Annals of Health Law

Volume 11
Issue 1 *2002*

Article 9

2002

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Sharon King Donohue
National Committee for Quality Assurance

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*Sharon King Donohue, J.D.**

I. INTRODUCTION

> Serious and widespread quality problems exist throughout American medicine. These problems, which may be classified as underuse, overuse, or misuse, occur in small and large communities alike, in all parts of the country, and with approximately equal frequency in managed care and fee-for-service systems of care. Very large numbers of Americans are harmed as a direct result. *Quality of care is the problem, not managed care* (emphasis added).[1]

Since 1990, the National Committee for Quality Assurance (NCQA) has been harnessing the power of information to improve the quality of health care for Americans. As an independent, not-for-profit organization, NCQA's mission is to improve health care by accrediting and assessing the quality of care provided by a variety of health care organizations (MCOs).[2] The ability of MCOs, health facilities and physicians to freely share quality assessment information is essential to improving the quality of American health care. This information is also a powerful tool for consumers and employers to compare the quality of care provided by MCOs, so that they can choose and purchase the best health care. Finally, the data provides tremendous insights for the improvement of health policy to local, state, and federal governments, as well as other interested parties. Greater access to quality of care information is therefore a strong catalyst to improving the quality of health care for U.S. consumers.

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* Sharon King Donohue is the General Counsel and Chief Privacy Officer of the National Committee for Quality Assurance located in Washington, DC.

1. Mark R. Chassin et al., *The Urgent Need to Improve Health Care Quality*, 280 J. AM. MED. ASS'N 1000, 1000 (1998).

2. NCQA currently accredits health maintenance organizations (HMOs), preferred provider organizations (PPOs), managed behavioral health care organizations, credentials verification organizations, physician organizations, disease management programs and human research programs for the Veterans Administration.

Health care quality cannot be improved without such measurement, but the willingness of MCOs to voluntarily submit to independent third party quality assessment is now threatened by current legal attacks on managed care. Many health care lawyers have advanced the quality of health care in America, and traditional civil malpractice suits against negligent practitioners and careless insurance firms have led to legitimate redress for injury and sometimes resulted in changing industry practice. However, the current spate of class actions and attacks on managed care in the state courts may undermine the very quality the lawyers purport to promote.

The number of class actions being filed in the United States has risen to epidemic proportions.[3] While brought under the guise of ensuring quality care, the self-acclaimed REPAIR team lawyers (RICO and ERISA Prosecutors Advocating for Insurance Industry Reform), are using class actions against MCOs as a self-serving enterprise bent on seeking massive profits through litigation, rather than defending the rights of the health care consumer. High profile trial lawyers have attempted to capitalize on the bad publicity of managed care by filing class-action lawsuits against MCOs, using Wall Street to impact the stock value of MCOs and attempting to force large settlements.[4] Some of these cases are brought on behalf of consumers, while others are brought on behalf of physicians and other providers. These suits seek massive damages and broad-sweeping injunctions under RICO and ERISA that would reshape health care in the U.S. And more recently, an increasing number of these cases are being brought in state courts.

The private bar, in its search for litigation gunpowder, is even attempting to use NCQA accreditation and assessment data as a weapon against managed care organizations. For example, NCQA is named as a non-party co-conspirator in the consolidated class actions pending before Judge Moreno in the Southern District of Florida, on the grounds that NCQA promotes the use of clinical practice guidelines and utilization management

3. *See infra* text accompanying note 19.

4. Much has been written about the sweeping federal class actions and the tactics used against MCOs brought by the REPAIR team lawyers who successfully prevailed against the tobacco industry and collected $14 billion in fees. *See, e.g.*, Andrew Julien, *Sworn Foe of HMOs Confident of Victory: On Insurers' Turf, Lawyer Lays Out Strategy*, HARTFORD COURANT, Feb. 11, 2000, at A1; Adam Bryant, *Who's Afraid of Dickie Scruggs*, NEWSWEEK, Dec. 6, 1999, at 46; Adam Cohen, *Are Lawyers Running America?*, TIME, July 17, 2000, at 22.

standards through its accreditation standards.[5] NCQA's confidential accreditation reports are also sought through discovery in malpractice actions which NCQA resists, in part because such data should be considered part of the peer review process and thus not discoverable. As a result of these cases, health plans, hospitals and physicians are concerned that third party accreditation and ongoing quality measurement will be used against them in litigation, to produce the proverbial "smoking gun." Their concern could be a valid one, if the plaintiff's bar is allowed to use accreditation standards and assessment information, which are designed to improve quality of care, as a means to establish in a liability context that a provider or health plan did not meet a particular standard of care.

This improper use of third party accreditation and quality assessment data could ultimately drive health plans, hospitals, and physicians away from participating in these quality tracking and improvement activities. Just as courts have found that a hospital's peer review process is privileged because its function is in the public's best interest, the disclosure of quality information for participation of health organizations in third party accreditation and ongoing quality measurement is similarly situated.[6] The information produced should also be privileged, because doing so would be in the best interest of all health care consumers. It would be a tragedy if MCOs and other health providers stopped sharing quality of care information through NCQA and other similar third parties because of litigation concerns. Furthermore, because of the recent trend of activity in the state courts, this privilege needs to be established at a federal level in order to protect national quality measurement initiatives. Large health care organizations will not participate in multi-state and national quality of care reporting systems if they are left open to substantial liability in individual states that have not passed the necessary information privilege laws.

This article explores the role of the private bar and quality of care information in the improvement of health care. Part II explains the NCQA's role in the improvement of quality of care.

5. Plaintiffs' Consolidated Amended Complaint, *In re* Managed Care Litigation, MDL No. 1334 (S.D. Fla 2001).

6. The Institute of Medicine promotes the disclosure and transparency of such quality information. *See* CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY (2001). Further, it recognizes that there is evidence that "open disclosure of [medical] errors may decrease the likelihood of malpractice loss. *Id.* at 80.

Part III describes the dramatic rise in federal and state class action lawsuits and attempts to use accreditation standards and information in litigation. Part IV suggests a possible solution, namely by extending liability protection to health care quality improvement initiatives.

II. The NCQA's Role in The Improvement of Quality of Care

The NCQA is a leader in the effort to assess, measure and report on the quality of care provided by MCOs, including HMOs. The NCQA is governed by a Board of Directors consisting of representatives from employers, consumers, labor groups, managed care organizations,[7] quality experts, and organized medicine. In its first decade, NCQA has accredited half of the HMOs in the country, representing 75% of the enrolled population in HMOs. The NCQA's efforts are organized around two activities: (1) accreditation, and (2) outcome performance measurement. These are complementary strategies for quality information to guide employer and consumer choice of health plans. Organizations that participate in accreditation and reporting of performance outcomes do so largely on a voluntary basis, although some states mandate participation in such activities.[8] The NCQA's work has demonstrated that health plans can play an important role in improving the quality of care for their enrolled populations. NCQA is also currently working on performance measures at the physician level.

The NCQA's accreditation standards generally look at whether health plans have systems in place to ensure quality.[9] For example, does the plan credential its physicians? Are the plan's utilization practices timely and based on the use of evidence-based clinical practice guidelines? If the plan delegates utilization review to a physician group, does the plan exercise appropriate oversight over the delegates to ensure that they are

7. NCQA's Board of Directors is currently composed of 15 members, only one of whom represents a health plan.

8. Delaware, Florida, Hawaii, Kansas, New Jersey, Oklahoma, Pennsylvania, and Rhode Island all require third party accreditation. Arizona, Iowa, Massachusetts, Maine, Michigan, Missouri, Montana, Nebraska, Nevada, and New Mexico give credit for compliance with quality standards to plans that are NCQA accredited.

9. Plans can achieve various levels of accreditation ranging from Excellent (the highest level), to Commendable, Accredited, and Provisional. Plans that fail to achieve accreditation are deemed to be Denied. NCQA publishes the outcomes of its accreditation reviews on its Web site, www.ncqa.org, as part of its Health Plan Report Card.

using evidence-based clinical practice guidelines? Does the plan ensure that its members get appropriate preventive care?[10] The outcome performance measures, of which there are approximately seventy, are known as The Health Plan Employer Data and Information Set (HEDIS®). HEDIS measures look at things like beta-blocker rates, diabetic screening rates, cholesterol management, mammography screening, and childhood immunization rates.[11]

Every year, the NCQA releases a "State of Managed Care Quality Report" which analyzes how plans are doing in terms of improving quality.[12] The dramatic impact that health plans have had in improving quality can be demonstrated by looking at HEDIS rates from 1996-2000. During that time, the rate at which beta-blockers were prescribed for cardiac patients improved from 63% to 89%.[13] Cervical cancer screening rates went from 70% to 78%.[14] Furthermore, in only three years, the chicken pox vaccination rate increased from 40% to 71%.[15]

The NCQA also publishes national and regional benchmarks for performance on a yearly basis, comprising complete comparisons of HEDIS rates, known as Quality Compass.[16] These benchmarks demonstrate that there is wide variation in performance among plans in different regions of the country. For example, New England health plans have historically outperformed, on average, health plans from all other regions. Plans in the South Central, Mountain and West North Central regions have historically scored lowest on the majority of HEDIS measures. Finally, the benchmarks demonstrate that accredited plans score better on average than unaccredited plans.[17]

While the NCQA views the documented improvements in health care as tremendous progress, we know that there are still vast improvements to be made, evidenced by the fact that not

10. *See* NCQA, Surveyor Guidelines for the Accreditation of Managed Care Organizations, (effective July 1, 2001).

11. *See* NCQA,HEALTH PLAN EMPLOYER DATA & INFORMATION SET, Vol. I-V (2001).

12. NAT'L COMM. FOR QUALITY ASSURANCE, THE STATE OF MANAGED CARE QUALITY, 2001, *available at* http://www.ncqa.org/somc2001.

13. *Id.* at http://www.ncqa.org/somc2001/BETA_BL/SOMC_2001_BBH.html.

14. *Id.* at http://www.ncqa.org/somc2001/CERVICAL/SOMC_2001_CERVICAL.html.

15. *Id.* at http://www.ncqa.org/somc2001/CHILD_IMM/SOMC_2001_CIS.html.

16. Quality Compass™ (Nat'l Comm. for Quality Assurance CD-ROM, current through 2002) (on file with author).

17. NAT'L COMM. FOR QUALITY ASSURANCE, *supra* note 12.

every health plan achieves an accreditation status of Excellent. HEDIS rates are still not 100 percent and do not cover every important disease or health condition. There is still wide variation in quality among regions of the country. In addition, we do not begin to claim that existing quality measures are perfect. It is hard, costly work to develop standards and measures that draw upon the knowledge of the best experts and the best available science (which is constantly changing). Information is the tool by which providers and plans can effectively deliver higher quality health care. It is only through collection, analysis and action upon information that our health care system can hope to reduce medical errors and improve quality. Health care quality information comparison must continue and extend to more areas and more participants.

III. The Rise in HMO Class Actions and State Actions

The fear of health care organizations involved in third party quality of care reporting systems is that lawsuits will increasingly be brought in federal and state courts to hold them liable as guarantors against malpractice or delivery of poor care. This is true even though MCOs are in most cases not involved in the direct delivery of patent care. Combined with the questionable results of health care related class actions, this could have a chilling effect on quality of care reporting systems. Plaintiffs' lawyers forced Dow Corning into bankruptcy by filing thousands of unfounded claims that the company's silicone breast implants caused health problems. After Dow acquiesced to a $3.2 billion settlement resulting in its bankruptcy, an independent panel of thirteen scientists at the Institute of Medicine concluded that silicone breast implants do not cause any major diseases.[18]

The scenarios from tobacco and breast implant litigation are starting to repeat themselves in the managed care industry. In the past three years, the number of class actions filed against the managed care industry has skyrocketed. Indeed, the use of class actions as a legal remedy in America has grown by astronomic proportions. A survey from RAND's Institute for Civil Justice

18. Institute of Medicine, Safety of Silicon Breast Implants 11 (2000), *available at* http://www.nap.edu/books/0309065321/html/.

found a similarly dramatic increase in state class actions.[19] A 1999 Federalist Society survey found that the companies surveyed experienced a 1,315% rise in pending state class actions, and a 340% rise in pending federal class actions over the ten-year period from 1988 to 1998.[20]

The most illustrative example of the class action litigation against the managed care industry is the Multi-District Litigation Panel cases now pending before Judge Moreno in the Southern District of Florida. Known as *In re Managed Care Litigation* (S.D. Fla. 2001), it combines more than forty class actions against almost every national MCO.[21] The Multi-District Litigation cases are divided into a subscriber tract and a physician tract.[22] Plaintiffs include physicians, medical associations, MCO members and subscribers, and state attorneys general. In the subscriber tract cases, the plantiffs allege RICO violations and breach of fiduciary duty under ERISA on the part of the MCOs.[23] The breach of fiduciary duty claims raise issues of quality of care on the grounds that well-known MCO methods of cost containment and benefit management adversely affect the quality of medical care received by subscribers. MCO practices that are claimed to harm quality of care include using utilization management guidelines that allegedly usurp "sound medical and clinical standards." No acts of malpractice resulting in medical injury to patients are alleged, and there are no allegations that plan members actually received "poor quality health care." Rather, the plaintiffs allege fraud in the sense that people didn't know they were getting "managed care" and therefore would fear some prospective injury. The plaintiffs' lawyers further contend that anyone involved in ensuring the use of clinical practice guidelines in medical decision making and in promulgating standards for utilization review (like NCQA) are co-conspirators of the managed care industry's purported fraud on the

19. DEBORAH HENSLER, *et al.*, Class Action Dilemmas: Pursuing Public Goals for Private Gain 5 (1999), *available at* http://www.rand.org/publications/MR/MR969.1/MR969.1.pdf.

20. Federalist Society for Law & Public Policy Studies, *Analysis: Class Action Litigation – A Federalist Society Survey, Part II*, CLASS ACTION WATCH, Vol. 1, No. 2, Spring 1999, at 3 fig.2, *at* http://www.fed-soc.org/Publications/classactionwatch/cawtoc.htm.

21. *In re Managed Care Litigation*, *supra* note 5.

22. A number of the claims have been dismissed or sent to arbitration but Judge Moreno recently ruled that certain RICO claims may proceed in the subscriber track. *See In re* Managed Care Litigation, 185 F. Supp. 2d 1310 (S.D. Fla. 2002).

23. *Id.*

American people. This argument leads to the conclusion that accreditation standards should have little if any credibility, which is ironic considering that the litigants making these claims are using the same accreditation standards to litigate against MCOs.

The lawyers litigating these cases are not after any improvement in the health care system; they are merely looking for deep pockets and a big payoff. These class actions do not merely seek to remedy an isolated injury to one patient; in effect they challenge the entire system of cost-contained health care. The private bar, whether they intend to or not, is effectively attempting to reshape public health policy by litigation rather than legislation.

The federal courts have taken notice and are starting to question the appropriateness of many managed care class actions. In its June 2000 decision in *Pegram v. Herdrich*, for example, the U.S. Supreme Court rejected the plaintiff's legal theory in part because the effect of adopting it "would be nothing less than the elimination of the for-profit HMO [and perhaps even] nonprofit HMO schemes."[24] In August 2000 a federal appeals court, in dismissing a major class action in *Maio v. Aetna Inc.*, took a cue from *Pegram* in concluding "we must decline appellants' invitation to pass judgment on the social utility of Aetna's particular HMO structure."[25] And another court has ruled that "plaintiff's concern about the soundness of managed care policy is best suited for resolution by branches of government other than the judiciary."[26]

The plaintiffs' bar is not taking these setbacks in federal court sitting down. "A series of recent decisions rejecting certification of purported nationwide class actions (both for trial and settlement purposes) and several proposed amendments to Fed. R. Civ. Pro. 23 appear to be stemming the flow of class action filings into the federal courts. However, these recent developments are spawning a rapidly increasing role for state courts in class action litigation, as plaintiffs' counsel seek new, potentially

24. 530 U.S. 211 at 233 (2000).

25. 221 F.3d 472 at 499 (3rd Cir. 2000).

26. Clark C. Havighurst, *Consumers Versus Managed Care: The New Class Actions*, 20 HEALTH AFFAIRS No. 4, at 12 (July-August 2001), *citing* Weiss v. Cigna Healthcare, 972 F. Supp. 748, 753 (S.D.N.Y. 1997)

friendlier fora in which to press arguments that have not faired well in the federal courts."[27]

The plaintiffs' bar is responding to the limitations that federal courts have set on class actions, which have been generally based on Rule 23. In addition, plaintiffs' lawyers have discovered that some state courts have a more receptive attitude toward class action lawsuits. This is often the case because state courts do not have the same resources that federal courts have in properly managing the complexities of class actions.[28] As a result, some state courts ignore the due process rights of both class members and defendants and certify for class treatment cases that lack all the necessary class certification prerequisites. Particularly disturbing, the ICJ/RAND study also suggests that in many state court class action settlements, the plaintiffs' attorneys receive greater remuneration from non-personal injury class actions than all class members combined.[29]

IV. Liability Protection for Health Care Quality Improvement Initiatives

"The self-critical analysis privilege" was first recognized almost 30 years ago in a federal case, *Bredice v. Doctors Hospital, Inc.*[30] "In *Bredice*, the court held that the minutes and reports created by a hospital's peer-review committee were not discoverable in a medical malpractice case."[31] The common law self-critical analysis privilege gives business the confidence to review legal and regulatory compliance without the jeopardy that the findings and working documents will be used as evidence in court. The privilege stands on three foundations: (1) the party seeking protection creates the information in a critical self-analysis; (2) the creation and usage of the information is in the public's interest; and (3) if discovery of the information were allowed, its creation would be hindered.[32] In addition, courts

27. Josh H. Beisner and Brian D.Boyle, *Class Actions: The Stampede to State Courts*, Litigation, Vol. 1, Issue 2, *at* www.fed-soc.org/Publications/practicegroupnewsletters/litigation/lt010202.htm.

28. John H. Beisner and Jessica Davidson Miller, *They're Making a Federal Case Out of It . . . In State Court*, 25 Harv. J. L. & Pub. Pol'y 143, 153-4 (2001).

29. *See* Hensler, *et al., supra* note 18, at 18.

30. 51 F.R.D. 187 (D.D.C. 1970).

31. Michelle R. Mosby-Scott and Michael Todd Scott, *Protecting Evidence of Self-Critical Analysis From Discovery in Illinois*, 88 Ill. B. J. 648, 648 (2000).

32. *Id.* at 649.

will consider the creator's expectation that such information would be confidential.[33]

The common law self-critical analysis privilege has been tremendously useful to protect information in internal reviews, such as those regularly performed by hospital peer review committees. However, it has not shielded third party reporting systems conducting the same kinds of analysis for primarily the same reasons, because such analysis is not *self* critical, and therefore fails to meet the first criterion and thus third party reporting systems are not strictly covered by the common law rule.

The lack of federal protection for information submitted to national patient safety reporting systems discourages the use of such systems. And it is not just MCOs that need liability protection for health care quality tracking and improvement initiatives. The Institute of Medicine's 1999 seminal report, *To Err is Human*, broadly outlined health care quality and error issues and made recommendations that quality of care and health care error information collected and distributed as part of a reporting system should be privileged.[34] The American Medical Association (AMA) is also a supporter of this issue: "The AMA strongly supports the principal underlying the Institute of Medicine Report that the health care system needs to transform the existing culture of blame and punishment that suppresses information about errors into a culture of safety that focuses on openness and information sharing to improve health care and prevent adverse outcomes. The AMA also supports the IOM's focus on the need for a system-wide approach to eliminating adverse outcomes and improving safety and quality, instead of focusing on individual components of the health system in an isolated or punitive way."[35]

Information collected and distributed as part of a quality measurement or error identification system needs to be privileged for state and federal judicial proceedings, in civil matters as well as administrative proceedings. This privilege should include information collected by MCOs and third parties for accreditation and ongoing performance monitoring. Four principles for

33. *Id.*

34. INSTITUTE OF MEDICINE, TO ERR IS HUMAN, 1999, *available at* http://www.nap.edu/catalog/9728.html.

35. *Medical Errors: Testimony Before the Subcommittee on Health of the House Comm. on Ways & Means*, 107th Cong. (2001) (statement of Thomas Reardon, M.D., President, American Medical Association), *available at* 2000 WL 11068009.

health care quality information privilege are supported by almost 100 health care organizations including the NCQA, the AMA, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and many state and specialist medical societies.[36]

First, this privilege should extend to discovery, subpoenas, testimony, or any other form of disclosure.[37] Second, the sharing of the information between health care organizations or with third parties should not abdicate this privilege.[38] Third, this information should not be subject to the Freedom of Information Act.[39] Finally, while a federal law is necessary, it should not preempt wider privileges available under state laws.[40]

Extension of the common law self-critical analysis privilege to multi-party or third parties reporting systems is not an attempt to privilege the underlying facts of health care quality or any specific error event including medical records and related documents that are created separate from the reporting system. Information required to be reported under state or other law would still not be subject to this privilege (but it may be subject to others). Most, if not all, information that is subject to legal discovery under current and future laws would remain discoverable.[41]

Health policy makers should keep these principles in mind when crafting patient rights legislation such as The Patients' Bill of Rights currently being debated in Congress. If properly crafted, patients' rights legislation will play a productive role in improving the quality of our health care system. However, the need to keep and extend liability protection on peer review information and processes that identify and report on health care errors and overall standards of care particularly at the national level should not be forgotten in the rush to respond to the public's apprehension about MCOs.

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36. U.S. PHARMACOPEIA, GENERAL PRINCIPLES FOR PATIENT SAFETY REPORTING SYSTEMS (2000), *at* www.usp.org/patient_safety.htm.

37. *Id.* at 5(a).

38. *Id.* at 5(b).

39. *Id.* at 5(c).

40. *Id.* at 5(d).

41. *Improving Health Care Quality: Statement for the Record of the American Medical Association to the Subcommittee on Health Comm. on Ways & Means*, 108th Cong. (2002), *available at* 2002 WL 2011552.

V. CONCLUSION

Third party accreditation, performance measurement and health care error information is a powerful consumer, management and health policy tool. It has improved the quality of our health care system, and should be encouraged, not diminished. While there is a legitimate role for the private bar to play in advancing health care quality, lawyers need to encourage plans, hospitals and physicians to measure and report on quality. They should encourage employers and consumers to responsibly use quality information to select and reward quality with their hard earned health care purchases. Lawyers can assist payors in creating systems to reward quality providers, lobby regulators to demand quality, and hold accountable those that seek to undermine and damage the quality of health care for their own personal profit.

While the courts will determine the general validity of various class actions, and state and federal legislation will create new safe harbors and openings to legal liability, one thing is certain. Third party accreditation and performance measurement data should not be used as a litigation instrument to create liability for managed care plans and providers. The collection, sharing and reporting of such data is integral to the improvement of health care at a system wide level and not just at an individual facility or organization. This privilege cannot be left only to state jurisdictions if the viability of nationwide quality of care reporting systems is to be encouraged. Federal legislative steps should be taken to protect this data from misuse, especially in the rising tide of state-level class actions. Such privileged information will allow nationwide third party accreditation and performance measurement reporting systems to flourish, so we can strive for the best health care possible for all American consumers.