no prior dealings or involvement with the targeted physician. With peer review, the likelihood that the decision-makers have had, and currently have, both personal and economic dealings with the targeted physician are high. Thus, in peer review, the risk to fairness is posed by both notice and arbitrary capriciousness concerns. Other conflicts of interests, such as a desire to conform to the wishes of the executive committee, or other powerful members of the hospital staff, to terminate the targeted physician may be at play. While vagueness concerns are important in both proceedings, the risks to a fair process are greater in peer review, requiring much greater clarity in the standards used.

plying a broad standard of care measure, yet conclude that this unfairness is unavoidable as judging physician competency is a purely subjective exercise.<sup>159</sup> Some courts, like the *Jackson* court, go so far as to question the advisability of even engaging in the attempt to articulate clear and objective criteria, finding that the establishment of objective criteria would somehow be incapable of timely revision to reflect scientific advancements.<sup>160</sup> While the courts focus on the impact of dated standards on patient safety, this quick rate of obsolescence also raises the specter that judgments regarding physician competence could be based on bad data. Thus, standards based on clear objective criteria, while being less vague, may well be arbitrary.

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<sup>159</sup> See, e.g., *Kaplan v. Carney*, 404 F. Supp. 161, 164–65 (E.D. Mo. 1975). In *Kaplan*, the plaintiff contended that he was denied due process in a peer review proceeding “because there were no guidelines or objective criteria governing the standard to which he was accountable.” *Id.* at 164. The standards that were used to judge the plaintiff’s performance included “that of acceptability in reference to the Hospital’s staff; the general standards of this country; the standards of the area; the standards of the hospital; or the standards of acceptability to the Executive Committee.” *Id.* Apparently in response to the multiple standards used by the hospital, an independent review panel which the hospital had consulted in the case, the Health Care Foundation of Missouri, Inc., recommended that “the hospital set up policies of audit and peer review so that there are standards of statistical validity by which a physician’s performance can be measured . . . standards of practice for the hospital should be available in written form and all physicians in the hospital measured against them.” *Id.* at 163. In spite of the position of these physicians that clearly articulated standards were feasible, the court in *Kaplan* held that “[w]hile it would perhaps be advantageous to have the Hospital establish definite standards, this court is unable to conclude that the standards employed by defendants are so unreasonable, arbitrary, or capricious as to amount to a denial of due process. Precise standards of competency would be difficult to establish . . .” *Id.* at 165. See also *Gaenslen v. Bd. of Dirs. of St. Mary’s Hosp. & Med. Ctr.*, 232 Cal. Rptr. 239, 242, 245 (Ct. App. 1985) (opining that standard that excluded physicians from staff privileges who did not provide “high quality” care was not vague, as those who made the determination of whether the standard was met were familiar with the standard of medical care in the community and in the hospital); *Huffaker v. Bailey*, 540 P.2d 1398, 1399–1401 (Or. 1975) (quoting *Sosa*, 437 F.2d at 176 (stating that the requirement that physicians provide a “high quality of medical care” is admittedly general but a more precise standard would be “difficult if not impossible to articulate”); *Edson v. Griffin Hosp.*, 144 A.2d 341, 344 (Conn. Super. Ct. 1958)). See generally *Dorr*, *supra* note 125.

<sup>160</sup> *Jackson*, 423 F. Supp. at 1005–06. “A ‘[d]etailed description of prohibited conduct is concededly impossible, perhaps even undesirable in view of rapidly shifting standards of medical excellence and the fact that a human life may be and quite often is involved in the ultimate decision of the board.” *Gaenslen*, 232 Cal. Rptr. at 243 (quoting *Britton v. Humphreys Mem’l Hosp.*, 370 So. 2d 433, 434 (Fla. Dist. Ct. App. 1979)); see also *Moore v. Bd. of Trs. of Carson-Tahoe Hosp.*, 495 P.2d 605, 607–09 (Nev. 1972) (finding that a by-law that allowed for termination for “unprofessional conduct” provided sufficient notice to physician and that a more detailed standard was unwise in light of rapidly changing standards of medicine). It should be noted that this argument also cuts the other way with regard to notice to the physician.

Most of this group of cases hold by implication that, on balance, as no fair standard can be formulated, it is better to allow competent physicians to be unfairly denied hospital staff privileges than to allow potential harm to the public by unlimited access to hospitals without regard to clinical competence.<sup>161</sup> One court explained this balancing in light of

[a common] procedure employed for appointment whereby members of the Active Staff (generally older, more established practitioners), hold the lifeline on the younger doctors by virtue of the fact that their recommendation is required for appointment. This, it is argued, grants the exclusive use of a tax supported institution to the doctors who agree among themselves that they are the most competent. . . .

On analysis, however, the suggested evils of the 'oligarchy' of the Active Staff leave less to fear than the alternative prospect of potential public harm arising from unlimited access to hospital facilities by licensed physicians without regard to clinical ability.<sup>162</sup>

This split in the lower courts raises three questions: First, overall, just how vague are the standards being used in peer review to evaluate clinical competence? Second, as a policy matter, does the utilization of these standards both properly balance the interests of the stakeholders and further the goals of peer review? Finally, if the standards currently being used to measure clinical competence are impermissibly vague, improperly skew the balance between stakeholders' interests and fail to further the goals of peer review, is it possible to create clearly articulated standards that both properly balance the interests at stake and further the goals of peer review?<sup>163</sup> The remainder of this Article attempts to deal with these questions.

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<sup>161</sup> *Dayan v. Wood River Twp. Hosp.*, 152 N.E.2d 205, 207–08 (Ill. App. Ct. 1958).

<sup>162</sup> *Id.* Another line of cases deals with contentions that the standard of measurement of physician competence is impermissibly vague by relying on what appears to be a variation on the business judgment rule. In *Marin v. Citizens Memorial Hospital*, 700 F. Supp. 354 (S.D. Tex. 1988), the targeted physician complained that there was no objective standard of competency for physicians at the hospital. *Id.* at 359. The court considered this complaint to be irrelevant, finding that "the pertinent question is whether the evidence relied upon by the Hospital was reasonably related to the operation of a hospital and its attending medical staff." *Id.* (citing *Yashon v. Hunt*, 825 F.2d 1016, 1025 (6th Cir. 1987)).

<sup>163</sup> These questions parallel the vagueness analysis most courts follow in the context of vagueness challenges to criminal statutes. See generally Robert Batey, *Vagueness and the Construction of Criminal Statutes—Balancing Acts*, 5 VA. J. SOC. POL'Y & L. 1 (1997):

In resolving questions under the vagueness doctrine, courts must first evaluate whether the allegedly deficient language raises problems of fair notice of the requirements of criminal law or of arbitrary and discriminatory enforcement by police or prosecutors. If there is suffi-

VI. 'STANDARD OF CARE' MEASUREMENTS AND VAGUENESS  
PRINCIPLES IN PEER REVIEW

As previously stated, the peer review process is usually triggered by the report of an event or series of events that raises questions about a physician's clinical competence.<sup>164</sup> The standards used to measure clinical competence by various hospitals across the country appear to fall generally into three basic categories: those which grant absolute discretion to the decision-makers; those which rely on customary care as practiced in the hospital or in some broader medical community; and, those which rely on general negligence standards.

The first two categories of standards act principally to broadly protect a hospital's general autonomy in making staffing decisions. These standards are so vague that they provide little or no protection either to physicians' interests in practicing their profession or to patients' interests in choosing their own physician.

The third category, which includes those standards which incorporate general negligence doctrine, is currently almost as problematic. However, these standards at least have the potential to provide some measure of notice to physicians and to place some limits on the discretion of the administrative decision-makers. This potential depends on adding a simple qualifier which pins down the locality from which evidence of customary care is to be drawn. Unfortunately, under the current system of evaluating physician competence, this modification, which enhances the protection of physicians' interests, comes with the downside of negatively impacting the quality of pa-

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cient concern on either of these fronts, a judge should balance the *necessity* for the ambiguous language to achieve the legislative goal against the chilling effect of the ambiguity on protected or desirable conduct.

*Id.* at 25–26 (emphasis added). Necessity, of course, implies that alternative, more precise, language is not feasible. *Id.* at 9. If there is other language that both achieves the goals of the legislation at issue and provides greater notice and limits on discriminatory enforcement, the statute is not likely to pass muster. *See id.* "Courts and other legal analysts implicitly signal their understanding of the centrality of balancing when they speak of the tolerability of ambiguity in a particular statutory provision. Toleration implies an acceptance of certain negative consequences because they are outweighed by positive ones." *Id.* at 8. It is important to note that the significance of the legislative goal is a factor:

[T]here is in effect a multiplier, which increases the tolerability of arguably vague language when the legislature enacted the language in pursuit of policies the court considers important. Of course, this is a baldly political assessment, not one that judges (even elected ones) are expected to perform, which is likely why judges are virtually silent about this aspect of the weighing of necessity.

*Id.* at 10 (footnote omitted).

<sup>164</sup> *See supra* note 65 and accompanying text.

patient care. Thus, all of the types of standards used under the current system of evaluating physician competence fail to achieve a proper balance between the interests of the stakeholders in the process.

A. *Standards Granting Absolute Discretion to the Hospital*

The most obvious example of a standard that expressly vests complete and unfettered discretion in decision-makers is one which gives a hospital's governing body "the right to remove any member of the medical staff or to deprive any physician or surgeon of the privileges of the hospital whenever in their sole judgment the good of the hospital or the patients therein may demand it."<sup>165</sup> Also included in this category are those by-laws which are less blatant but, in application, still call for a purely subjective determination. These standards define the required level of competence as that which the decision-makers determine is the "best possible care,"<sup>166</sup> or "adequate medical care"<sup>167</sup> or "high quality medical care."<sup>168</sup>

None of the standards in this category contain any limits on the discretion of decision-makers. Nor do they provide any notice to physicians of what conduct will satisfy or violate the competency requirement.<sup>169</sup> This allows the administrative decision-makers the flexibility to define incompetence in a 'we know it when we see it'

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<sup>165</sup> N. Broward Hosp. Dist. v. Mizell, 148 So. 2d 1, 2-5 (Fla. 1962); *see also* Tasher v. St. Tammany Parish Hosp., No. 87-1139, 1988 U.S. Dist. LEXIS 1018, \*5 (E.D. La. 1988) (executive committee had complete discretion to summarily suspend privileges "whenever action must be taken immediately in the best interest of patient care in the hospital"; this same broad standard was applied at the post-deprivation hearing).

<sup>166</sup> Wyatt v. Tahoe Forest Hosp. Dist., 345 P.2d 93, 95 (Cal. Ct. App. 1959) (only physicians and surgeons who, in the judgment of the board, would provide the "best possible care and professional skill" were granted staff privileges); *see also* Duby v. Jordan Hosp., 341 N.E.2d 876, 880 (Mass. 1976) (hospital, "in judging the [physician's] professional competence[,] required that he give his patients the 'best possible care'"); Huffaker v. Bailey, 540 P.2d 1398, 1399 (Or. 1975) (physician must provide to patients "a high quality of medical care").

<sup>167</sup> Koelling v. Bd. of Trs. of Mary Francis Skiff Mem'l Hosp., 146 N.W. 2d 284, 296-97 (Iowa 1966) (failure to provide 'adequate' medical care); *see also* Bock v. John C. Lincoln Hosp., 702 P.2d 253, 255 (Ariz. Ct. App. 1985) (physician's staff privileges were terminated because Executive Committee determined that the physician "failed to demonstrate to the Medical Committee that [he was] qualified to practice as an Internal Medicine specialist.").

<sup>168</sup> Gaenslen v. Bd. of Dir. of St. Mary's Hosp. & Med. Ctr., 232 Cal. Rptr. 239, 242 (Ct. App. 1985) (standard that excluded physicians from staff privileges who did not provide "high quality" care); Huffaker, 540 P.2d at 1399-401 (requirement that physicians provide a "high quality of medical care").

<sup>169</sup> *See* Moore v. Bd. of Trs. of Carson-Tahoe Hosp., 495 P.2d 605, 607-09 (Nev. 1972) (by-law that allowed for termination for "unprofessional conduct").

fashion, creating the real possibility that the standard could be a moving target, varying with the make-up of the deciding body. The list of process protections that most hospitals now provide and are required under HCQIA, such as a hearing and the right to counsel,<sup>170</sup> are all empty formalities if, after the proceedings are completed, the decision-makers can decide to take whatever action their personal inclinations dictate. Physicians' interests in the ability to practice their profession and patients' interests in choosing their own physicians find little to no protection in these standards. Thus, the standards which fall into this category appear to be vague on their face.

This type of broad standard also creates the greatest risk that decisions to exclude certain physicians could be made based on reasons having nothing to do with the interests of patient safety.<sup>171</sup> These reasons could be economic,<sup>172</sup> personal dislike,<sup>173</sup> or discriminatory in nature.<sup>174</sup> The immunity protections put into place by both HCQIA and state immunity legislation result in a loss of access to the judicial system by these aggrieved physicians. If peer review is being used for purposes unrelated to quality of care, then this loss of legal recourse is unjustified.

Tying into this consideration is the fact that these vague standards raise questions about the meaningfulness of judicial review. As the court in *Kiester* described, absent clearly articulated criteria, "it is impossible for any reviewing body to objectively and independently determine if an applicant has established 'competence.'"<sup>175</sup> Thus, courts will be unable to determine if the peer review result was driven by considerations unrelated to the quality of patient care.

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<sup>170</sup> See *supra* Part IV.

<sup>171</sup> As HCQIA immunity was put into place to encourage peer review that enhanced the quality of patient care while at the same time protecting physicians' interests, it is questionable whether peer review proceedings that act merely to protect hospital autonomy in decision-making should enjoy HCQIA protections. This type of standard coupled with HCQIA immunity unjustifiably cuts off a physician's ability to challenge staffing decisions unrelated to quality of care concerns through a judicial appeal.

<sup>172</sup> See generally John D. Blum, *Economic Credentialing: A New Twist in Hospital Appraisal Process*, 12 J. LEGAL MED. 427 (1991); John D. Blum, *Hospital-Medical Staff Relations in the Face of Shifting Institutional Business Strategies*, 14 U. PUGET SOUND L. REV. 561 (1991); Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431 (1988); Judith E. Orie, *Economic Credentialing: Bottom-Line Medical Care*, 36 DUQ. L. REV. 437 (1998).

<sup>173</sup> See generally PEER REVIEW GUIDEBOOK, *supra* note 60, at app. B.

<sup>174</sup> See, e.g., *id.*, at app. A.

<sup>175</sup> *Kiester v. Humana Hosp. Alaska, Inc.*, 843 P. 2d 1219, 1226 (Alaska 1992).

*B. In-House Standards*

The second category includes what this Article refers to as ‘in-house’ standards. Examples that fall into this category include holding physicians to a standard of care as measured by the “[hospital’s] standard of competence”<sup>176</sup> or the “standard of the hospital or the medical staff”<sup>177</sup> or “the general standards of the surgical committee.”<sup>178</sup> These standards are referred to as ‘in-house’ standards as one interpretation is that these standards refer to the standard of care that is practiced within the hospital itself. Another interpretation is that these standards give the medical staff or hospital the freedom to choose a standard of care from among those practiced by the general medical community outside the hospital. While both interpretations bring their own unique set of problems to peer review, both contain the same flawed reliance upon customary care as a marker for quality patient care.

1. Problems with the Customary Care Measurement of Physician Competence

Generally, when a physician is referring to the standard of care for a particular condition under a particular set of circumstances, the physician is referring to that care which would customarily be given by other physicians under the same or similar circumstances. Based on this customary care referent, an argument could be made that the standards which fall into this category provide greater clarity, and therefore, greater notice to physicians of what conduct is sanctionable. In addition, this clarity arguably brings with it a greater limitation on the decision-makers’ ability to terminate staff privileges based on personal predilections unrelated to the quality of patient care. These arguments are based on two highly questionable presump-

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<sup>176</sup> *Adkins v. Sarah Bush Lincoln Health Ctr.*, 544 N.E.2d 733, 736 (Ill. 1989) (physician’s treatment of patients failed to conform to “the Center’s standard of competence”).

<sup>177</sup> *Campbell v. St. Mary’s Hosp.*, 252 N.W.2d 581, 588 (Minn. 1977) (corrective action appropriate when “professional conduct of any member of the staff shall be considered to be lower than the standard of the hospital or the medical staff . . .”); *see Helling v. Carey*, 519 P.2d 981, 983 (Wash. 1974); *see also* DAN B. DOBBS, *THE LAW OF TORTS* § 242, at 633 (1st ed. 2000).

<sup>178</sup> *Rhee v. El Camino Hosp. Dist.*, 247 Cal. Rptr. 244, 246, 248–49, (Ct. App. 1988) (Newly minted surgeon who had excellent credentials and training evaluations during his residency ran afoul of a group of surgeons in the hospital where he started his practice. Members of this group of physicians both served on the peer review panels charged with judging whether the new surgeon met this in-house standard and testified that the new surgeon “did not ‘meet the general standards of the surgical community at El Camino Hospital . . .’”).

tions. First, they presume that there are standards of care for the diagnosis and treatment of medical conditions that are commonly known, and agreed upon, in the medical community. Second, they presume that adherence to these customs does in fact further the quality of patient care.

However, numerous studies raise serious questions regarding the existence of knowable 'customary care' for many medical conditions.<sup>179</sup> Other studies point out that, to the extent some customary care exists, many of those customs have been detrimental to the quality of patient care.<sup>180</sup> Finally, a whole body of scientific evidence concludes that the rate of physician agreement on what care actually is quality patient care is only slightly above that which would be expected from chance.<sup>181</sup>

a. The Fiction of Customary Medical Care

A series of startling scientific studies raises the question of whether the concept of 'customary care' is, in fact, a fiction.<sup>182</sup> These studies reveal striking and unjustifiable variations in the choices that physicians made in the diagnosis and treatment of the same clinical condition.<sup>183</sup> These variations were observed both between regions, and, in some cases, between providers in the same locale.<sup>184</sup> "This observed variation in practice approaches implies either that practitioners do not really know what works in medicine and, so, are just 'fir-

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<sup>179</sup> See *infra* notes 182–87 and accompanying text.

<sup>180</sup> See *infra* notes 188–96 and accompanying text.

<sup>181</sup> See *infra* note 203 and accompanying text.

<sup>182</sup> Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, LAW & CONTEMP. PROBS., Spring 1991, at 87, 88 [hereinafter Havighurst, *Practice Guidelines as Legal Standards*].

<sup>183</sup> Mark A. Hall & Michael D. Green, Introduction, 37 WAKE FOREST L. REV. 663, 670–71 (2002) (citing Bruce E. Landon et al., *Personal, Organizational, and Market Level Influences on Physician Practice Patterns: Results of a National Survey of Primary Care Physicians*, 39 MED. CARE 889, 889 (2001) (failing to find, through the use of clinical vignettes, any evidence of "a consistent practice style" for certain common discretionary medical decisions)).

<sup>184</sup> See generally Mark R. Chassin et al., *Variations in the Use of Medical and Surgical Services by the Medicare Population*, 314 NEW ENG. J. MED. 285, 287 (1986) (measuring variation in rates of use by Medicare beneficiaries); David M. Eddy, *Variations in Physician Practice: The Role of Uncertainty*, HEALTH AFF., Fall 1984, at 74, 77–80 (detailing physician variations in choice of diagnosis and of procedure); John E. Wennberg, *Dealing With Medical Practice Variations: A Proposal For Action*, HEALTH AFF., Summer 1984, at 6, 7 (variations in surgical procedures and medical treatments were documented); John E. Wennberg et al., *Professional Uncertainty and the Problem of Supplier-Induced Demand*, 16 SOC. SCI. MED. 811, 812–17 (1982) (detailing differences in surgical practices); John Wennberg & Alan Gittelsohn, *Small Area Variations in Health Care Delivery*, 182 SCI. 1102 (1973).



ing blind,' or else that some do know what works and are doing it right while others, for some reason, are not."<sup>185</sup> For example,

in Maine, by the time women reach seventy years of age in one hospital market the likelihood they have undergone a hysterectomy is 20 percent while in another market [it] is 70 percent. In Iowa, the chances that male residents who reach age eighty five have undergone prostatectomy range from a low of 15 percent to a high of more than 60 percent in different hospital markets. In Vermont the probability that resident children will undergo a tonsillectomy has ranged from a low of 8 percent in one hospital market to a high of 70 percent in another.<sup>186</sup>

Thus, "to ask an expert . . . what the 'customary practice' is [for a particular condition] on a national basis . . . is to ask a question to which there cannot be, for many diagnosis and treatment decisions, a coherent answer."<sup>187</sup>

The most recent studies describing the disparity in treatment choices for the same condition between physicians are based on data collected in 2004.<sup>188</sup> This data shows that doctors and hospitals "fail with alarming frequency to deliver essential life-saving treatments for some of the most common causes of death—heart attack, pneumonia

<sup>185</sup> Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369, 371 (1995); see also Havighurst, *Practice Guidelines as Legal Standards*, *supra* note 182, at 89 ("These revelations undermined one of the crucial premises on which the health care industry has long operated—namely, the assumption that, by and large, individual physicians are guided by medical science and the norms and standards of their profession to pursue appropriate courses of diagnosis and treatment.").

<sup>186</sup> Wennberg, *supra* note 184, at 9.

<sup>187</sup> James F. Blumstein, *The Legal Liability Regime: How Well Is It Doing In Assuring Quality, Accounting for Costs, and Coping with an Evolving Reality In The Health Care Marketplace*, 11 ANNALS HEALTH L. 125, 137 (2002).

<sup>188</sup> Ford Fessenden, *It's the Simple Things, but Some Hospitals Don't Do Them*, N.Y. TIMES, Aug. 21, 2005, § 4, at 43. This study was made possible by section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). Pub. L. No. 108-173, 117 Stat. 2066 (to be codified in scattered sections of 26 U.S.C., 42 U.S.C.). Under the MMA,

[b]eginning with discharges in 2004, eligible acute care hospitals could elect to report quality data in order to receive the incentive payment established by [MMA]. To obtain increased payment, the provision requires eligible hospitals to report on an initial set of 10 quality performance measures . . . and to agree to have their data publicly displayed.

United States Department of Health & Human Services, Hospitals Compare, <http://www.hospitalcompare.hhs.gov/Hospital/Static/Data-Professionals.asp> [hereinafter Hospital Quality Alliance Project], (last visited Apr. 29, 2006). This project is called the Hospital Quality Alliance Project. *Id.*

and heart failure . . . .”<sup>189</sup> For example, patients who are given aspirin within the first twenty-four hours after a heart attack may have up to a thirty percent increase in the rate of survival.<sup>190</sup> However, of 3500 hospitals studied, physicians in those hospitals failed to give aspirin to one out of every sixteen patients.<sup>191</sup> In 2004, a total of 12,000 patients in these hospitals alone did not receive this simple life-saving treatment.<sup>192</sup> The report shows there is a wide variation, from state to state, from hospital to hospital and from physician to physician within the same hospital, in whether it is customary to provide this life saving treatment or whether it is customary not to provide the treatment.<sup>193</sup> For example, the data showed that the hospitals studied in Massachusetts provided this treatment ninety-seven percent of the time,<sup>194</sup> whereas the hospitals in Arkansas provided the treatment only eighty-five percent of the time.<sup>195</sup> In most states, some hospitals provided the treatment one-hundred percent of the time, while other hospitals in the same community provided it only fifty percent of the time.<sup>196</sup>

This body of research undermines the position that the term ‘standard of care’ is given clarity by reference to customs that are generally known, and agreed upon, in the medical profession.

b. Customary Care: An Appropriate Quality Measure?

In addition to the studies that question the existence of known customs, a separate line of studies reveals “serious weaknesses in the scientific underpinnings of many customary practices”<sup>197</sup> and the

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<sup>189</sup> Fessenden, *supra* note 188 (citing Hospital Quality Alliance Project).

<sup>190</sup> *Id.*

The heart is a muscle that gets oxygen through blood vessels. Sometimes blood clots can block these blood vessels, and the heart can't get enough oxygen. This can cause a heart attack. Chewing an aspirin as soon as symptoms of a heart attack begin may help reduce the severity of the attack.

Hospital St. Luke's Hospital, Reports on Patient Care Quality – Heart Attack Core Measures, [http://www.stlukes-stl.com/patient\\_care/chart\\_heart\\_attack.html](http://www.stlukes-stl.com/patient_care/chart_heart_attack.html) (last visited Apr. 28, 2006).

<sup>191</sup> Fessenden, *supra* note 188.

<sup>192</sup> *Id.*

<sup>193</sup> *Id.*

<sup>194</sup> *Id.*

<sup>195</sup> *Id.*

<sup>196</sup> *Id.*

<sup>197</sup> Havighurst, *Practice Guidelines as Legal Standards*, *supra* note 182, at 88–89 & n.6 (citing, for example, David M. Eddy & John Billings, *The Quality of Medical Evidence: Implications for Quality of Care*, HEALTH AFF., Spring 1988, at 19, 20 (“[F]or at least some important practices, the existing evidence is of such poor quality that it is virtu-

“substantial overuse of many medical and surgical procedures.”<sup>198</sup> For example, the use of certain respiratory techniques and gastric freezing of ulcers, which were quickly adopted as ‘standard practice,’ were ultimately discredited by scientific studies.<sup>199</sup> In addition, there are wide variations in the use of “laboratory tests, prescription drugs, X-rays, return appointments, and telephone consultations among similarly trained doctors in a wide variety of practice settings. Research on appropriateness indicates that from one quarter to one third of medical services may be of no value to patients.”<sup>200</sup>

For example, one study on the insertion of pacemakers in a large group of individuals indicated that “44% of the implants were definitely indicated, 36% possibly indicated, and 20% were not indicated.”<sup>201</sup> Another example is a study which demonstrated that carotid endarterectomies, which remove blood clots in the arteries leading to the brain, were only indicated in thirty-two percent of the cases reviewed.<sup>202</sup>

c. Level of Physician Agreement on Quality Patient Care

Compounding this problem is a series of studies conducted in the 1990s which concluded that “physician agreement regarding quality of care is only slightly better than the level expected by

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ally impossible to determine even what effect the practice has on patients, much less whether that effect is preferable to the outcomes that would have occurred with other options.”); David M. Eddy, *Clinical Policies and the Quality of Clinical Practice*, 307 NEW ENG. J. MED. 343, 343 (1982) (“[T]here is reason to believe that there are flaws in the process by which the profession generates clinical policies.” (alteration in original))).

<sup>198</sup> *Id.* at 88–89 & n.7 (quoting Robert Brook et al., *Predicting the Appropriate Use of Carotid Endarterectomy, Upper Gastrointestinal Endoscopy, and Coronary Angiography*, 323 NEW ENG. J. MED. 1173, 1173 (1990) (“[W]e concluded that 17 percent of coronary angiographies, 17 percent of endoscopies, and 32 percent of endarterectomies represented inappropriate overuse [using a liberal standard].” (alterations in original))).

<sup>199</sup> BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 33 (5th ed. 2001) [hereinafter FURROW ET AL., CASEBOOK].

<sup>200</sup> *Id.* at 34 (citing Robert Brook & Kathleen Lohr, *Will We Need To Ration Effective Medical Care?*, ISSUES IN SCI. & TECH., Fall 1986, at 68. Another study found a “seventeen-fold variation in lab use among internists dealing with clinical patients.” FURROW ET AL., CASEBOOK, *supra* note 199, at 34 (citing Steven A. Schroeder et al., *Use of Laboratory Tests and Pharmaceutical Variation Among Physicians and Effect of Cost Audit on Subsequent Use*, 225 J. AM. MED. ASS’N 969 (1973)).

<sup>201</sup> FURROW ET AL., CASEBOOK, *supra* note 199, at 34 (citing Lee Goldman et al., *Costs and Effectiveness of Routine Therapy with Long-Term Beta-Adrenergic Antagonists After Acute Myocardial Infarction*, 319 NEW ENG. J. MED. 52 (1988)).

<sup>202</sup> Mark R. Chassin et al., *Does Inappropriate Use Explain Geographic Variations In The Use Of Health Care Services? A Study Of Three Procedures*, 258 J. AM. MED. ASS’N 2533, 2533–37 (1987).

chance.”<sup>203</sup> The conclusions drawn by these studies are not surprising in light of the remarkably wide variation in practices utilized by physicians evidenced by the studies described in the prior sections.

These studies on the variation and effectiveness of customary treatment and the very low level of agreement among physicians regarding what care is quality care, raise serious questions regarding the appropriateness of the use of customary care as evidence of physician competence.

## 2. In-House Standards in Peer Review: Internal Customs

Over and above the questions regarding the use of customary care as a measurement of physician competence are the problems associated with applying an in-house measurement in peer review. Many of these problems can be identified by the lessons learned by the use of customary care evidence in medical malpractice litigation.

In a medical malpractice case, in order to meet the ‘standard of care,’ a physician must “possess and use the care, skill and knowledge ordinarily possessed and used under like circumstances . . . .”<sup>204</sup> The majority rule is that conclusive evidence<sup>205</sup> of this failure occurs when the physician does not take the same actions customarily taken by other physicians in similar circumstances.<sup>206</sup> The medical malpractice law of the different states varies with regard to the locality from which they draw their customary practices. States have chosen to apply the customs followed by the practitioners in the local community under the “same locality rule”<sup>207</sup> or another community under the “similar

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<sup>203</sup> Ronald L. Goldman, *The Reliability of Peer Assessments of Quality of Care*, 267 J. AM. MED. ASS’N 958, 958 (1992); Rodney Hayward et al., *Evaluating the Care Of General Medicine Inpatients: How Good Is Implicit Review?*, 118 ANNALS INTERNAL MED. 550, 550 (1993); Haya R. Rubin et al., *Watching the Doctor Watchers: How Well Do Peer Review Organization Methods Detect Hospital Care Quality Problems*, 267 J. AM. MED. ASS’N 2349, 2349 (1992).

<sup>204</sup> *Burns v. Metz*, 513 N.W.2d 505, 509 (Neb. 1994); *Vergara v. Doan*, 593 N.E.2d 185, 188 (Ind. 1992) (judging the physician’s conduct by a “‘minimum standard of care for the particular practice’”). For an excellent overview of medical malpractice law, see DOBBS, *supra* note 177, § 243, at 634–35.

<sup>205</sup> See generally Philip G. Peters, Jr., *The Role of the Jury In Modern Malpractice Law*, 87 IOWA L. REV. 909 (2002) (discussing the merits of the role of custom as conclusive evidence of the standard of care in malpractice litigation and the movement by many states to use custom as only some evidence of the standard of care).

<sup>206</sup> See DOBBS, *supra* note 177, § 243, at 634.

<sup>207</sup> See *infra* notes 210–16 and accompanying text. DOBBS, *supra* note 177, § 244, at 636 (citing *Trindle v. Wheeler*, 143 P.2d 932 (Cal. 1943); *Morris v. Thompson*, 937 P.2d 1212 (Idaho 1997)). See *Small v. Howard*, 128 Mass. 131 (1880) (original case finding that the locality rule applied in a medical malpractice action); see also *Branch v. Hempstead County Mem’l Hosp.*, 539 F. Supp. 908, 919 (W.D. Ark. 1982) (Only

community” rule,<sup>208</sup> or customary care on a national level under the “national rule.”<sup>209</sup> However, over time, a large number of states<sup>210</sup> have chosen to abandon the locality rule in the context of medical malpractice litigation.

Because of both the reluctance of physicians from the same community to testify against one another and the possibility that the physicians in a particular community will establish a standard degree of care and skill, many jurisdictions have expanded the “same locality” rule by requiring a general practitioner to possess and exercise the degree of care and skill normally employed in similar circumstances by physicians in good standing in the same, or a similar, locality.<sup>211</sup>

This initial movement from the same locality rule to the similar community rule, instead of a national rule,<sup>212</sup> was reflective of the view “that a physician or surgeon who practices in a small or rural community does not have the same opportunities and resources for keeping abreast of the advances in medical science as do the doctors practicing in the larger, more sophisticated cities.”<sup>213</sup> However, there has been a marked trend by state courts to move to a national standard of care for both general practitioners and specialists.<sup>214</sup> These courts have reevaluated the

justification for a different and perhaps lower standard of care in a geographically defined area, namely, the lack of opportunity to

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doctors who provide patient care in a “non-negligent manner” are qualified for staff privileges; as such, targeted physician was denied staff privileges as he demonstrated a “lack of competence, skill and knowledge ordinarily possessed by members of the medical profession in the locality.”); *Gaenslen v. Bd. of Dir. of St. Mary’s Hosp. and Med. Ctr.*, 232 Cal. Rptr. 239, 242 (Ct. App. 1985) (standard that excluded physicians from staff privileges who did not provide “high quality” care was based on the standard of medical care in the community and in the hospital).

<sup>208</sup> See generally James O. Pearson, Jr., Annotation, *Modern Status of “Locality Rule” in Malpractice Action Against Physician Who Is Not a Specialist*, 99 A.L.R. 3d 1133 (2005).

<sup>209</sup> See *infra* notes 228–33 and accompanying text.

<sup>210</sup> See generally Pearson, *supra* note 208; see also Howard L. Nations & Jay Sargent, *Medical Malpractice and the Locality Rule*, 14 S. TEX. L. REV. 129 (1973); Jon R. Waltz, *The Rise and Gradual Fall of the Locality Rule in Medical Malpractice Litigation*, 18 DEPAUL L. REV. 408 (1969).

<sup>211</sup> Pearson, *supra* note 208, § 2 (emphasis added) (footnotes omitted).

<sup>212</sup> Some courts focus on geographic proximity to determine similarity, and some look to general socioeconomic variables, while others consider “factors relating to the practice of medicine such as the equivalence of the medical facilities in the communities.” Jay M. Zitter, Annotation, *Standard of Care Owed to Patient by Medical Specialist as Determined by Local, “Like Community,” State, National, or Other Standards*, 18 A.L.R. 4th 603, § 2 (2005).

<sup>213</sup> *Id.*

<sup>214</sup> *Id.*; see also Pearson, *supra* note 208, § 6.

keep up with modern trends, is no longer valid in an age of ubiquitous national communication networks, increasing standardization of medical and specialist training and equipment, free flow of scientific information among medical institutions throughout the country, and professional journals and numerous other networks of continuing education which are national in scope . . . .<sup>215</sup>

In spite of the choice in malpractice cases by state courts to move away from a narrow locality rule in favor of either a similar community rule or a national rule, the choice of a large number of hospitals<sup>216</sup> has been to impose a standard in peer review that is even

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<sup>215</sup> Zitter, *supra* note 212, § 2.

<sup>216</sup> In *Laje v. R.E. Thomason General Hospital*, 564 F.2d 1159 (5th Cir. 1977), the plaintiff, Dr. Laje, was discharged as clinical director of psychiatry for the defendant hospital as a result of a personal conflict with another physician that was found to have had no relation to clinical care. *Id.* at 1160–62. After his discharge, Dr. Laje applied for staff privileges at the hospital. *Id.* at 1160. The application was denied based on the evidence of several of the department of psychiatry physicians that, in their opinion, Dr. Laje's treatment of several patients was below a level of competence that they personally found acceptable. *Id.* at 1161. The trial court concluded that the finding of incompetency was not based on substantial evidence, as only .0082% of the files of patients treated by Dr. Laje were reviewed and the review was conducted in a hasty fashion. *Id.* The court of appeals reversed, holding that "[t]he hospital, and not the courts, must set the level of competence to be required of staff members." *Id.* at 1162. The role of the court is to ensure that the "procedures employed by the hospital are fair, that the standards set by the hospital are reasonable, and that they have been applied without arbitrariness or capriciousness." *Laje*, 564 F.2d at 1162.

*See also* *Tasher v. St. Tammany Parish Hosp.*, No. 87-1139, 1988 U.S. Dist. LEXIS 1018, at \*2 (E.D. La. Feb. 8, 1988) (practice of targeted physician "deviated significantly" from the practices of other members of the department); *Nafirawi v. Hendrick Med. Ctr.*, 676 F. Supp. 770, 776 (N.D. Tex. 1987) (targeted physician did not have the "requisite medical competence" in the opinions of other hospital staff members); *Murdoch v. Knollwood Park Hosp.*, 585 So. 2d 873, 875 (Ala. 1991) (after a hearing in which members of the Executive Committee quizzed the targeted physician on the "appropriate" treatment for patients in several hypothetical situations, staff privileges were denied based on "standard of patient care practice being less than the aims of the medical staff . . ."); *Cipriotti v. Bd. of Dirs. of Northridge Hosp. Found. Med. Ctr.*, 196 Cal. Rptr. 367, 370 (Ct. App. 1983) (corrective action taken when professional conduct falls below "standards or aims of the medical staff"); *Adkins v. Sarah Bush Lincoln Health Ctr.*, 544 N.E.2d 733, 736 (Ill. 1989) (physician's treatment of patients failed to conform to the "Center's standard of competence"); *Pulido v. St. Joseph Mem'l Hosp.*, 547 N.E.2d 1383, 1386–87 (Ill. App. Ct. 1989) (summary suspension of staff privileges when performance of doctor was "deficient" as it did not meet "the standards and aims of the medical staff"); *Head v. Lutheran Med. Hosp.*, 516 N.E.2d 921, 924 (Ill. App. Ct. 1987) (measuring physician competence by application of "a standard of reasonableness as dictated by the quality of medical care expected from a member of the Medical Staff of Lutheran General Hospital"); *Koelling v. Bd. of Trs. of Mary Francis Skiff Mem'l Hosp.*, 146 N.W.2d 284, 286 (Iowa 1966) (failure to provide "adequate" medical care as judged by an in-house standard); *Campbell v. St. Mary's Hosp.*, 252 N.W. 2d 581, 588 (Minn. 1977) (corrective action appropriate when "professional conduct of any member of the

more limited in scope than the locality rule. These hospitals have adopted what can be seen as a ‘super-locality rule’; in other words, the standard of care which is practiced within the hospital itself. This standard is referred to in this Article as the ‘in-house’ measurement. This choice is especially problematic in its potential to unlink peer review decision-making from quality of care concerns and to negatively impact quality of patient care.

The lesson from tort jurisprudence that should be carried over to peer review is that incorporating the locality rule, much less a super-locality rule, into hospital peer review could act to insulate a collection of poor quality practitioners who treat patients in accordance with scientifically invalidated local customary care. If this situation developed, the hospital could be barred from raising the quality of its patient care to national standards. This situation could occur, for instance, when an incompetent physician is identified and this physician is a member of a majority which is resistant to setting higher practice standards. Under an in-house standard, the only available in-house testimony may support the same low standard of care as is being practiced by the targeted physician. Thus, the quality of patient care could remain stalled at a very poor level.

Or other problems could arise. There are many different acceptable customs within the medical profession on how to handle a particular medical situation and there can be wide variations in the practices followed among physicians working in the same hospital. The majority of the medical staff may choose to follow one custom, while a minority may follow another. While both are accepted methods of treatment, under the standards in this category, the minority group’s staff privileges could be at risk merely because they follow a different custom than the majority. If the standard of care is established by an in-house measurement and if, for example, the targeted physician is an ob/gyn, the very group of ob/gyns who have identified the allegedly incompetent physician in the first place are likely to be the ‘experts’ whose testimony will be used to establish the in-house standard of care.<sup>217</sup> The targeted physician may have a difficult, if not

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staff shall be considered to be lower than the standard of the hospital or the medical staff . . . .”); *Moss v. Albany Med. Ctr. Hosp.*, 403 N.Y.S.2d 568, 570 (1978) (failure to meet “hospital’s standards of surgical competence”).

<sup>217</sup> For example, in *Rhee v. El Camino Hospital District*, 247 Cal. Rptr. 244 (Ct. App. 1988), a newly minted surgeon who had excellent credentials and training evaluations during his residency ran afoul of a group of surgeons in the hospital where he started his practice. *Id.* at 483. Members of this group of physicians both testified that Dr. Rhee “did not ‘meet the general standards of the surgical community at El Camino Hospital’” and served on the peer review panels charged with judging

impossible, task attempting to convince another physician from that ob/gyn practice group to testify on his or her behalf. This is especially true if the adverse testimony is coming from either the head of the department, or another powerful member of the medical staff, or from multiple members of the staff.<sup>218</sup>

The in-house standard may also have the negative impact of stifling innovation. It is possible that this minority may be comprised of those who have adopted cutting edge innovative practices which enhance medical outcomes and increase patient safety. The staff privileges of physicians who have adopted the innovative practices are at high risk as these physicians are practicing ahead of the curve. The physicians who wish to adopt new innovative practices may be deterred from doing so out of a reluctance to place their staff privileges at risk.

For example, take the hypothetical case of a brilliant, newly minted ob/gyn who has been trained in all the latest theories and techniques in a major metropolitan area. She finishes her internship and residency in a major city at one of the best hospitals in the country. She then moves into a small rural community to be near her aging parents who are farmers. She is the first new ob/gyn to have staff privileges in the small local hospital in twenty years. The ob/gyns and general surgeons resent the new physician as her new practice immediately carves into their patient base. Her cutting edge training leads both the new physician and many patients of the incumbent physicians to question the use of dated, highly questionable methods of treatment by the incumbent physicians. A high risk patient of the new physician dies in child birth through no misstep of the new physician. Merely because other members of the medical staff would have handled the patient differently, with no evidence of a better outcome, the new physician's staff privileges could be terminated as she did not comply with the customary care of the hospital. It is

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whether Dr. Rhee met this in-house standard. *Id.* at 249. *See also* Lee v. Trinity Lutheran Hosp., 408 F.3d 1064, 1067 (8th Cir. 2005) (physician lost staff privileges in peer review proceeding where her experts opined that a mixture of two drugs was within standard of care; hospital's expert opined that it was not. The mixture of two drugs later became a common treatment for AIDS.); *Islami v. Covenant Med. Ctr.*, 822 F. Supp. 1361, 1364-68 (N.D. Iowa 1992) (whether a patient's condition requires surgery is a matter of judgment; in a case where privileges were terminated, physician's expert witnesses supported his judgment, but hospital's expert witnesses disagreed); *Moss*, 403 N.Y.S.2d, at 569-71 (pointing out that a case where privileges were denied based on a failure to meet a hospital's standards of competence involved matters of judgment in procedure and technique; the physician's witnesses supported his exercise of judgment but hospital's chief of surgery disagreed).

<sup>218</sup> *See infra* note 259.



unlikely that the courts will reach the merits of her case as her appeal will be summarily denied as long as the process protections, such as a hearing, right to counsel, and cross-examination of witnesses, were provided.

This in-house measurement could also create a very costly and protracted process. It is possible that a physician appealing a recommended sanction will propound discovery requests that include disclosure of the patient records of other colleagues in the relevant department to demonstrate what the custom is in that department<sup>219</sup> and that he or she conforms to that custom.<sup>220</sup> In addition, expert testimony is likely to be introduced to show that the targeted physician's conduct was comparable or better than that of other physicians in the same department.<sup>221</sup>

Finally, a physician may be deterred from identifying another member of the department who is not competent as the patient re-

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<sup>219</sup> The standards of admissibility of evidence are much more liberal in peer review proceedings than at trial. Generally, medical staff by-laws will specify that admissibility issues should be weighed against one commonly used standard: "whether or not a responsible person would normally rely on this evidence when conducting serious business affairs." AM. HEALTH LAWYERS ASS'N, HEARING OFFICER GUIDEBOOK 33 (1998); see also 42 U.S.C. § 11112(b)(3)(C)(iv) (2000) (stating that the physician has the right to present evidence determined to be relevant by the hearing officer, regardless of its admissibility in a court of law).

<sup>220</sup> For example, in *Tasher v. St. Tammany Parish Hospital*, No. 87-1139, 1988 U.S. Dist. LEXIS 1018 (E.D. La. Feb. 8, 1988), the Executive Committee established that the targeted physician did not meet the standard of care of the hospital, as his practice "deviated significantly" from the practices of the other members of the department. *Id.* at \*2. The Executive Committee relied on a review it conducted that compared the targeted physician's complication rate and frequency of multiple surgical procedures with the complication rates and performance of multiple surgeries by other members of the department. *Id.* In addition, the review revealed that the targeted physician routinely performed some surgeries that were rarely performed by other members of the department. *Id.*

Just as such a comparison is relevant to show nonconformity with an in-house standard, it is relevant to show conformity as well. *But see* *Richards v. Emanuel County Hosp. Auth.*, 603 F. Supp. 81, 86 (S.D. Ga. 1984) (finding no merit to a targeted physician's claim of a violation of equal protection of the law because he was the only one targeted even though "other members of the medical staff [we]re no better"; when "a standard reasonable on its face is applied in good faith, the one who fails to meet the standard has not been denied constitutional equal protection just because others have not likewise been held accountable" (quoting *Woodbury v. McKinnon*, 447 F.2d 839, 845-46 (5th Cir. 1971)).

<sup>221</sup> The broad scope of relevant discovery will expose private and sensitive patient information to an ever-expanding circle of individuals well beyond the expectations of the patient, with greater chances of inadvertent disclosure. This is especially true if the case actually proceeds to court. While the oft-touted solution is to redact identifying patient information, a crew of individuals is needed to complete this task. Plus, identifying information may be inadvertently missed.

cords of all the physicians in the department may become subject to scrutiny for comparative purposes. Thus, applying the in-house standard of care could act to short circuit the goal of peer review to enhance the quality of patient care.

Adding to the confusion, the language used by the standards which fall into this category allows for a situation where the decision-makers could define the standard of care themselves *ex ante*, only after the targeted physician's competency has been questioned. As with the first category of standards, this allows the administrative decision-makers the discretion to define incompetence without limitation in a 'we know it when we see it fashion.' Further complicating matters is the same possibility that arose with the first category of standards; it is possible that the standard used by the hospital could be a moving target, varying depending on the make-up of the decisional body.

### 3. Customs of the Medical Community

Another interpretation of these in-house standards is that they are referring to the fact that the medical staff or hospital can choose the standard it wants to govern. This means that the medical staff or the hospital could choose either the customs followed in the hospital or those of the medical community generally. In other words, when a by-law allows for corrective action when clinical care falls below the "standards or aims of the medical staff,"<sup>222</sup> the medical staff is not limited to the application of the customs employed within the hospital, but is free to choose to follow the customs of the broader medical community.

This interpretation creates even more challenges for a physician who is trying to conform to the standards for competency. Are the "standards or aims of the medical staff" to impose a standard of care which applies in the locality,<sup>223</sup> the same or similar community,<sup>224</sup> or those which apply on a national level?<sup>225</sup> Decades of tort jurisprudence in the area of medical malpractice and the series of studies re-

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<sup>222</sup> *Cipriotti v. Bd. of Dir. of Northridge Hosp. Found. Med. Ctr.*, 196 Cal. Rptr. 367, 370 (Ct. App. 1983).

<sup>223</sup> See *supra* notes 211-15 and accompanying text.

<sup>224</sup> See *supra* notes 211-15 and accompanying text.

<sup>225</sup> *Kaplan v. Carney*, 404 F. Supp. 161, 164 (E.D. Miss. 1975). In *Kaplan*, the standards that were used to judge plaintiff's performance included "that of acceptability in reference to the Hospital's staff; the general standards of this country; the standards of the area; the standards of the hospital; or the standards of acceptability to the Executive Committee." *Id.*

ferred to earlier<sup>226</sup> have established that the customs applied by each of these measurements can be strikingly different.<sup>227</sup> Nothing in these types of standards give a physician any guidance with regard to which customs will apply. In one case, this ambiguity meant that the physician was subjected to all four standards in the same proceeding.<sup>228</sup>

Once again, the adoption of the standards in this category unjustifiably skews the balance between competing interests in favor of hospital autonomy in staffing decisions, providing little to no protection to physicians' interests in the practice of their profession and the patients' right to choose their own physician. The standards that fall into this category still unjustifiably allow a grave risk of the termination of staff privileges based on inappropriate considerations under the guise of enhancing the quality of patient care.

### C. *Negligence Standards*

Finally, there are those standards that expressly incorporate tort law doctrine such as by-laws which state that clinical care will warrant corrective action when a physician fails to provide patient care in a 'non-negligent manner'<sup>229</sup> or has committed 'gross negligence.'<sup>230</sup> Also included in this category are those standards which impliedly incorporate tort doctrine by modeling themselves on the tort standard of care which is used to evaluate liability for harm. Examples include language that allows for corrective action when a physician "failed to exercise the degree of care and skill that a reasonably careful and skilled surgeon would have exercised in the circumstances"<sup>231</sup> or "failed to possess the degree of care and skill ordinarily possessed by reasonably skilled surgeons"<sup>232</sup> or when there is a "failure to conform

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<sup>226</sup> See *supra* Part VI.B.1.

<sup>227</sup> See *infra* notes 182–203 and accompanying text.

<sup>228</sup> *Kaplan*, 404 F. Supp. at 164–65.

<sup>229</sup> *Branch v. Hempstead County Mem'l Hosp.*, 539 F. Supp. 908, 917 (W.D. Ark. 1982) ("The governing body has a duty to establish procedures that will insure that only qualified doctors provide services to patients of the hospital in a non-negligent manner . . .").

<sup>230</sup> *Storrs v. Lutheran Hosps. & Homes Soc'y of Am., Inc.*, 609 P.2d 24, 30 (Alaska 1980) (staff privileges only reduced or terminated upon finding of gross negligence).

<sup>231</sup> *Klinge v. Lutheran Charities Ass'n*, 523 F.2d 56, 59 (8th Cir. 1975) (hearing panel terminated staff privileges, finding that the surgeon "failed to exercise the degree of care and skill that a reasonably careful and skilled surgeon would have exercised in the circumstances," and "failed to possess the degree of care and skill ordinarily possessed by reasonably skilled surgeons").

<sup>232</sup> *Id.*

to the standards of care and skill prevailing among reasonably competent orthopedic surgeons . . . .”<sup>233</sup>

Arguably, the standards in this category offer the greatest clarity because they can be interpreted to incorporate the standards that apply generally in a medical malpractice case.<sup>234</sup> Thus, these standards rely on the large corpus of tort jurisprudence that has developed over the past decades which parallel rapid advances in medicine and technology. However, as Professor Clark Havighurst points out,

[a]s malpractice law is currently administered, its requirements are extraordinarily vague and unpredictable. . . . Given the considerable vagueness of the standards it imposes so rigorously on physicians, the tort system would probably not survive scrutiny under constitutional norms of due process if it operated as a public regulatory program *de jure* as well as *de facto*.<sup>235</sup>

The due process concerns raised by vague standards are more serious in the context of peer review than in malpractice litigation or medical licensure proceedings. The decision-makers in malpractice litigation or medical licensure proceedings are judges, juries and administrative officials who are unlikely to have had prior dealings or involvement with the targeted physician. With peer review, it is highly likely that the decision-makers have had both personal and economic dealings with the targeted physician.<sup>236</sup> Peer review members may feel pressure to bow to the wishes of the executive committee (or other powerful members of the hospital staff) to terminate the targeted physician. While vagueness concerns are important in all of these proceedings, the risks to a fair process are greater in peer review, requiring much greater clarity in the standards used.

As stated earlier, in order to meet the ‘standard of care’ under tort law, a physician must “possess and use the care, skill and knowl-

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<sup>233</sup> *Stiller v. La Porte Hosp., Inc.*, 570 N.E.2d 99, 104 (Ind. Ct. App. 1991) (loss of staff privileges for “failure to conform to the standards of care and skill prevailing among reasonably competent orthopedic surgeons”); *see also* *Head v. Lutheran Gen. Hosp.*, 516 N.E.2d 921, 924 (Ill. App. Ct. 1987) (measuring physician competence by application of “a standard of reasonableness as dictated by the quality of medical care expected from a member of the Medical Staff of Lutheran General Hospital”).

<sup>234</sup> Another possible interpretation is that these standards are referring to the standards which apply in a general negligence action, not a medical malpractice action. Unlike general negligence cases that allow custom as some evidence of the standard of care, the general rule in most states is that custom is conclusive evidence of the standard of care in a malpractice action. *See infra* note 258.

<sup>235</sup> Havighurst, *Practice Guidelines as Legal Standards*, *supra* note 182, at 96.

<sup>236</sup> *See generally* Blum, *supra* note 24, at 470–74 (explaining how credentialing includes economic considerations blurring the line between business and quality judgments).

edge ordinarily possessed and used under like circumstances . . . .”<sup>237</sup> Evidence of this failure occurs when the physician does not take the same actions customarily taken by other physicians in similar circumstances.<sup>238</sup> This customary practice standard is ordinarily established by the introduction of the testimony of medical experts.<sup>239</sup>

Once again, the uncertainties and ambiguities associated with the customary care measure arise. Even if knowable customs do exist, the standards in this category fail to provide notice of which customary rules should apply; those which would be found by applying the in-house rule, the same locality rule, the similar community rule, or the national rule.<sup>240</sup> Depending on the rule followed, the customs used to measure physician competence could be markedly different. Thus, as discussed in much greater detail in the next sections, measuring clinical competence by a negligence standard is also inherently vague.

*D. Extraordinary Vagueness of Standards Currently Used in Peer Review*

All three categories of the standards currently being utilized are extremely vague. These standards do not provide notice to the physicians, do not limit the discretion of the decision-makers in peer review and do not provide the opportunity for any meaningful judicial review of peer review decisions. As such, peer review hearings which employ these vague standards are not fundamentally fair. An essential precondition for immunity from suit by an aggrieved physician under HCQIA is that the peer review process be fundamentally fair. The vagueness of all three categories of standards currently applied in peer review places all of the participants in the peer review process at risk of the loss of HCQIA immunity.

In addition, this vagueness allows for peer review to be used both to hold physicians accountable for poor performance and to protect hospital autonomy in staffing decisions based on reasons unrelated to quality of care concerns. Whether these standards are narrowly tailored enough to justify the limits HCQIA and state statutes place on aggrieved physicians’ access to the judicial system is questionable.

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<sup>237</sup> Burns v. Metz, 513 N.W.2d 505, 508 (Neb. 1994); Vergara v. Doan, 593 N.E.2d 185 (Ind. 1992). For an excellent overview of medical malpractice law, see DOBBS, *supra* note 177, § 243, at 634–35.

<sup>238</sup> See DOBBS, *supra* note 177, § 243, at 634.

<sup>239</sup> *Id.*

<sup>240</sup> For a description of these rules, see *infra* notes 241–56 and accompanying text.

As they are currently drafted, even the third category of standards, which incorporate tort doctrine, still appear to be too vague to protect physicians' interests and too overbroad to justify the immunity granted by federal and state legislation. But what if these standards were redrafted both to provide expressly the locality from which customary care evidence was to be drawn and that customary care should only be some evidence, instead of conclusive evidence, of the standard of care? Would physicians' interests be better protected? And what impact would importing tort doctrine into the peer review process have on the quality of patient care? Finally, is a better solution to replace vague standard of care language entirely with contract principles based on clinical practice guidelines?

#### VII. A VIABLE SOLUTION TO VAGUENESS CONCERNS: TORT DOCTRINE OR CONTRACT PRINCIPLES?

There are three possible routes to implementing a more balanced approach to measuring clinical competence. One path is to amend a hospital's medical staff by-laws to reflect a whole-sale adoption of malpractice doctrine to evaluate physician competence, being sure to specify the locality from which any evidence of customary care will be taken. Another path is to rewrite the medical staff by-laws to use express contractual terminology such as 'expectations of performance' as evidenced by clinical practice guidelines ("CPGs"). There are problems with both of these options. While the whole-sale adoption of tort doctrine will provide enhanced protection to physicians' interests, it may negatively impact the quality of patient care. The alternative, the application of contract principles incorporating CPGs, is a viable solution which will take time (perhaps measured in decades rather than years) to fully implement. For an immediate solution, a marriage between contract principles using CPGs and a carefully carved out portion of tort doctrine dealing with the standard of care can act as a stop-gap measure. Over time, as evidence-based medicine continues to develop, contract principles using CPGs can increasingly be used to supplant this stop-gap measure of clinical competence.

##### A. *Applying Malpractice Doctrine in Peer Review*

Amending a hospital's by-laws to both adopt malpractice doctrine and expressly designate the locality from which the customary practice will be drawn may greatly increase protection for physicians' interests. However, the price to be paid in patient safety by going this route may be too great. The questionable merit of the main precept

upon which the malpractice system is based and the different goals of each process should be carefully considered when contemplating whether this is the right solution. Malpractice doctrine was developed to evaluate liability based on the concept of fault for harm to a single patient through litigation. In contrast, the peer review process is designed to measure the competence of a physician's care of multiple patients<sup>241</sup> over a long period of time.<sup>242</sup> Fault is not a factor in

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<sup>241</sup> *Adkins v. Sarah Bush Lincoln Health Ctr.*, 544 N.E.2d 733, 737 (Ill. 1989) (staff privileges terminated based upon peer review evaluation of thirteen areas of deficient performance based on thirty patient charts); *Knapp v. Palos Cmty. Hosp.*, 531 N.E.2d 989, 990 (Ill. App. Ct. 1988) (peer review considered six general charges based on thirty-eight patient charts); *Campbell v. St. Mary's Hosp.*, 252 N.W.2d 581, 584 (Minn. 1977) (peer review hearing considered 231 separate deficiencies which occurred in the treatment of eighty-six different patients). A one-time incident of poor judgment is insufficient evidence of overall incompetence. However, in *Maimon v. The Sisters of the Third Order of St. Francis*, 458 N.E.2d 1317 (Ill. App. Ct. 1983), the targeted physician had a history of conflict with hospital administration. *Id.* at 1319. A complaint for corrective action alleged that the targeted physician had attempted to induce a woman's labor solely for the physician's convenience. *Id.* The targeted physician's admitting privileges were restricted while the peer review process was pending. *Id.* The additional allegations of non-compliance with hospital rules dealt with a failure to comply with the terms of this suspension. *Id.* In spite of the fact that this was a one-time judgment call and there were no complaints regarding the quality of care of hundreds of other patients, the executive committee terminated the physician's staff privileges. *Id.* at 1319-20. A similar situation occurred in *Moore v. Board of Trustees of Carson-Tahoe Hospital*, 495 P.2d 605 (Nev. 1972), where a physician's privileges were terminated based on only two incidents, neither of which caused any harm to a patient. *Id.* at 606-09. The first involved a failure to use sterile gloves when performing a spinal tap. *Id.* at 610. The second involved arriving to perform surgery when in no condition physically or mentally to do so. *Id.* The physician readily acquiesced to a request to reschedule the surgery and successfully performed the operation at a later time. *Id.* As the dissent pointed out, "[s]uch an isolated act without injury cannot be a reasonable basis for revocation of staff privileges, for if it is, and if enforced equally and without discrimination, medical staffs will disappear entirely. Every professional man errs from time to time." *Id.* at 610 (Thompson, J., dissenting).

<sup>242</sup> If there is an isolated incident, the head of the department should counsel the physician. Only if there are repeated incidents should peer review be triggered. Normally, peer review focuses on the treatment of a large number of patients over a period of time. This is because the focus of peer review is to determine the overall competence of a physician. As a physician commonly treats hundreds of patients a year, this means the review of a large number of patient charts to determine if there is a pattern or practice of low quality care. However, there are occasions when the treatment of a single patient can trigger peer review that ends in the termination of staff privileges. Logically, as the goal of peer review is not for the purposes of punishment but to enhance the quality of care, termination of staff privileges should only be warranted if the injury to this single patient was both severe (or potentially so) and the incident indicates some greater problem with the physician's overall competency which raises the possibility of harm to other patients. It is fair to assume that, as physicians are human and are not perfect, mistakes will be made. It is only when those mistakes create a pattern that demonstrates incompetence that termina-

this calculus. Attention should be paid to the fact that tort doctrine carries with it a whole series of qualifiers which are aimed at limiting liability to 'faulty' conduct. When used in the context of peer review, these qualifiers may tip the balance between the stakeholders in the peer review process toward protecting the interests of the physician, but only at an unacceptable cost to patient safety.

### 1. Customary Care as a Measure of Physician Competence

Both malpractice theory and the current use of customary care measurements in hospitals are based on the premise that there are identifiable customs or norms against which to measure a physician's conduct. In peer review, this measure is being used to determine competence. In tort, this measure is being used to determine fault and, therefore, culpability. However, research has raised serious questions about both the existence of knowable and agreed upon medical customs and the medical benefits of some customary care.<sup>243</sup> Moreover, many customs that do exist are suspect having evolved during the fee-for-service system of health care reimbursement that encouraged the over-utilization of medical services by both physicians and patients through economic incentives.<sup>244</sup> Therefore, framing a solution that continues to rely on custom may be ill-advised as it is fraught with uncertainties with regard to the scientific bases upon which many customs or practice norms are grounded, may be based on a fiction that medical custom standards or norms actually exist, and, to the extent that they do exist, such medical custom standards or norms may be tainted by insurance induced 'moral hazard.'<sup>245</sup>

### 2. Choosing Customs

The medical malpractice common law of the different states varies with regard to the locality from which they draw their customary practices. States have chosen to apply the customs followed by the practitioners in the local community under the "same locality rule"<sup>246</sup> or another community under the "similar community rule,"<sup>247</sup> or cus-

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tion is appropriate. Otherwise, as the dissent in *Moore* points out, all physicians will ultimately lose staff privileges. 495 P.2d at 610 (Thompson, J., dissenting).

<sup>243</sup> See *supra* notes 177–201 and accompanying text.

<sup>244</sup> See *supra* notes 177–201 and accompanying text.

<sup>245</sup> Havighurst, *Practice Guidelines as Legal Standards*, *supra* note 182, at 98 n.33. "Moral hazard arises whenever one person (for example, a doctor or patient) is in a position to spend or risk resources belonging to another (for example, a health insurer)." *Id.*

<sup>246</sup> See *supra* note 210 and accompanying text.

<sup>247</sup> See *supra* note 208 and accompanying text.



tomary care on a national level under the “national rule.”<sup>248</sup> If a hospital chooses to adopt a malpractice standard, it will also have to make this choice. Regardless of whether one accepts that customs or norms do exist, the impact on quality of patient care by adopting tort doctrine still may depend on this choice.<sup>249</sup> The problems associated with the choice of an in-house standard or a local standard have already been discussed in prior sections.<sup>250</sup> Adopting tort doctrine which incorporates these choices into peer review would merely be perpetuating these same problems. But what if the by-laws expressly state that the national standard of care will be used as the measure of competency?

### 3. The National Standard of Care

Arguably, adopting the national standard of care is the choice of measures of clinical competence that will both protect the interests of physicians and enhance the quality of patient care. Any expert testimony must establish the basis for asserting that the target physician’s conduct falls below the national standard. On the surface at least, adopting the national standard limits the discretion of the peer review panel by linking their ability to act to quality of patient care concerns. However, as explained above, the idea that there is such a national standard of care is suspect in the first instance. Compounding this concern, the representative of the hospital who is prosecuting the case is likely to choose experts based on the positions that the experts will take.<sup>251</sup> As such, the experts are likely to become mere proxies for

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<sup>248</sup> See *supra* notes 214–15 and accompanying text.

<sup>249</sup> See *supra* notes 210–15 and accompanying text.

<sup>250</sup> See *supra* Part VI.B.

<sup>251</sup> Experts are chosen on the basis of the positions they will take and their perceived ability to persuade a jury, or a peer review panel, to accept their view of the targeted physician’s conduct. Havighurst, *Practice Guidelines as Legal Standards*, *supra* note 182, at 98. For example, in *Islami v. Covenant Medical Center*, 822 F. Supp. 1361 (N.D. Iowa 1992), the peer review matter came down to a battle of the experts. *Id.* at 1364–68. Based on a charge that a physician was performing surgeries unnecessarily, the highly-qualified expert hired by the executive committee to provide an outside review recommended the corrective action of requiring that the targeted physician obtain a second opinion prior to performing all major surgeries. *Id.* at 1366. The three highly-qualified experts hired by the targeted physician disagreed that the surgeries were unwarranted. *Id.* at 1367. The case came down to a battle of the experts, with the executive committee ultimately giving more credibility to their own expert in setting especially harsh corrective measures that effectively terminated the targeted physician’s staff privileges. *Id.* at 1368.

the standard of care judgments of the complaining members of the medical staff as given voice by the executive committee.<sup>252</sup>

Moreover, overall clinical competence is an assessment that should be made over a period of time which involves the care of multiple patients.<sup>253</sup> This means that a series of incidents, each standing alone, may not be sufficient for corrective action. But viewed in toto, these incidents could add up to a pattern of overall poor quality of care. As such, the physician is likely to challenge the assessment of each incident on the proper practice custom and whether that standard was violated. This boils down to a battle of the experts on what the standard of care is for each event and whether the physician has violated that standard. This, in all likelihood, involves multiple 'trials within a trial.' Such a proceeding, extraordinarily expensive and time consuming enough when dealing with the care of just one patient, would involve an enormous amount of time and expense.<sup>254</sup>

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<sup>252</sup> While it does not erase the issue of whether a national standard of care actually exists, those hospitals which send patient files to outside organizations which provide an independent review by physician specialists appear to provide the most objectively fair evaluation of physician competence under this current system of evaluation. For example, the hospital in *Harris v. Bellin Memorial Hospital*, 13 F.3d 1082 (7th Cir. 1994), requested that Confidential Peer Review, Ltd. ("CPR") provide an independent review. CPR is an organization comprised of physicians with both academic and medical credentials which reviews the performance of health care providers throughout the United States. *Id.* at 1084. "A CPR review consists of four phases: determining the case mix and time frame to be reviewed; reviewing administrative records; on-site inspection of medical records selected by the team; and preparing a final report that includes findings, conclusions, and recommendations." *Id.*; see also *Lee v. Trinity Lutheran Hosp.*, 408 F.3d 1064, 1068 (8th Cir. 2005) (five charts sent for external review by expert who opined that physician did "not [meet] the standard of care."); *Islami*, 822 F. Supp. at 1364-68 (patient charts sent to outside expert); *Branch v. Hempstead County Mem'l Hosp.*, 539 F. Supp. 908, 912-13 (W.D. Ark. 1982) (noting that the hospital sent charts of operations performed by the targeted physician to the Arkansas Foundation for Medical Care, which is the "Professional Standards Review Organization (PSRO) for the State of Arkansas with the responsibility to review all federally funded patients, to assure that the care that they receive meets professionally recognized standards").

<sup>253</sup> One example of an objective national standard is the comparison of a physician's mortality and morbidity rates with the national standards for the type and nature of the physician's practice. See, e.g., *Rees v. Intermountain Health Care, Inc.*, 808 P.2d 1069, 1071 (Utah 1991) (loss of staff privileges for elective cardiac surgery for excessive complication and mortality rates compared with national standards). It is important to note that evaluation of competence should not be limited to this type of measure, which is reflective of low quality care that has, in fact, caused harm. A hospital should not be limited to merely a reactive role by being barred from acting until incompetence actually causes harm. A hospital must be able to proactively prevent harm.

<sup>254</sup> For example, in *Spencer v. Community Hospital of Evanston (Spencer II)*, 408 N.E.2d 981 (Ill. App. Ct. 1980), the hearing on the evaluation of the charges against the target physician as part of the formal peer review took a total of twenty-five ses-

These transaction costs may deter the hospital from proceeding unless absolutely necessary and under circumstances where the likelihood of success is high. Such an event would also unduly burden both the physicians who sit on the appeals panel and their patients by keeping the reviewing physicians from attending to their practices for a protracted period of time.

Hospitals engaging in a risk/benefit analysis to determine whether to initiate an investigation and pursue corrective action against an incompetent physician are likely to balance the expenditure of resources in time and money against the chances of success and the potential for suit by an injured patient<sup>255</sup> if the physician proceeds to provide poor care without intervention. The overwhelming burdens of the current formal peer review process may discourage hospitals from engaging in peer review<sup>256</sup> until a sufficient number of adverse events has occurred so that the incompetence of the physician is irrefutable. Playing such a waiting game could place all of the hospital's patients at risk until there was an acceptable level of certainty of a positive outcome.

Thus, adopting the national standard of care into the peer review process would only perpetuate the current system which relies on customs and norms. Over and above this concern, adopting a negligence standard could add new problems to the mix.

#### 4. Tort Concepts Designed to Assign Liability on the Basis of Fault

There are many doctrines that are part and parcel of malpractice law that are not relevant to peer review and should not be con-

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sions over a period of three months. *Id.* at 984. When considering the number of hours this entailed for the physician-members of the ad hoc hearing committee, the witnesses (all of whom were medical personnel taking time from patient care), the attorneys, the court reporter, and the hearing officer, the expenses, both in terms of dollars and time away from patient care, were tremendous. Then add in the time spent by the various medical committees to investigate the matter initially and then to hear the appeals. *See also* *Spencer v. Cmty. Hosp. of Evanston (Spencer I)*, 332 N.E.2d 525 (Ill. App. Ct. 1975). Finally, consider the extraordinary amount of time (from 1974, when the conflict began, until the final court verdict in 1980) and expense it took to go through the court proceedings in both *Spencer I* and *Spencer II*.

<sup>255</sup> "An analogy between a surgeon and an airline pilot is not inapt: a hospital which closes its eyes to questionable competence and resolves all doubts in favor of the doctor does so at the peril of the public." *Rhee v. El Camino Hosp. Dist.*, 247 Cal. Rptr. 244, 250 (Ct. App. 1988).

<sup>256</sup> This may be one of the reasons that hospitals are not engaging in peer review in spite of the added encouragement of immunity created by state statutes and HCQIA. *See generally* Scheutzow, *supra* note 96 (study that suggests that providing immunity does not encourage peer review).

sidered as part of the peer review process. For example, the causation and damages elements of a negligence action are not relevant as the issue in peer review is not whether the physician has actually caused harm, but whether the physician is providing poor quality care that might lead to patient harm.<sup>257</sup> Other examples include the defenses of assumption of the risk and contributory negligence. As the focus of peer review is solely on the conduct of the physician, not the patient, these defenses are not relevant.

While greatly enhancing the protection of physicians' interests, the addition of these doctrines could actually be destructive to the goals of peer review. Because the tort system is designed to evaluate liability for harm based on fault, malpractice jurisprudence revolving around standard of care measurements is packed with doctrines aimed at limiting liability to faulty conduct.<sup>258</sup> Examples include the

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<sup>257</sup> There are five main elements of a cause of action for negligence: duty, breach, legally recognized harm, cause in fact and proximate cause. See generally W. PAGE KEETON, DAN B. DOBBS, ROBERT E. KEETON, & DAVID G. OWEN, PROSSER AND KEETON ON THE LAW OF TORTS § 30, 164–68 (5th ed. 1984). The only elements relevant to peer review are duty and breach. Duty being defined as the responsibility of a physician to “possess and use the care, skill and knowledge ordinarily possessed and used under like circumstances.” DOBBS, *supra* note 177, § 243, at 634. Breach is defined as a failure to provide that level of care. *Id.* Whether a physician has actually caused harm is not relevant. Corrective action is necessary for the physician who is providing poor quality care that *might* cause harm. The physician who has repeated ‘near misses’ comes to mind, where only the diligence of others or just plain luck has averted patient injury.

<sup>258</sup> For example, under the tort law of the majority of states, if a physician follows the medical custom of the relevant community, he has not fallen below the standard of care “regardless of how risky the custom or how unnecessary.” DOBBS, *supra* note 177, § 242, at 633. But see *Helling v. Carey*, 519 P.2d 981, 983–84 (Wash. 1974) (holding that the physician’s adherence to customary care did not insulate him from liability). In other words, the malpractice jurisprudence of the majority of states dictates that custom is the conclusive evidence of the standard of care. Peters, *supra* note 205, at 911–21. Unlike a regular negligence case, the jury in a malpractice case is evaluating whether the physician has conformed to the applicable custom. *Id.* at 919–20. If so, the physician is not liable. The issue for the jury is not what the physician should have done under the circumstances, but what he actually did. *Id.* Thus, if the physician has conformed to acceptable social norms (customs) as defined by tort law, the physician is not at fault and would not be liable for any patient injury in a malpractice suit. *Id.* But, this physician may still be causing unnecessary and easily avoidable injuries to patients. By incorporating tort theory into the peer review process, the physician may be insulated from any corrective measures and can proceed to subject patients to an unnecessary risk of harm. Many new safety practices have recently been introduced since the *To Err Is Human* report, see *supra* note 1, approximately seven years ago. Wachter, *supra* note 3, at 540. However, the newer the safety precautions are, the less likely that they will be seen to be part of customary practice under tort law. In fact, the safety precaution may be so new that basically no one in the relevant community has yet to follow it. An even more problematic situation is created when a new safety practice reflects the exact opposite of a practice

‘two schools of thought’ doctrine or the ‘respectable minority rule,’<sup>259</sup> the ‘honest error rule,’<sup>260</sup> and the ‘minimum competence’ doctrine.<sup>261</sup>

that the profession at large customarily follows, but that scientific evidence reveals to unduly risk patient safety. In all of these scenarios, adopting the standard of care used in malpractice litigation may insulate from corrective action a physician who willfully ignores new treatments, practices or procedures that are safer and/or more effective.

<sup>259</sup> A similar result will be achieved in those jurisdictions that accept the ‘respectable minority’ or ‘differing school of thought’ doctrines. DOBBS, *supra* note 177, § 245, at 637. “The two schools of thought doctrine provides an absolute defense to medical malpractice liability when a physician has chosen one medically acceptable course of action over alternative treatments that enjoy the support of other medical experts.” Joan P. Dailey, Comment, *The Two Schools of Thought and Informed Consent Doctrines in Pennsylvania: A Model for Integration*, 98 DICK. L. REV. 713, 713 (1994). Generally, a second school of thought “exists when ‘reputable and respected’ medical authorities support a particular mode of treatment.” *Id.* However, some courts have attempted to limit this definition by holding that a second school of thought only will be legally recognized when it is supported by a “considerable number of recognized and respected professionals . . . .” *Jones v. Chidester*, 610 A.2d 964, 969 (Pa. 1992).

In the context of peer review, as long as one group of physicians, or a respectable minority of physicians, refuses to adopt the new treatments or procedures, the recalcitrant physician can avoid corrective action. On the other hand, a physician who is on the cutting edge of health care and adopts a new highly effective treatment risks sanction, as she is ahead of her colleagues and is not a part of a respectable minority or school of thought. An example that arose in the context of a peer review case is *Lee v. Trinity Lutheran Hospital*, 408 F.3d 1064 (8th Cir. 2005). In *Lee*, one of the reasons the physician’s privileges were terminated was that she was using a combination of drugs to treat AIDS that only later became the standard of care. *Id.* at 1067. Thus, this rule has a chilling effect on those physicians who may wish to employ a new treatment that is no longer experimental but has not yet been adopted by a considerable number of physicians. As the court pointed out in *Hubbard v. Calvin*, 147 Cal Rptr. 905 (Ct. App. 1978), a physician should be liable only if he or she failed to provide reasonable care under the circumstances, not because the physician does not follow his or her colleagues. *Id.* at 907.

<sup>260</sup> Another example of tort doctrine focusing on finding liability for fault that could place patient safety at risk is the very dated rule that a physician is “not liable for a bad result, nor for a mistake or error in judgment where he acted in good faith.” DOBBS, *supra*, note 177, § 243, at 634 (citing *Dotson v. Hammerman*, 932 S.W.2d 880 (Mo. Ct. App. 1996); *Donaldson v. Maffucci*, 156 A.2d 835 (Pa. 1959); *Gerald v. Sacred Heart Med. Ctr.*, 937 P.2d 1104 (Wash. Ct. App. 1997)). If adopted into peer review, the honest error, or the good faith mistake, rule may allow the physician who continuously makes mistakes and errors over a period of years to avoid corrective action. If the physician is continually injuring patients, his subjective good faith is not relevant to peer review. The vast majority of states have rejected this rule, with many replacing it with a new rule that states that a physician is not liable if he or she makes a good faith or honest error in judgment between two alternative courses of treatment, if both alternatives are reasonable under the circumstances. DOBBS, *supra* note 177, § 243, at 635. See also *Perkins v. Walker*, 406 N.W.2d 189, 190 (Iowa 1987) (jury instruction that “a doctor cannot be found negligent merely because he makes a mistake in the diagnosis and treatment of a patient”); *Hunsaker v. Bozeman Deaconess Found.*, 588 P.2d 493, 506–07 (Mont. 1978) (approved instruction “that an unsuccessful effort, a mistake, or an error in judgment is not necessarily negli-

However, fault is not relevant in the context of peer review. The focus of peer review is to identify and deal with those physicians who provide poor quality care.<sup>262</sup>

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gent"); *Roach v. Hockey*, 634 P.2d 249, 252 (Or. 1981) (After defining reasonable care by a physician, the court properly instructed "if the defendant in good faith and in the exercise of reasonable care erred in such judgment, then he would not be negligent"); *Miller v. Kennedy*, 588 P.2d 734, 738 (Wash. 1978) (approving instruction "that a physician is not liable for an honest error of judgment where he or she has exercised the requisite degree of care and skill in arriving at the judgment"). The problem, once again, is with the physician who repeatedly makes the wrong choice with multiple patients. If the physician is continually injuring patients, his lack of fault as defined by tort doctrine is not relevant to peer review.

<sup>261</sup> Should the physician be held to ordinary customary care, minimal customary care or reasonable care, or the best possible care? Any one of these standards could apply. In some jurisdictions, only minimal competence is required. For example, in the medical malpractice case of *Hall v. Hilbun*, the standard of care expectation was set at a very low level:

Each physician may with reason and fairness be expected to possess or have reasonable access to such medical knowledge as is commonly possessed or reasonably available to *minimally competent* physicians in the same specialty or general field of practice throughout the United States, to have a realistic understanding of the limitations on his or her knowledge or competence, and, in general, to exercise *minimally adequate* medical judgment.

*Hall v. Hilbun*, 466 So. 2d 856, 871 (Miss. 1985) (emphases added). In spite of the fact that other states have not opted to adopt this measure into their medical malpractice law, hospitals in several states appear to have embraced the minimum competence rule as the standard of care that applies in peer review proceedings. *See, e.g., Poe v. Charlotte Mem'l Hosp., Inc.*, 374 F. Supp. 1302, 1307 (W.D.N.C. 1974) (peer review showed a failure on the part of the physician "to meet the minimum standards of care for patients"); *Balkissoon v. Capitol Hill Hosp.*, 558 A.2d 304, 305 (D.C. 1989) (physician hospital privileges terminated based on "failure to satisfy minimal standards"). Adopting the *Hall v. Hilbun* version of the standard of care places a ceiling on quality aspirations and ties the hands of medical staffs which either seek to furnish clinical privileges solely to physicians who provide the highest quality of care, or a quality of care that is above ordinary care. Or, in states which adopt the minimal competence rule, impede hospitals which desire to grant clinical privileges to physicians who are at least more than minimally competent. Finally, there is one case where the hospital had at one time adopted a gross negligence rule into its peer review process. In *Storrs v. Lutheran Hospitals and Homes Society of America, Inc.*, 661 P.2d 632 (Alaska 1983), staff privileges were only reduced or terminated upon a finding of gross negligence. *Id.* at 633-34. This standard is so weighted in the favor of the interests of the physician that it discounts the interests in patient safety entirely. Under this standard, a physician who was repeatedly negligent, but was not grossly negligent, in the care of his or her patients could maintain his or her hospital staff privileges.

<sup>262</sup> *The End of the Beginning* documents this very phenomenon:

[W]ith the implementation of new safety systems (such as "sign your site" or read-backs of oral orders), a new problem has emerged: what to do with providers who willfully violate reasonable safety rules. Nothing undercuts an institution's effort to fully comply with safety regulations more than having an individual provider (particularly a prominent physician) regularly ignore the regulations. As James Reason, one of

Wading through the morass of malpractice doctrines to decide which should or should not apply and the resultant impact the decisions will have on the scope of discovery and other evidentiary issues could well bog down the peer review hearing process with endless motions and arguments. As these cases are unlikely to reach the courts based on the limited scope of judicial review currently being applied, much of the decision-making in the context of formal peer review will go unreported and unreviewed. This results in each hospital across the country reinventing the wheel at each separate peer review hearing, examining the competency of physicians on an ad hoc case-by-case basis. This piecemeal system can only culminate in a lack of uniformity in the treatment of physicians from hospital to hospital, and even from physician to physician within the same hospital.

Overall, adopting malpractice doctrine to provide greater clarity to the measures of competence currently being applied in peer review would be inadvisable. While affording physicians' interests greater protection by limiting the loss of staff privileges to situations where there has been a finding of fault, this limitation comes at too great a cost to the public's interests in patient safety.

*B. Clinical Practice Guidelines in Peer Review*

Describing the expectations of physician performance in contractual terms using clinical practice guidelines may avoid many of the pitfalls that are attendant to the current categories of standard of care measurements and could deflect the temptation to import inappropriate and destructive legal and evidentiary principles into the peer review process. At least in theory, this approach will foster a more equitable balancing of the hospital's quality of care concerns with the interests of the physician in a fair process of review for staff privileges. This alternative arguably does more to ensure HCQIA protections for all involved in the process.

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the giants of systems theory, notes, "Seeing them get away with it on a daily basis does little for morale or for the credibility of the disciplinary system."

Wachter, *supra* note 3, at 540 (quoting JAMES REASON, *MANAGING THE RISKS OF ORGANIZATIONAL ACCIDENTS* 212 (1997)).

### 1. What are Clinical Practice Guidelines?

The Institute of Medicine describes clinical practice guidelines (“CPGs”)<sup>263</sup> as “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.”<sup>264</sup> Modern medical science, based on clinical outcomes and effectiveness research that integrates powerful computer technologies with an ever-growing body of treatment data, can evaluate the optimum treatment approach for many types of clinical conditions. CPGs are based on this modern medical science and represent “well-considered opinions of expert panels, based upon reviews of the best available data, as to how physicians should approach certain clinical problems.”<sup>265</sup> It is widely believed that CPGs will enhance the quality of care by reducing variation in practice and will move physicians more quickly toward current understandings of best medical practice derived from outcomes research.<sup>266</sup> At the same time, CPGs can reduce the cost of care by promoting lower cost choices that produce the same outcomes as higher cost alternatives.<sup>267</sup>

CPGs can generally be placed in three different categories, depending upon their auspice and purpose.<sup>268</sup> First, there are those which were created to improve clinical outcomes, called ‘standard of

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<sup>263</sup> CPGs are also referred to as ‘practice parameters,’ ‘clinical pathways,’ or ‘clinical algorithms.’

<sup>264</sup> INST. OF MED., CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM 8 (Marilyn J. Field & Kathleen N. Lohr eds., 1990).

<sup>265</sup> Richard E. Leahy, Comment, *Rational Health Policy and the Legal Standard of Care: A Call for Judicial Deference to Medical Practice Guidelines*, 77 CAL. L. REV. 1483, 1506 (1989).

<sup>266</sup> Rosoff, *supra* note 185, at 369; AM. MED. ASS’N, LEGAL IMPLICATIONS OF PRACTICE PARAMETERS (1990); PHYSICIAN PAYMENT REVIEW COMM’N, 1989 ANNUAL REPORT TO CONGRESS 219–36 (recommending federal support for outcome research and creation of practice guidelines based thereon); *see generally* Brook et al., *supra* note 198; David M. Eddy, *Clinical Decision Making: From Theory to Practice*, 263 J. AM. MED. ASS’N 287 (1990); Clark Havighurst, *Practice Guidelines for Medical Care: The Policy Rationale*, 34 ST. LOUIS U. L.J. 777 (1990) [hereinafter Havighurst, *Practice Guidelines for Medical Care*]; Eleanor D. Kinney & Marilyn D. Wilder, *Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities*, 22 U.C. DAVIS L. REV. 421 (1989); Leahy, *supra* note 265; William Roper et al., *Effectiveness in Health Care: An Initiative to Evaluate and Improve Health Care*, 319 NEW ENG. J. MED. 1197 (1988) (officials of the Health Care Financing Administration proposal); Symposium, *Getting It Right: The Makings of Practice Guidelines*, QUALITY REV. BULL., Feb. 1990, at 40.

<sup>267</sup> Rosoff, *supra* note 185, at 370.

<sup>268</sup> *Id.* at 370 (citing John Ayres, *The Use and Abuse of Clinical Practice Guidelines*, 15 J. LEGAL MED. 421, 436–38 (1994) (CPGs are created to assure quality of care, maximize efficient utilization or maximize profits for third party payers)); *see also* Maxwell J. Mehlman, *Assuring the Quality of Medical Care: The Impact of Outcome Measurement and Practice Standards*, 18 LAW MED. & HEALTH CARE 368, 375 (1990) (surveying the various forms CPGs can take).



care' guidelines.<sup>269</sup> Second, there are those which were created to improve cost effectiveness, referred to as 'appropriateness guidelines.'<sup>270</sup> Many of the CPGs in this category only consider quality concerns to the extent that quality is not unduly negatively impacted by cost reduction.<sup>271</sup> In the third category, there are CPGs that couple the best of both worlds as they are both quality-enhancing and cost-reducing.<sup>272</sup>

While CPGs have played a role in the practice of medicine for a considerable period of time, there has been a relatively recent marked increase in the notice paid to the possible advantages of a greatly expanded role for CPGs in the delivery of patient care. This increase in attention was triggered by the health systems research that revealed striking and unjustifiable variations in the choices that physicians made in the diagnosis and treatment of the same clinical condition.<sup>273</sup>

In response to the concerns these studies engendered in the general public and among insurers, managed care organizations, and the government, the American Medical Association strongly advocated that private professional physician groups establish 'practice parameters' and instituted criteria and procedures for their development.<sup>274</sup> Private physician organizations representing physicians in specific practice areas responded by expending considerable efforts toward standardizing specifications for both the procedures for and the management of medical conditions.<sup>275</sup> For example, very detailed and well-defined CPGs were developed by the American College of Physicians by virtue of the Clinical Efficacy Assessment Project.<sup>276</sup> Other examples include those enacted by the American College of Obstetrics and Gynecologists, the American Academy of Pediatrics,<sup>277</sup>

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<sup>269</sup> Troyen A. Brennan, *Practice Guidelines and Malpractice Litigation: Collision or Cohesion?*, 16 J. HEALTH POL. POL'Y & L. 67, 67 (1991) [hereinafter Brennan, *Practice Guidelines*].

<sup>270</sup> *Id.*

<sup>271</sup> Rosoff, *supra* note 185, at 371.

<sup>272</sup> *Id.*

<sup>273</sup> See *supra* notes 182–98 and accompanying text.

<sup>274</sup> AM. MED. ASS'N, ATTRIBUTES TO GUIDE THE DEVELOPMENT OF PRACTICE PARAMETERS (1990).

<sup>275</sup> Havighurst, *Practice Guidelines as Legal Standards*, *supra* note 182, at 89.

<sup>276</sup> See INST. OF MED., ASSESSING MEDICAL TECHNOLOGIES 275–85 (1985).

<sup>277</sup> See generally OFFICE OF QUALITY ASSURANCE, AM. MED. ASS'N., LISTING OF PRACTICE PARAMETERS, GUIDELINES, AND TECHNOLOGY ASSESSMENTS (1989); INST. OF MED., MEDICAL TECHNOLOGY ASSESSMENT DIRECTORY: A PILOT REFERENCE TO ORGANIZATIONS, ASSESSMENTS AND INFORMATION RESOURCES (1988).

and those originally developed at Harvard to govern the delivery of anesthesia.<sup>278</sup>

Government agencies also joined the CPG movement. The Agency for Health Care Policy and Research runs the Medical Treatment Effectiveness Program<sup>279</sup> which “supports research, data development, and other activities to develop and review clinically relevant guidelines, standards of quality, performance measures, and medical review criteria, in order to improve the quality and effectiveness of health care services.”<sup>280</sup>

## 2. Use of Clinical Practice Guidelines in Peer Review

This proposal envisions physicians, who make up a specific practice group within a hospital, setting up a working committee. The task of this working committee is to propose to the entire practice

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<sup>278</sup> John Eichorn et al., *Standards for Patient Monitoring During Anesthesia at Harvard Medical School*, 256 J. AM. MED. ASS'N 1017 (1986) (reductions of anesthesia-related injuries directly attributed to implementation of practice guidelines originally developed at Harvard); Paul R. McGinn, *Practice Standards Leading to Premium Reductions*, AM. MED. NEWS, Dec. 2, 1988, at 1. In addition, private hospitals are engaged in the ongoing process of developing clinical pathways. Clinical pathways are similar to CPGs. See generally DONNA D. IGNATAVICIUS & KATHY A. HAUSMAN, CLINICAL PATHWAYS FOR COLLABORATIVE PRACTICE 10 (1995); Karen A. Butler, Comment, *Health Care Quality Revolution: Legal Landmines for Hospitals and the Rise of the Critical Pathway*, 58 ALB. L. REV. 843 (1995). Clinical pathways are interdisciplinary plans of care for more long-term conditions that detail the optimal sequence and timing of treatments for patients with particular medical conditions as they progress through different stages of their disease process. The team of practitioners, including the physicians and support staff, meet to tailor the decision pathways to the needs of the particular patient. The goal is to optimize the quality of the patient's care by planning ahead for events that are likely to occur. This planning can reduce delays, decrease the use of resources and provide a degree of certainty for both patients with long-term illnesses and those who care for them. For example, University Hospitals of Cleveland generated a critical pathway for individuals who are ventilator dependant. By performing a retrospective chart review and projected reimbursement by third party payers, the Hospital was able to reduce the cost of caring for this population. Another example is a critical pathway that was created by Johns Hopkins Hospital for individuals requiring the removal of their prostate gland.

<sup>279</sup> The Agency for Health Care Policy and Research (“AHCPR”) was created by The Omnibus Budget Reconciliation Act of 1989, 42 U.S.C. § 299 (2000). The AHCPR was created within the Public Health Service, a subdivision of the Department of Health and Human Services. *Id.* A separate office was created within the AHCPR called the Forum for Quality and Effectiveness in Health Care. Havighurst, *Practice Guidelines as Legal Standards*, *supra* note 182, at 90. This Forum appoints panels of physician experts and consumer representatives to oversee development of CPGs either by the panels themselves, by private organizations or by independent contractors. See *id.*

<sup>280</sup> FURROW ET AL., CASEBOOK, *supra* note 199, at 204. The Agency for Health Care Policy and Research is a part of the Public Health Service, which is a division of the Department of Health and Human Services.

group a set of CPGs that have been modified to fit the clinical care expectations of the practice group as a whole. For example, the cardiology practice group of a hospital may want to start with the CPGs promulgated by the American College of Cardiology (“ACC”). The CPG working committee would then take the suggestions of the entire practice group regarding modification of these CPGs to fit the collective practice style and professional judgments of all of the physicians in the practice group.

Once the practice group adopts the first set of comprehensive guidelines, a CPG committee would be appointed on a yearly basis which would assume the responsibility for CPG review and updating. Whenever new CPG provisions or revisions of existing CPGs were distributed by the ACC (or other appropriate CPGs), the CPG committee would be responsible for making recommendations to the cardiology practice group on the appropriateness of adoption, with or without revision, or rejection. In addition, the cardiology CPG committee could modify these CPGs on an ongoing basis to keep pace with scientific developments over and above the CPGs suggested by the ACC. The CPGs adopted by the cardiology practice group would then become the expectations of performance for all of the cardiology practice group’s physicians. These performance expectations would become part of the medical staff by-laws by virtue of an appendix.

For example, scientific studies have long established that providing aspirin to a patient within twenty-four hours of a heart attack may increase that patient’s chances of survival by thirty percent.<sup>281</sup> Yet in hospitals across the country, physicians are failing to provide this simple life-saving treatment up to fifty percent of the time.<sup>282</sup> Under this proposal, the CPG committees of all of the hospital cardiology departments across the country should propose that the CPG of the ACC<sup>283</sup> recommending this treatment be adopted as an expectation of performance of the medical staff of the hospital’s cardiology department.

A legitimate criticism of this proposed process is the amount of time, duplication of effort and expense associated with this CPG review enterprise. A possible solution to these concerns is similar to

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<sup>281</sup> Hospital Quality Alliance Project, *supra* note 188.

<sup>282</sup> *Id.*

<sup>283</sup> The ACC/AHA Guidelines for the Management of Patients with Acute Myocardial Infarction, and updates to the guidelines, are published in the *Journal of the American College of Cardiology*, 28 J. AM. C. CARDIOLOGY 1328–428 (1996); 34 J. AM. C. CARDIOLOGY 890–911 (1999) (updates), available at <http://content.onlinejacc.org/>.

that which is used by the institutional review boards (“IRBs”) of medical institutions conducting multicenter trials during clinical investigations of drugs and devices.<sup>284</sup>

[S]ometimes the IRB at each center of a multicenter trial conducts a complete review of the protocol and informed consent. Such multiple reviews by multiple IRBs can result in unnecessary duplication of effort, delays, and increased expenses in the conduct of multicenter clinical trials. Greater reliance on a centralized IRB review process, in appropriate circumstances, could reduce IRB burdens and delays in the conduct of multicenter trials.<sup>285</sup>

For example, central IRBs have been created to review multicenter trials dealing with a particular type of condition. “[T]he National Cancer Institute . . . has created a freestanding central IRB . . . to provide the option for centralized IRB review for the many multicenter cancer trials conducted by NCI.”<sup>286</sup> Similarly, CPG committees with comparable practice specialties could contract with a centralized CPG review group to perform a continuous review of CPGs to reflect scientific developments. The recommendations of this centralized CPG group could then be submitted to the CPG committee of the local institution for adoption, adoption with modification, or rejection. This pooling of resources is one way to deal with the concerns of duplication of effort, delay and expense.

In choosing the appropriate CPGs, a CPG committee should examine two important questions.<sup>287</sup> First, who developed the CPGs? And second, what methodologies were used? Most probably, physicians will be drawn to CPGs generated by those groups with ‘auspice legitimacy’;<sup>288</sup> in other words, those developers with excellent reputations for accuracy and technical expertise. These are most likely to be prestigious national groups representing practice specialties, such as the ACC or the American Heart Association. On the other hand, physicians are likely to avoid those CPGs promulgated by payors, referred to by some as ‘boundary guidelines.’ Boundary guidelines “are

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<sup>284</sup> See U.S. Food & Drug Administration, Guidance for Industry Using a Centralized IRB Review Process in Multicenter Clinical Trials, at Part II, <http://www.fda.gov/cder/guidance/OC2005201fml.htm> (last visited Apr. 28, 2006).

<sup>285</sup> *Id.* (citations omitted).

<sup>286</sup> *Id.* at Part VII.B.

<sup>287</sup> These are adapted from the set of four questions that Professor Rosoff recommends that a judge ask when deciding which CPGs should have evidentiary weight, and how much, in malpractice proceedings. Rosoff, *supra* note 185, at 384–95.

<sup>288</sup> *Id.* at 384 (citing Mehlman, *supra* note 268, at 377 (citing Kinney & Wilder, *supra* note 266, at 448)).

used by payors to define a range of practice options within which physicians could act without incurring financial or other sanctions.”<sup>289</sup> Based on altruistic motives, physicians are likely to perceive these types of CPGs as unduly limiting treatments necessary for patient welfare based on cost/benefit decisions made by profit conscious payors.<sup>290</sup> Physicians may also shun CPGs developed by payors based on self-protective motives.<sup>291</sup> Payor-developed CPGs which call for the provision of less care may be viewed as increasing the risk of malpractice exposure.<sup>292</sup> As the literature documenting the practice of defensive medicine demonstrates, the fear of liability greatly influences physician choices making these types of CPGs unlikely choices for adoption.<sup>293</sup>

Next, a CPG committee should examine the scientific basis for the CPG carefully. Was the clinical practice data base sufficiently large? Were the results based on solid scientific outcomes research? Were the methodologies used appropriate and employed with the guidance of qualified medical professionals? Is there provision for the timely updating of the CPG based on clinical experience with the CPG? If the answers to any of these questions are negative, the CPG under consideration should be viewed with suspicion. In contrast, CPGs which are created by competent scientists based on careful analysis of an appropriately large data base (controlling for confounding, bias and probability issues) created to optimize quality of care should be carefully considered for adoption.<sup>294</sup>

### 3. Expectations of Performance

Once the CPGs are adopted by the practice group, each physician who is a member of that department will be expected to comply with the CPGs except in situations where, in the judgment of the physician, they are not appropriate. In those circumstances, the physician will be expected to engage in documentation of the reasons for deviating from the CPGs. A physician who fails to comply with the

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<sup>289</sup> Havighurst, *Practice Guidelines for Medical Care*, *supra* note 266, at 778 n.3 (citing L. LEWIN & J.E. ERIKSON, LEADERSHIP IN THE DEVELOPMENT OF PRACTICE GUIDELINES: THE ROLE OF THE FEDERAL GOVERNMENT AND OTHERS 3 (rev. ed. 1989) (prepared for the Physician Payment Review Commission’s Conference on Practice Guidelines, Washington, D.C., Oct. 11, 1988)).

<sup>290</sup> See generally Rosoff, *supra* note 185, at 376 (generally describing some of the reasons for negative physician attitudes toward CPGs).

<sup>291</sup> *Id.*

<sup>292</sup> *Id.*

<sup>293</sup> *Id.*

<sup>294</sup> *Id.*

CPGs without a well-documented rationale should be subject to corrective action.<sup>295</sup>

For example, if a CPG on aspirin treatment of heart attack victims has been adopted and if a heart attack patient is admitted to the hospital with a condition that contradicts the provision of this treatment, the physician must document this fact. Otherwise, the failure to provide the treatment will violate the performance expectation as set forth in the adopted CPG.

This documentation exception should avoid a rigid expectation that the CPG be followed in all circumstances. It recognizes that patient care does not always follow the norm and allows for flexibility to adjust to a patient's unique needs.<sup>296</sup> As Professor Rosoff explains:

The goal of . . . CPGs is not, despite what some physicians may believe, to remove all elements of discretion and professional judgment from medical care. There will always be the need—and, one would hope, the latitude—for the exercise of professional judgment. Still, as the body of what is knowable and what is known grows, the degree of latitude will inevitably be impacted by the extant knowledge base. When one does not know what is right or wrong, everything is fair game to do. Knowledge brings limitations, or at least, the basis for limitations to be imposed. As an Institute of Medicine committee on Practice Guidelines has stated, the formal recognition of the practice guidelines movement “can be seen as part of a significant cultural shift, a move away from unexamined reliance on professional judgment toward more structured support and accountability for such judgment.”<sup>297</sup>

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<sup>295</sup> If physician competence is questioned based on frequent deviations from the CPGs, the pattern of conduct should be evaluated in peer review by a reasonable care standard. The CPG which was avoided, customary care standards, and evidence regarding the benefits and risks associated with the physician's choices in the provision of patient care would all be relevant. See *infra* Part VII.B.7 for a discussion of the appropriate reasonable care standard. Instituting this system could provide earlier notice of a physician who exercises poor judgment on a continual basis. Earlier notice allows for earlier intervention in the form, for example, of required attendance at educational seminars. Instituting corrective action before patient harm occurs enhances the quality of patient care. In addition, earlier interventions may lead to less dire correctional measures. The less dire the correctional measures, the more likely that the physician will accept these actions informally, avoiding the costs associated with the formal peer review process.

<sup>296</sup> Rosoff, *supra* note 185, at 375.

<sup>297</sup> *Id.* (footnotes omitted) (quoting INST. OF MED., *supra* note 264, at 2).

#### 4. Enhancing the Quality of Patient Care

While CPGs generally are still in their infancy, as evidence-based medicine moves forward,<sup>298</sup> under this proposal, the CPGs of hospital departments can develop apace. A benefit of introducing CPGs into the peer review process is that it requires physicians to keep step with current practice. At the same time, the committee approach encourages the practice group to make an educated rejection of a CPG rather than a rejection through inertia either from indifference or from the burdens of daily practice which leave little time for reviewing, assessing, and integrating the almost constant flow of new scientific developments. Collectively shouldering this burden through this process protects an entire practice group from lagging behind new scientific developments. Physicians will no longer be able to ignore new suggested CPGs out of hand, but will be required under the by-laws to make informed decisions to accept, modify and accept, or reject them. There is little doubt that the quality of patient care will benefit from this process.

Applying contractual expectations of performance provisions also side steps doctrines inherent in customary care measurements and tort 'standard of care' analysis. The locality rule,<sup>299</sup> honest error rule<sup>300</sup> and the good faith mistake rule,<sup>301</sup> which can sometimes act to immunize an incompetent physician from corrective action, all become irrelevant. The concept of fault is properly eliminated from

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<sup>298</sup> "Medical knowledge about evidence-based medicine has accumulated at a staggering rate. Between 1966 and 1995, the number of clinical research articles based on randomized clinical trials jumped from about 100 per year to 10,000 annually." FURROW ET AL., HEALTH LAW, *supra* note 99, § 6-2, at 274 (citing Mark R. Chassin, *Is Health Care Ready for Six Sigma Quality?*, 76 MILBANK QUARTERLY 565, 574 (1998)). "Web-based databases have proliferated to help physicians gain efficient and use-friendly access to this proliferation of guidelines and other medical information." *Id.* (citing Barry R. Furrow, *Broadcasting Clinical Guidelines on the Internet: Will Physicians Tune In?*, 25 AM. J. LAW & MED. 403 (1999)):

The National Guideline Clearinghouse [<http://www.guideline.gov>] offers free access by physicians and others to the current clinical practice guidelines . . . . A search produces all guidelines on a given subject, along with an appropriateness analysis of each guideline. The Clearinghouse provides a standardized abstract of each guideline, and grades the scientific basis for its recommendations and the development process for each.

*Id.* (footnotes omitted). Other commercial internet-based services include MDConsult, <http://www.mdconsult.com> (last visited Apr. 29, 2006), and Medscape, <http://www.medscape.com> (last visited Apr. 29, 2006). See FURROW, ET AL., HEALTH LAW, *supra* note 99, at 275.

<sup>299</sup> See *supra* notes 206–14 and accompanying text.

<sup>300</sup> See *supra* note 260.

<sup>301</sup> See *supra* note 260.

the process. In addition, hospitals will not be barred from choosing to employ physicians who adopt 'best practices' instead of those who are minimally competent.

5. Decreasing Transaction Costs While Still Enhancing Quality of Care

Finally, with regard to the scope of discovery, little room remains for an argument that the care provided by other physicians in the department is relevant. This means that discovery can be confined to the patient records of the allegedly incompetent physician. This streamlines the process and makes the hospital less reluctant to act on evidence of incompetence on the part of a physician. Hospitals may be willing to formally intervene with a recalcitrant physician much sooner as evidence comes to light of issues of incompetence, instead of waiting until the evidence becomes incontrovertible, the situation becomes dire and the only choice becomes termination of staff privileges. This benefits the physician as intervention earlier rather than later may mean that the sanctions imposed will be less severe than termination, allowing the physician the opportunity to remedy the situation. The less dire the sanctions, the more willing the physician may be to accept them without triggering the costly formal peer review process. Earlier intervention also inures to the benefit of patient safety as hospitals are more likely to intervene and take corrective actions to deal with incompetent physicians before a patient has actually suffered harm.

6. Physician Due Process and Immunity Concerns

Physicians may be motivated by self-interest to support adoption of CPGs to decrease uncertainty regarding the conduct that will trigger formal peer review proceedings and the resultant notice to the National Practice Data Bank. Adopting CPGs as the expectation of performance provides more adequate notice of the type of conduct which will subject the physician to corrective action. The physician can then avoid this conduct. It also provides the physician with a better ability to prepare for a challenge to the suggested corrective action. As a result, HCQIA immunity is more likely to be bestowed on those who participate in the process.

7. Including the Tort 'Reasonable Care' Standard as a Stop-Gap Measure

As stated earlier, while growing at a staggering rate, medical knowledge grounded in evidence-based medicine is still in its infancy.



Thus, using CPGs created from evidence-based medicine will not provide an immediate solution for all situations involving allegedly incompetent physicians. When CPGs with auspice authenticity have yet to be promulgated, relying on the standard of reasonable care as defined by negligence law can provide a workable stop-gap measure. This reasonable care standard must be divorced from most, if not all, of the other doctrinal trappings of medical malpractice jurisprudence for the reasons outlined earlier.<sup>302</sup> In adopting this measure, medical staff by-laws should comport with the growing number of states which have rejected the use of customary care as conclusive evidence of the quality of patient care.<sup>303</sup> Among other reasons, these states have found that such rigid application of custom can both insulate a physician whose practice has lagged behind scientific advancements or stifle a physician from engaging in reasonable innovation to meet the needs of his or her patients. Instead, custom should be used as *some* evidence of what constitutes reasonable care, along with other relevant evidence of the risks and benefits associated with the patient care choices of the physician.

#### 8. Use of CPGs in Malpractice Litigation Post Adoption by the Medical Staff

To date, courts have allowed CPGs to be used both defensively and offensively by both plaintiffs and physicians as evidence of the standard of care in medical malpractice actions.<sup>304</sup> This use has drawn a great deal of support and criticism. Many of the criticisms of this use are met if the CPGs relied upon by the courts are first adopted by the medical staff by-laws.

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<sup>302</sup> See *supra* notes 256–60 and accompanying text.

<sup>303</sup> Peters, *supra* note 205, at 913–16.

<sup>304</sup> See, e.g., *Basten v. United States*, 848 F. Supp. 962, 967 (M.D. Ala. 1994) (use of American College of Obstetricians and Gynecologists guidelines relating to screening procedures for medical condition); *Green v. Goldberg*, 630 So. 2d 606, 609 (Fla. Dist. Ct. App. 1993) (expert testimony supported by American College of Obstetricians and Gynecologists bulletin dealing with breast cancer treatment); *Miles v. Tabor*, 443 N.E.2d 1302, 1303 (Mass. 1982) (violation of the American College of Obstetricians and Gynecologists guidelines to fail to resuscitate an infant immediately post-delivery); *Roper v. Blumenfeld*, 706 A.2d 1151, 1156 (N.J. Super. Ct. App. Div 1998) (plaintiff's use of *1992 Parameters of Care for Oral and Maxillofacial Surgery: A Guide to Practice, Monitoring and Evaluation* to establish breach of standard of care); *Frakes v. Cardiology Consultants, P.C.*, No. 01-A-01-9702-CV-00069, 1997 WL 536949, at \*2 (Tenn. Ct. App. Aug. 29, 1997) (use of Exercise Test Parameters Associated with Poor Prognosis and/or Increased Severity of CAD [Coronary Artery Disease] contained in a brochure produced by the American College of Cardiology and the American Heart Association as standard of care).

Historically, the scope of the evidentiary use of CPGs was vested in the hands of the courts. Except for some recent legislative initiatives discussed below, courts generally have the discretion to give CPG evidence a whole range of weights in establishing the standard of care, from no value, to highly or conclusive probative value. Thus, CPGs currently serve the same function as expert testimony, just to different degrees in different courts.<sup>305</sup>

Advocates of this use of CPGs in malpractice litigation point out that CPGs are far more specific than vague tort standards, may lower litigation costs by simplifying trials, make trial outcomes more predictable facilitating settlements, and may decrease uncertainty with regard to the legal system's expectations, thereby lowering the cost of defensive medicine.<sup>306</sup> In addition, CPGs would ameliorate complaints with regard to the quality of expert testimony involving scientific issues.<sup>307</sup> In light of these possible benefits, some commentators have gone so far as to advocate that CPGs be given judicial notice as *conclusive* evidence of the standard of care.<sup>308</sup> This proposal is problematic. The American Medical Association explains that the medical profession as a whole is far from recognizing any one set of CPGs that is controlling.<sup>309</sup> Rule 201 of the Federal Rules of Evidence explains

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<sup>305</sup> In reaching a decision on what weight, if any, a CPG should be given, a court may consider its auspice. Mehlman, *supra* note 268, at 377 (taking the position that CPGs promulgated by nationally recognized groups should be the only judicially-recognized CPGs); Rosoff, *supra* note 185, at 379. The greatest amount of weight would likely be given to CPGs issued by the federal AHCPR, followed by those issued by well-regarded professional bodies such as the American College of Obstetrics and Gynecology. Mehlman, *supra* note 268, at 377; *see also* Kinney, *supra* note 25, at 448. Those issued by an HMO are likely to carry the least weight. Mehlman, *supra* note 268, at 377.

<sup>306</sup> Havighurst, *Practice Guidelines as Legal Standards*, *supra* note 182, at 96; *see also* Brennan, *Practice Guidelines*, *supra* note 269, at 67–68; Mark Hall, *The Defensive Effect of Medical Practice Policies in Malpractice Litigation*, LAW & CONTEMP. PROBS., Spring 1991, at 119, 119.

<sup>307</sup> Brennan, *Practice Guidelines*, *supra* note 269, at 74 (practice guidelines in health policy); *see generally also* Troyen A. Brennan, *Helping Courts with Toxic Torts: Some Proposals Regarding Alternative Methods for Presenting and Assessing Scientific Evidence in Common Law Courts*, 51 U. PITT. L. REV. 1 (1989); Jack Weinstein, *Litigation and Statistics*, 3 STAT. SCI. 289 (1988); Milton R. Wessel, *Adversary Science and the Adversary Scientist: Threats to Responsible Dispute Resolution*, 28 JURIMETRICS 379, 380–81 (1988) (detailing societal disillusionment with the “battle of the experts”).

<sup>308</sup> Leahy, *supra* note 265, at 1506–08 (advocating for judicial notice of CPGs as evidence of the legal standard of care); *see generally* Mehlman, *supra* note 268, at 378 (arguing that a presumption should be created that CPGs issued by reputable medical organizations are evidence of national standards).

<sup>309</sup> For a detailed explanation of the problems associated with the use of CPGs in malpractice litigation, *see* Michelle M. Mello, *Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 674 & n.130

that judicial notice is inappropriate when the fact at issue is “subject to reasonable dispute” as it is not established by either common knowledge or “sources whose accuracy cannot be reasonably questioned.”<sup>310</sup> The number of CPGs, over 1600,<sup>311</sup> creates a formidable task for a judge who attempts to make a determination of which CPG should be blessed by judicial notice. A judge is unlikely to have the necessary expertise to make this choice.<sup>312</sup>

However, when the physicians in a hospital practice have, as a group, identified the CPGs which will govern their practice, it provides greater guidance to judges in deciding as an evidentiary matter what CPGs are relevant to defining the standard of care if one of the members of that practice is sued. Physicians have the medical knowledge needed to accurately assess the risks, benefits and burdens involved with different CPGs. Patients already rely on physicians to engage in exactly this kind of decision-making that will maximize patient outcomes. Judicial acknowledgment of the physician choices of CPGs may lower the cost of litigating this issue. If this comes to pass, the extent of defensive medicine may be driven down as the physician is provided with some degree of certainty<sup>313</sup> with regard to what will be deemed to be ‘appropriate care’ by the tort system.<sup>314</sup>

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(2001) (citing Ed Hirshfeld, *Use of Practice Parameters as Standards of Care and in Health Care Reform: A View from the American Medical Association*, 19 JOINT COMM’N J. ON QUALITY IMPROVEMENT 322, 323 (1993) (explaining that CPGs only use should be as evidence of the standard of care)).

<sup>310</sup> *Id.* at 674 (quoting FED. R. EVID. 201(b)).

<sup>311</sup> *Id.*

<sup>312</sup> It is true that CPGs can first be fairly easily categorized (as described above) based on the entity which promulgated them. Then, choosing the most favored auspice category should also be relatively easy. However, finally choosing which CPG from the auspice category of choice which is appropriate to the clinical situation is a commission best undertaken by an individual with medical training and experience. A judge is unlikely to have the necessary expertise.

<sup>313</sup> Hall & Green, *supra* note 183, at 669 (“Much of the concern about costs created by ‘defensive medicine’ (physicians incurring unnecessary costs and risks simply to avoid suit) would be mitigated if physicians had stronger assurance they will be held only to standards that reflect genuinely prevailing professional practices and opinions.”).

<sup>314</sup> *Id.* In addition,

[m]edical drug and device companies regularly use the fear of liability to motivate physicians to adopt new, expensive technologies, sometimes prematurely or excessively, by arguing that physicians could be held accountable for not quickly adopting a “state of the art” innovation. If physicians knew that they could document pockets of skepticism about these profit-motivated claims, they could more safely resist inappropriate expansions of new technologies whose risks and benefits are not yet thoroughly understood or whose costs may be excessive.

*Id.*

Some tort reformers advocate carving out a greater role for CPGs in malpractice litigation by legislative initiatives.<sup>315</sup> Other types of suggested legislative initiatives include obligating physicians and patients to agree to be contractually bound by a set of CPGs which would define the standard of care or requiring that courts take judicial notice of CPGs as conclusive evidence of the standard of care.<sup>316</sup> However, CPGs as conclusive evidence of the standard of care is prob-

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<sup>315</sup> *Id.* (pointing out that several states have listened to this advice). For example, Kentucky passed the following legislation allowing the use of CPGs by physicians to establish an affirmative defense to malpractice:

Any provider of medical services under this chapter who has followed the practice parameters or guidelines developed or adopted pursuant to this subsection shall be presumed to have met the appropriate legal standard of care in medical malpractice cases regardless of any unanticipated complication that may thereafter develop or be discovered.

KY. REV. STAT. ANN. § 342.035(8)(b) (West 2005). Both Maine and Minnesota passed legislative initiatives. The Maine legislation provided physicians with immunity from suit if the physician acted in compliance with approved CPGs. ME. REV. STAT. ANN. tit. 24, § 2972(1) (Supp. 1994). This legislation was repealed in 1999. 1999 Me. Laws c.668, s.104. The Minnesota version provided an absolute defense for physicians who complied with approved CPGs. MINN. STAT. § 62J.34(3)(a) (1994). This was also repealed in 1995. 1995 Minn. Laws c. 234, art.5, s.24. Mello, *supra* note 309, at 707.

<sup>316</sup> Mello, *supra* note 309, at 693–94. Those who advocate for the contractual model argue that consumers will be enfranchised by their ability to choose between physicians based on the quality of care provided as set forth in the different CPGs adopted. *See, e.g.*, Havighurst, *Practice Guidelines as Legal Standards*, *supra* note 182, at 113. However, this consumer choice opportunity is a partially empty one based on “imperfect information, imperfect rationality and imperfect freedom of choice.” Mello, *supra* note 309, at 669. Consumers do not have the medical knowledge needed to accurately assess the risks and benefits involved with different CPGs. Adding to this information disconnect are studies that suggest that consumers do not necessarily make decisions based on objective considerations that would lead to a maximization of long-term benefits. *Id.* (citing Thomas Rice, *Can Markets Give Us the Health System We Want*, 22 J. HEALTH POL. POL’Y & LAW 383, 404–11 (1997) (challenging the utilization of consumer choice theory in the health care market)). Subjective concerns that have little to do with rational choices can lead a consumer’s decision-making away from optimizing the potential for positive outcomes. *Id.* at 670 & n.114 (explaining that some consumers fail to take advantage of plans that provide better coverage simply out of a reluctance to make change) (citing Daniel Kahneman, *New Challenges to the Rationality Assumption*, 150 J. INSTITUTIONAL & THEORETICAL ECON. 18, 18 (1994) (“[P]eople are myopic in their decisions, may lack skill in predicting their future tastes, and can be led to erroneous choices by fallible memory and incorrect evaluation of past experiences.”) (alteration in original)). Moreover, the idea that a consumer has freedom to choose among practitioners ignores the reality that those with employer provided insurance have either a limited number of choices among health plans, perhaps two or three at the most, or no choice at all. *Id.* at 670–71. Of those employees who do have a choice on paper, the reality is that the only real option is the lower cost plan as a result of budgetary concerns. It is the plan that dictates which physicians the individual can use.

lematic regardless of the mechanism of their imposition.<sup>317</sup> Such rigid rules could insulate a physician whose practice group has lagged behind scientific advancements in updating their CPGs. These rigid rules could also stifle a physician from exercising the option to deviate from the practice group's CPGs in order to engage in reasonable innovation to meet the needs of his or her patients. The better rule would be to call for judicial notice of the use of CPGs adopted by practice groups as some evidence, but not conclusive evidence, of the standard of care.

A final criticism is that some CPGs espouse optimal care rather than reasonable care.<sup>318</sup> The argument is that this standard eschews the basic premise that tort liability be based on fault as defined by either failure to adhere to socially acceptable conduct (custom), or at the most, a violation of reasonable care. No other type of professional is held to a standard of optimal care under tort law. Furthermore, if the law proceeds to hold a physician to an optimal standard of care, malpractice insurance premiums may skyrocket.

However, if the physician has agreed to provide a certain level of care by agreeing to the adoption of the CPG in the first place, the question of fairness to the physician becomes irrelevant. In addition, those hospital departments that do adopt CPGs as a part of their expectations for performance may be able to negotiate lower malpractice insurance rates for all members of the department. The department may also be in a stronger position to draw a line in the sand with reimbursement insurers which are striving to impose limits on the provision of care that are antithetical to the quality of care provided by the department.

#### VIII. CONCLUSION

Using vague 'standard of care' measures of clinical competence in the formal peer review process brings a whole bag of rules and premises, both legal and evidentiary, that unduly confuse, burden, and jeopardize the validity of the peer review process. Applying these vague and ambiguous 'standard of care' rules ex post facto creates an arguably unfair process of review for physicians and places all of the participants in the process at risk of losing HCQIA immunity. Ultimately, the hospital may be unduly reluctant to initiate such a bur-

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<sup>317</sup> See generally Ayres, *supra* note 268, at 436–38; Hall & Green, *supra* note 183, at 663; Andrew L. Hyams, David Shapiro & Troyen Brennan, *Medical Practice Guidelines in Malpractice Litigation: An Early Retrospective*, 21 J. HEALTH POL. POL'Y & LAW 289 (1996); INST. OF MED., *supra* note 264, at 8; Rosoff, *supra* note 185.

<sup>318</sup> Hall & Green, *supra* note 183, at 665.

densome and expensive process, placing patient safety at risk. Replacing vague 'standard of care' language with express contractual terminology, such as 'expectations of performance,' and incorporating specifically chosen and uniquely tailored Clinical Practice Guidelines ("CPGs") directly into the medical staff by-laws, may result in a more equitable balancing of the public's quality of care concerns with the interests of the physician in a fair process of review of adverse formal peer review actions. In addition, this shift to contract principles could streamline the formal peer review process making a hospital less reluctant to engage in peer review, and allowing peer review to live up to its promise as an effective system of accountability for the enhancement of patient care.