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Will Pay for Performance Be Worth the Price to Medical Providers?

A Look at Pay for Performance and Its Legal Implications for Providers

Stacy L. Cook, J.D., LL.M*

“There’s a price to pay if you want to make things better, a price to pay just for leaving things as they are, a price for everything.” – Harry Browne

I. INTRODUCTION

Quality is the new mantra of healthcare payors. While quality is a long-standing theme in the healthcare industry, tying compensation to results has been a new focus in health care.¹ The pay for performance concept represents the latest strategy developed by healthcare payors to control costs while improving quality.² Simply stated, pay for performance (P4P) is an incentive program that measures several defined aspects of a provider’s care and compensates the provider according to the performance achieved.³

The turn to quality or performance as related to reimbursement is a natural progression given society’s changing perspective of the healthcare system. Traditionally, medicine was not considered a typical commodity because quality could not be easily measured. The practice of medicine was considered more of an art than a science and was a localized and

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3. AHRQ RESOURCES ON PAY FOR PERFORMANCE (P4P), http://www.ahrq.gov/QUAL/pay4per.htm#toc (last visited September 27, 2006).
individualized profession. Today, health care is generally viewed from a national, and sometimes even global, perspective. Consumers’ ability to compare services provided across geographic regions affects the concept of quality. For example, in 2003, Medicare studied regional differences for hospital services involving hip fractures, colorectal cancer, and acute myocardial infarction. While Medicare found that hospitals in higher spending areas provided sixty percent more care than hospitals in lower spending areas, there was no significant difference in the quality of care provided. Technology and consumerism have also prompted the spread of information and education to consumers and payors. In addition, science has evolved to allow a more standardized approach in evaluating and treating disease. The emergence of these factors has consequently put quality and performance in the spotlight.

This article considers the legal implications of P4P programs mainly from the perspective of healthcare providers. Although P4P programs vary, most share four common attributes: (1) adherence to clinical guidelines; (2) collection of data from the healthcare provider; (3) measurement of the provider’s performance; and (4) acknowledgement of the provider’s performance with recognition and pay. All of these components of P4P will affect the practice of medicine in many ways, and this article examines the likely effects that P4P programs will have on provider liability and rights.

Part II begins by explaining how P4P programs have emerged. Part III explains the structure and operation of these programs. Part IV then details the potential legal effects of P4P, including managed care liability, provider termination rights, and the discovery and admissibility of clinical guidelines and information collected in the performance programs. The goal of this

4. See JOHNS HOPKINS MEDICINE, THE FOUR FOUNDING PHYSICIANS, http://www.hopkinsmedicine.org/about/history/history5.html (noting Dr. Osler’s role as one of the four founding physicians of The Johns Hopkins School of Medicine); Amy Jurevic Sokol & Christopher J. Molzen, The Changing Standard of Care in Medicine, 23 J. LEGAL MED. 449, 475-76 (2002) (illustrating that the standard of care was previously defined within a local community. Now practitioners are generally held to a national standard of care).


6. Id.

7. Id.


9. The use of the term “provider” in this article includes physicians and hospitals, the two major participants in P4P programs.
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The article is to shed some light on P4P programs and to anticipate their influences so that providers and their counsel can intelligently evaluate participation in specific programs. Additionally, this article demonstrates that if providers participate in the evolution of P4P, they may be able to minimize the more detrimental consequences and take advantage of the potential legal effects that might benefit providers, such as additional peer review protection.

II. THE EMERGENCE OF PAY FOR PERFORMANCE PROGRAMS

In recent years, the number of P4P programs has increased dramatically. According to Med-Vantage, a California health informatics company, as of February 2006 there were approximately one hundred fifteen P4P programs. Three years earlier, only thirty-five such programs existed. These programs have emerged largely as the result of employer, health plan, and government initiatives.

A. Employer-Based Initiatives

P4P really gained momentum with the organization of employers. Indeed, no discussion of the genesis of P4P would be complete without mention of the Bridges to Excellence (BTE) program and the Leapfrog Group. These organizations have played a leading role in the development of performance programs.

Bridges to Excellence is a multi-state program initiated by employers. Some of the current employer-participants include General Electric, UPS, and Procter & Gamble. In addition to employers, other participants include the National Committee for Quality Assurance (NCQA), various health plans, and WebMD Health. BTE was formed in response to the Institute of Medicine’s 2001 report, “Crossing the Quality Chasm,” and in particular the report’s recommendation to redesign reimbursement in order

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11. Id.
14. BRIDGES TO EXCELLENCE, FREQUENTLY ASKED QUESTIONS: BTE OVERVIEW, supra note 13.
to effectuate quality improvement. The three key principles that guide BTE are as follows:

- Reengineering care processes to reduce mistakes will require investments, for which purchasers should create incentives;
- Significant reductions in defects (misuse, underuse, overuse) will reduce the waste and inefficiencies in the health care system; and
- Increased accountability and quality improvements will be encouraged by the release of comparative provider performance data, delivered to consumers in a compelling way.16

In general, participating employers pay bonuses to physicians for program compliance. Currently, BTE consists of three programs: Physician Office Link, Diabetes Care Link, and Cardiac Care Link.17 For example, physicians who participate in the Diabetes Care Link program can receive up to an eighty-dollar bonus per year for each diabetic patient.18 Some of the payors that have participated in BTE include Humana, UnitedHealthcare, and Anthem.19

The Leapfrog Group was officially formed in 2000 after a group of large employers expressed an interest in influencing the quality and affordability of health care.20 One of the Leapfrog Group’s stated missions is to promote “high-value health care through incentives and rewards.”21 In 2005, it initiated a nationally-standardized rewards program for participating hospitals.22 The program focuses on measuring effectiveness and affordability in five clinical areas: acute myocardial infarction (acute MI); coronary artery bypass graft (CABG); percutaneous coronary intervention; pneumonia; and deliveries.23 Hospitals that demonstrate excellence or show improvement are rewarded in the form of bonus payments, higher reimbursement rates, and public recognition.24

17. Id.
18. Id.
22. Id.
24. Id.
B. Health Plans

Health plans have also implemented individualized incentive programs.\(^{25}\) For example, Harvard Pilgrim Health Care, a non-profit HMO in the northeast, implemented an incentive program during negotiations for rate increases.\(^{26}\) The subsequently enacted rate increase included a portion that evaluated performance in specific areas, including adult diabetes, pediatric asthma, and inpatient utilization.\(^{27}\) In this program, providers receive the full amount of withheld funds if they demonstrate improved performance.

Similarly, in California, multiple health plans have collaborated with a statewide initiative known as Integrated Healthcare Association (IHA) to establish a P4P program.\(^{28}\) IHA was formed in July of 2000 by health plan medical directors, physician group executives, and purchasers who realized that even though there was much discussion about "value-based purchasing," few programs were actually implemented.\(^{29}\) The IHA P4P program was unveiled on January 15, 2002, with six plans participating: Aetna, Blue Cross, Blue Shield, CIGNA, Health Net, and PacifiCare Health Systems.\(^{30}\) Performance measurements began in 2003, and the first payments based on those measurements were made one year later.\(^{31}\) For example, in 2004, PacifiCare Health Systems awarded bonuses in the amount of fourteen million dollars to 124 out of 130 of its medical groups.\(^{32}\)

C. Medicare

Pay for performance may be catapulted into the industry if implemented by Medicare. For approximately two years, the Medicare Payment Advisory Commission ("MedPAC") has been analyzing P4P by studying private P4P programs and testing various programs through demonstration projects, such as the Physician Group Practice demonstration.\(^{33}\) Ten large

26. Id.
27. Id.
29. Id.
30. Id.
31. Id.
33. Hearing on Medicare Physician Payments, supra note 5.
physician groups from different communities across the country are participating in the Physician Group Practice project. Reimbursement in that program is based on fee for service, but participants may also earn performance bonuses.

Another project, the Premier Hospital Quality Incentive Demonstration, helps to determine whether providing financial incentives to hospitals will improve patient outcomes and reduce costs. Participation is voluntary and hospitals can receive bonuses in Medicare payments based upon performance of certain quality measures. Conversely, hospitals that do not perform well will be financially penalized in the third year of the project.

On July 27, 2005, MedPAC revealed its position on P4P when the Executive Director of MedPAC testified before the United States Senate Finance Committee. At the beginning of his testimony he stated:

MedPAC has concluded that Medicare is ready to implement pay for performance as a national program and that differentiating among providers based on quality is an important first step towards purchasing the best care for beneficiaries and assuring the future of the program.

Furthermore, MedPAC recommends that Medicare adopt P4P programs for hospitals, physicians, home health agencies, Medicare Advantage plans, dialysis facilities, and physicians who treat dialysis patients.

With respect to physicians, MedPAC recommends implementation of P4P in two stages. During the first stage, physicians will be encouraged to adopt information technology (IT) and will be required to report whether they have certain IT capabilities. Medicare will include the actual use of IT as a quality outcome measurement and will reward outcome achievement. The second stage, which would occur two or three years later, will involve measuring the clinical process of care for certain health

34. Id.
35. Id.
36. Id.
37. Id.
38. Id.
40. Id. at 3.
41. Id.
42. Id. at 2.
43. Id.
44. Id.

http://lawcommons.luc.edu/annals/vol16/iss1/7
MedPAC recommends that Medicare include all specialties within the P4P programs. MedPAC recommends that the P4P program should reward providers for exceeding certain benchmarks, as well as for making improvements in care. The purpose of this approach is to encourage low-scoring providers to improve care. As a funding recommendation, Medicare should set aside a small share of payments and take a budget-neutral approach. MedPAC recommends that Medicare start with one to two percent of current provider payments, since that would be the least disruptive for providers and beneficiaries. The amount should increase as providers gain more experience with P4P.

As the Centers for Medicare and Medicaid Services (CMS) waited for Congressional approval of the proposed P4P Medicare programs, it implemented a voluntary performance-reporting program. The Physician Voluntary Reporting Program (PVRP), which started on January 3, 2006, is essentially a simple P4P program without the payment incentive. Under PVRP, physicians may report certain patient care data to CMS. That data will then be analyzed to measure physician performance. Currently, neither the participation in the program nor the physician’s performance results will affect reimbursement.

At first, CMS proposed the use of thirty-six performance measures under PVRP, but after receiving concerns from physician groups it reduced the number of initial performance measures to sixteen. Physicians in any specialty can participate in the program. CMS reports that it will analyze and measure each physician’s performance and will provide physicians with

45. Pay for Performance in Medicare, supra note 39, at 2.
46. See id. at 6 (noting that CMS has already started collaborating with the American College of Surgeons, Society of Thoracic Surgeons, and other specialty groups to implement quality measures).
47. Id. at 3.
48. Id. at 4.
49. Id.
51. Id.
52. Id.
53. Id.
feedback regarding the results. CMS estimates that feedback will be available to physicians as early as summer 2006.

III. PAY FOR PERFORMANCE SPECIFICS

Not all P4P programs are the same. The most important distinctions include how performance is measured, who sponsors the program, the level of provider involvement, and how providers are compensated for quality or performance.

A. How P4P Programs Are Commonly Structured

Even though P4P programs vary, most can be categorized into a few common models. In the first model, employers pay individual doctors for achieving performance measures or improving performance. The BTE program is an example of this model in which physicians earn a bonus for each patient. The payments are usually true bonuses and have the potential to change behavior. The second model is similar, but involves a group of health plans that coordinates bonus payments to individual physicians for improved performance measures. IHA is an example of this model. In the third model, single health plans or Medicare may reward individual physicians for performance. These programs are likely to be limited with respect to the conditions covered by the performance plan, which usually translates to smaller rewards for doctors. Additionally, the Harvard Pilgrim Health Care plan withholds funds rather than giving physicians a

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56. Id.


59. Id.

60. Id.
true bonus. In that program, if physicians do not meet performance measures, they will not experience the negotiated rate increase.

Furthermore, the American Medical Association (AMA) and many physicians have voiced concerns that some P4P programs are nothing more than disguised withholding programs that managed care previously implemented to limit care. According to Kevin Grumbach, M.D., a physician with the Primary Care Research Center of the University of California, there is a significant difference between these two schemes:

We’ve found that bonuses based on the limitations of referrals and on productivity heighten physician performance anxiety and their perceptions that care may be compromised in these areas. Incentive programs based on meeting quality measures and improving patient satisfaction are associated with significantly higher physician job satisfaction.

Thus, the AMA has developed a set of five principles to address physician concerns such as payment. The principles are meant to be used as a guide in designing P4P programs and are summarized as follows:

- Ensure Quality of Care—Use evidence-based measures created by physicians and allow for variations based on sound clinical judgment;
- Foster the Patient-Physician Relationship—Fair programs should support the relationship and recognize some obstacles such as the patient’s financial circumstances and compliance;
- Participation Should Be Voluntary—The programs should not adversely affect physicians who choose not to participate;

61. DELAWARE HEALTHCARE ASSOCIATION GLOSSARY OF HEALTH CARE TERMS AND ACRONYMS, http://www.deha.org/Glossary/GlossaryW.htm#top (defining a withhold fund as: “The portion of the monthly capitation payment to physicians withheld by the managed care plan until the end of the year or other time period to create an incentive for efficient care. If the physician exceeds utilization norms for other members of his group or geographic region, he or she loses the fund or part of it. The principal of the withhold fund may be applied to hospital services, specialty referrals, laboratory usage, etc.”).
62. Id.
63. Martin Sipkoff, Is Pay for Performance Part of the Cure or the Problem?, MANAGED CARE MAG., July 2005, (observing that one major issue for physicians in a P4P program is where the “performance money” is coming from. In some programs funds are just redistributed. Employer-sponsored programs and programs supported by grants are more likely to provide additional funds). See also Bodenheimer, supra note 58, at 1.
64. Bodenheimer, supra note 58, at 3.
Use Accurate Data and Fair Reporting—Physicians should be allowed to review, comment and appeal the results; and

Incentives Should Be Fair—New funds should be provided for positive incentives. 65

The final P4P model involves individual health plans or Medicare paying performance bonuses to physician organizations instead of to individual physicians. 66 The organization may distribute the bonuses to its members, or it may use the bonuses to invest in IT or quality improvements. 67

Other programs have also been disguised as P4P. Probably the most infamous is the United HealthCare Performance program, implemented in the St. Louis area in 2005. In this program, United HealthCare identified providers who had achieved quality and cost control. 68 These providers were designated as “star” providers. 69 Enrollees who sought services from non-star providers had to pay significant out-of-pocket expenses. 70 Physicians and health systems had no input in the program and no warning prior to its implementation. 71

Claims data from 2002 and 2003 helped in the development of the United HealthCare Performance program. 72 Some quality measurements existed, but the star rating was largely based on costs. 73 Originally, only twenty-six percent of Illinois physicians and twenty-seven percent of Missouri physicians in the network received a star rating. 74 Shortly after the program began, the area’s largest healthcare system gave notice that it


67. Id.

68. Judith VandeWater, BJC Warns it May Drop United Healthcare, ST. LOUIS POST-DISPATCH, March 18, 2005 (noting that General Motors and UPS used the plan while DaimlerChrysler Corporation planned to switch its hourly employees to this plan).

69. Id.

70. Id.

71. Id.

72. Id.

73. Id.

74. VandeWater, supra note 68.
would terminate its contract with United HealthCare. Several months later the parties announced that they reached an agreement regarding the Performance program. The parties did not disclose the specifics of the agreement.

If bonus payments are a defining P4P characteristic, then many Medicare programs will probably not meet the definition in the long run. The stated purpose of the Medicare P4P program is to pay less for substandard services. In order to do this, the Medicare performance program will differentiate among providers. "Pay for performance will . . . address an inequity in the current system: paying the provider who gives his patients better care the same as the provider who does not." Medicare plans to implement the program without any additional costs, which means that the payments to higher performing providers will come out of the pockets of the lower performing providers.

The amount of the payment incentive may also be a major factor in the Medicare program. In its proposal to the Senate Finance Committee, MedPAC recommends initial payments of only one to two percent of current payments. The Director of MedPAC acknowledged that concerns have already been raised regarding the insufficiency of the planned payments. In order to participate in P4P, providers will be burdened with extra costs of technology and labor. The performance payments may not be worth these costs to providers, and it has been noted that the primary effect of P4P will be to harm low-performing providers and discourage Medicare participation. MedPAC does not do much to alleviate these concerns, continually stressing that the purpose of P4P is to differentiate among providers. Some are concerned that the real goal of P4P programs like the Medicare proposal is not to encourage providers to achieve higher goals, but to eliminate the lower performing providers.

The AMA has been critical of the Medicare P4P program and the Medicare PVRP. On November 7, 2005, the AMA voted to oppose Medicare P4P initiatives that do not comport with AMA principles and

75. Id.
76. Patrick L. Thimanqu, BJC, UnitedHealthCare Reach Agreement, ST. LOUIS BUSINESS JOURNAL, June 23, 2005.
77. Pay for Performance in Medicare, supra note 39, at 1.
78. Id. at 9.
79. Id. at 3.
80. Id. at 1.
81. Id. at 9.
82. See id. But cf. Girion, supra note 10 (describing a plan to increase performance-based pay).
guidelines. Additionally, the AMA voted to oppose PVRP prior to its implementation. One of its main concerns with PVRP is the manner in which physicians report data. Physicians who participate in the program must report patient care information through the use of so-called “G-Codes,” which are meant to be a temporary reporting mechanism until physicians are able to submit data through electronic health records. The G-Codes do not replace other billing and diagnostic codes that are already required, but will instead be used in addition to those codes. The AMA is concerned that the use of G-Codes for reporting data will significantly burden some physicians, especially when they report data for patients with multiple problems. Moreover, private insurers and other P4P programs do not use G-Codes. The AMA is also concerned that the program will become mandatory and that there will be a correlation between performance data and future reimbursement rates.

B. What Is Measured In A P4P Program

According to the National Committee for Quality Assurance, most P4P programs measure performance in both clinical and non-clinical areas. Patient satisfaction constitutes a common P4P performance measure that falls outside of the clinical realm. Additionally, many programs use information technology as the primary non-clinical measure. An adequate IT structure is required for efficient collection and reporting of relevant measurement criteria. P4P programs may evaluate whether physicians have

85. Id.
86. CENTERS FOR MEDICARE & MEDICAID SERVICES, PHYSICIAN VOLUNTARY REPORTING PROGRAM FACT SHEET 3, supra note 55, at 2.
87. Id.
88. Lubell, supra note 84.
89. Id.
90. Id.
adequate IT infrastructures and whether they are actually being used. 93 Since IT is an integral component of P4P, the cost of IT may be one of the major obstacles to the widespread implementation of P4P programs. One independent physician association in California reported that it paid $150,000 for technology to track claims, lab results, and prescriptions so that it could report data in the IHA performance program. 94

Clinical measurements can be categorized as process-oriented or outcome-oriented. 95 P4P programs may measure several aspects of the process of care. For example, the programs may review whether a provider uses a tracking system to remind patients to follow up on treatments, tests, or medication reviews. 96 A program may also measure whether a provider uses any tools, such as education or resources, to assist patients in managing their own conditions. 97 Programs typically measure whether all patients with a certain disease are provided with specific medications or diagnostic screenings. Finally, a major part of the process measurement is whether providers follow clinical guidelines or evidence-based medicine for certain conditions. 98

Most P4P programs also measure clinical outcomes. 99 For example, a program may measure whether hypertension patients are within a range of acceptable blood pressure levels. 100 This is probably the most controversial aspect of performance measurement because outcomes are not entirely within the provider’s control. A patient’s clinical outcome depends on many factors unrelated to a provider’s performance, and some may argue that this measurement fails to consider those factors.

In 2004, several groups jointly proposed a set of basic standards for all P4P plans. 101 Subsequently, the Ambulatory Care Quality Alliance, American Academy of Family Physicians, American College of Physicians, America’s Health Insurance Plans, and Agency for Healthcare Research and Quality announced the final set of twenty-six standards in the spring of

93. Pay for Performance in Medicare, supra note 39, at 5.
95. Pay for Performance in Medicare, supra note 39, at 2, 10 (describing Medicare’s approach to P4P as three-fold: structure, process and outcomes).
96. Id. at 5.
97. See id.
98. See id. at 5-6.
100. Id.
101. Sipkoff, supra note 63, at 7.
These standards are a good example of a very basic set of P4P standards and are summarized as follows:

**Preventative Measures**
- Breast cancer screening
- Colorectal cancer screening
- Cervical cancer screening
- Tobacco use inquiry
- Advice to quit smoking
- Flu vaccine
- Pneumonia vaccine

**Coronary Artery Disease**
- Percentage of patients with coronary artery disease who were prescribed lipid-lowering therapy
- Beta-blocker treatment immediately after MI
- Persistent beta-blocker treatment months after discharge

**Heart Failure**
- Certain patients who were prescribed ACE inhibitor or ARB therapy
- Left ventricular failure assessment

**Diabetes**
- Perform one or more A1c tests
- Percentage of patients with most recent A1c level greater than 9.0% (poor control)
- Percentage of patients with blood pressure below 140/90
- Percentage of patients with at least one LDL test
- Percentage of patients with most recent LDL less than 100mg/dL or 130 mg/dL
- Percentage of patients who received retinal or dilated eye exam by specialist

**Asthma**
- Percentage of patients identified as having persistent asthma who were prescribed medications
- Percentage of patients who were prescribed preferred long-term control medication or acceptable alternative

102. *Id.*
Depression
- Percentage of adults diagnosed with a new episode of depression who were treated with an antidepressant and remained on medication during eighty-four day acute treatment phase
- Percentage of adults who remained on antidepressant for six months

Prenatal Care
- Percentage of patients screened for HIV during first or second prenatal visit
- Percentage of Rh negative patients who received anti-D immune globulin at twenty-six to thirty weeks

Quality Measures Addressing Overuse or Misuse
- Percentage of patients diagnosed with upper respiratory infection and not given antibiotic within three days
- Percentage of patients diagnosed with pharyngitis, prescribed an antibiotic, and received group A streptococcus test

IV. POTENTIAL LEGAL IMPLICATIONS OF P4P PROGRAMS

It is important not to lose sight of the basic structure and purpose of P4P programs as the potential legal effects of such programs are reviewed. P4P may influence managed care and provider liability. The influences may occur directly or indirectly, such as through the use of discovery and the type of evidence allowed at trial. It is also important for providers to be cognizant of any potential rights they may have with respect to these programs.

A. Liability of Health Plans and Managed Care Organizations

Health plans and managed care organizations (MCOs) have a credentialing process for the selection and retention of providers. MCOs
have been found liable to enrollees for negligence in their selection and retention process under various legal theories. One such theory is the doctrine of corporate negligence, which was first established in *Darling v. Charleston Community Memorial Hospital.*\(^{105}\) In *Darling*, the Illinois Supreme Court held that a hospital owes a duty of care to patients independent of the physicians who practice within the hospital.\(^{106}\) The concerns raised in the *Darling* case included the hospital’s failure to review the particular physician’s care and failure to require physicians to obtain consultations in certain circumstances.\(^{107}\) Today, the doctrine of corporate negligence encompasses a hospital’s responsibility to appropriately screen applicants for privileges, select and retain only competent physicians, oversee those who provide care within its walls, and implement policies and rules for the delivery of quality care to patients.\(^{108}\)

The doctrine of corporate negligence has been extended at least in part to MCOs.\(^{109}\) In *Jones v. Chicago HMO Ltd. of Illinois*, the court ruled that the corporate negligence doctrine, which was initially applied to hospitals, should also be applied to MCOs because they play a role in the healthcare industry that is similar to hospitals in many respects.\(^{110}\) The court noted that, like hospitals, MCOs are comprised of many individuals who work together to arrange for and provide comprehensive healthcare services to members.\(^{111}\)

Additionally, at least one court has imposed liability based upon another legal theory. In *McClellan v. Health Maintenance Organization of Pennsylvania*, a thirty-nine year old female, who was enrolled in an Independent Practice Association (IPA) Health Maintenance Organization (HMO), presented to her designated primary care physician for the removal of a mole.\(^{112}\) Even though the patient informed the doctor that the mole had recently changed significantly in size and color, the physician discarded the

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105. 211 N.E.2d 253 (Ill. 1965).
106. *Id.* at 257-58.
107. *Id.* at 258.
110. 730 N.E.2d 1119, 1128 (Ill. 2000).
111. *Id.*
mole without obtaining a biopsy. The patient died a few years later of malignant melanoma.

The patient’s family brought suit against the physician and HMO alleging medical malpractice and misrepresentation. The family argued that the doctrine of corporate negligence should be applied to the HMO and that it should be held liable for negligently selecting and retaining the physician in its network. The Pennsylvania Supreme Court held that it was not necessary to extend the corporate negligence doctrine to the IPA HMO model for this claim because the court had previously adopted Section 323 of the Restatement (Second) of Torts for “liability regarding services rendered.” The court held that the plaintiffs’ claim could proceed because they met the requirements of the Restatement by alleging the following:

(1) That the HMO has undertaken to render services to the subscriber;
(2) Which the HMO should recognize as necessary to protect its subscriber; (3) That the HMO failed to exercise reasonable care in selecting, retaining, and/or evaluating the primary care physician; and (4) That as a result of the breach of care the risk of harm to the subscriber was increased.

The court in McClellan also ruled that the plaintiffs could maintain a cause of action against the HMO for misrepresentation. The plaintiffs claimed that the HMO made false and/or misleading statements when it stated that every primary care physician in its network was qualified and met the HMO’s stringent screening criteria.

In addition to these theories of liability, some states have enacted statutes that provide a cause of action against managed care organizations. While the statutes may not specifically mention selection of physicians, they usually impose a general duty of care that is broad enough to include an

113. Id. at 1055.
114. Id. at 1054-55.
115. Id. at 1055.
116. Id. at 1058-59.
117. Id. at 1059.
119. Id. at 1060.
120. Id. at 1060-61.
argument for liability for negligent credentialing and oversight of physicians.\textsuperscript{122}

Pay for performance programs will likely increase the risk of liability of health plans and managed care organizations for selection and retention of participating physicians. In order to implement P4P, health plans and MCOs will compile and maintain significant data regarding each physician’s performance. The data will also be compared to other providers. Thus, at the very least, the data will make it easier for an enrollee to evaluate an MCO’s conduct with respect to its physicians. This information may be used as direct evidence that an MCO had knowledge that it should not have selected or retained a particular physician.

For example, if a physician fails to provide breast cancer screening for a patient and the patient brings a claim against the MCO for negligent credentialing, she may be able to obtain the performance data collected by the MCO through discovery. This should tell the patient the percentage of patients for which the physician has obtained breast cancer screenings and how this percentage compares to other physicians. If the data show that the physician repeatedly scored low as compared to others, then the patient has direct evidence that the MCO had knowledge of the doctor’s low performance. In addition, if the MCO gave this physician a “star” or other type of satisfactory rating or seal of approval, the patient may have another claim for misrepresentation.

As MCOs will retain direct data on the quality of their physicians, they may be forced into the difficult position of choosing whether to start terminating low-performing providers or, alternatively, to subject themselves to increased liability exposure. Since the goal of P4P is supposedly to improve care and not to eliminate providers, it may be beneficial for MCOs to establish timeframes for its physicians to meet certain performance standards. This might create a balance between protecting against liability and improving care.

B. Physician Rights Regarding Report Cards and Plan Termination

If MCOs feel the pressure from increased liability exposure, they may take more action to terminate physicians. Additionally, P4P participants will receive performance scores or ratings that could significantly impact reimbursement. The ratings will also be communicated to the public, which might impact provider business.\textsuperscript{123} This raises the question of whether

\textsuperscript{122} See \textit{cf. ARIZ. REV. STAT. ANN. § 20-3153 (2005)} (showing a very narrow statute that does not include credentialing issues).

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physicians have any rights to challenge termination decisions or performance ratings. As noted previously, one of the AMA’s major concerns is that P4P programs should include the ability of physicians to review and appeal ratings. Legal rights to challenge terminations and performance ratings can potentially be found in three different areas: the Fifth and Fourteenth Amendment Due Process Clauses of the Constitution, statutes, and contracts.

Due process is not required in all situations, so the first issue is whether a physician actually has a due process right to challenge a performance rating or termination from a health plan. If a due process right exists, then the physician should be given notice of the proceeding and an opportunity to be heard and present evidence. Several conditions must exist in order to implicate due process rights. First, there must be some protected interest at stake. Generally, the due process guarantee does not apply unless there is some attempt to deprive a person of life, liberty, or property. The North Dakota Supreme Court addressed this issue in North Dakota Commission on Medical Competency v. Racek. In that case, the Commission on Medical Competency (Commission) was investigating a physician. The physician requested a temporary injunction, asking that the Commission provide him with notice of all complaints against him and conduct a confidential hearing before it filed a formal disciplinary complaint against him. The physician argued that the potential damage to his reputation constituted a protected interest. The court rejected this argument and held that reputation is not a protected interest. This case demonstrates that physicians will likely be unsuccessful in arguing that there are due

system used in California).

124. P4P PRINCIPLES, supra note 65.
125. U.S. CONST. amend. V (stating that no person shall “be deprived of life, liberty, or property, without due process of law . . . “); U.S. CONST. amend. XIV (stating “nor shall any State deprive any person of life, liberty, or property, without due process of law . . . ”).
126. See e.g. Willner v. Comm. on Character and Fitness, 373 U.S. 96, 105 (1963) (requiring both notice of grounds for bar application denial and a fair and full hearing on grounds for denial for procedural due process); Fuentes v. Shevin, 407 U.S. 67, 82 (1972) (requiring right to notice and opportunity to be heard at a meaningful time and in a meaningful manner for procedural due process while allowing for variance in the type of hearing, depending upon the nature of the case and the importance of the interests involved).
127. See Fuentes, 407 U.S. at 80-81.
128. See id.
129. 527 N.W.2d 262 (N.D. 1995).
130. Id. at 263. The Commission was investigating the doctor at this point. No legal proceeding had yet been filed nor any attempt made by the Commission to impose restrictions on the doctor’s license.
131. Id. at 266-67.
132. Id. at 267.
process rights to review or in challenging performance ratings or report cards. Moreover, while a bad report card may significantly affect a physician's reputation and business, it does not affect a protected right.

Physicians may fare no better with respect to termination from a plan or MCO. In *Eye Clinic v. Jackson-Madison County General Hospital*, a group of ophthalmologists and optometrists brought suit after they were denied participation in a preferred provider organization ("PPO"). The group argued that they were denied due process because they were not given a hearing or even an explanation for the denial. The Tennessee Court of Appeals held that participation in the PPO was not a protected property interest. The court explained that due process rights attach only when a property interest is more than a "unilateral expectation" or "abstract need or desire." Further, the property interest must be "a 'legitimate claim of entitlement' to a specific benefit" to warrant any consideration in a due process action.

Second, due process protection must relate to some state action. The due process clause prohibits federal and state governments from unfairly depriving individuals of life, liberty, or property. However, due process does not apply to the conduct of private parties. Therefore, if an MCO is a private entity, it may argue that physicians have no due process rights with respect to its decisions. The issue of state action has been argued extensively with respect to hospitals terminating medical staff privileges. Although some variations exist among jurisdictions, most courts have held that even though hospitals provide charitable benefits, receive tax exemption, receive Medicare and Medicaid payments, and are subject to extensive state and federal regulation, a hospital's actions are not governmental actions. These hospital cases could be used to argue against the presence of state action in MCO decisions.

134. Id. at 578-79.
135. Id. at 580-81.
136. Id.
137. Id. (noting, however, that plaintiff did not allege that the PPO failed to follow its own procedures, which may indicate the court might have been inclined to review the action if the PPO failed to follow its own guidelines).
In *Carlini v. Highmark*, however, a physician successfully argued that an HMO was a state actor for due process purposes. The defendants in this case were Keystone, an HMO, and its parent corporation, Highmark Blue Cross and Blue Shield (Highmark), a professional health services plan corporation (PHSPC). Keystone notified Dr. Carlini that the credentials committee denied his re-credentialing application due to his history of malpractice claims. Dr. Carlini appealed and was given a hearing before a panel of two physicians. The hearing panel recommended reversal of the credentials committee decision. Despite this recommendation, the credentials committee upheld its initial decision. Dr. Carlini brought an action against the defendants, alleging violation of his due process rights because the hearing process was not conducted in a fair and impartial manner.

The defendants first argued that the HMO Act should apply because Dr. Carlini was terminated from Keystone and not Highmark. The distinction was significant because the HMO Act did not grant a right to a hearing. On the contrary, the Professional Health Services Plan Corporation Act (PHSPCA) mandated a hearing prior to termination. Additionally, the PHSPCA provided that all disputes should be considered and determined by the bylaws of the corporation. Highmark’s bylaws required a medical review committee to conduct a hearing. Furthermore, under Highmark’s bylaws, the medical review committee’s decision was dispositive. The court held that the PHSPCA applied. During the termination process, Highmark sent a letter to Dr. Carlini notifying him that all of its managed care networks, including Keystone, used its bylaws for their credentialing processes. Additionally, the court held that the HMO Act and the PHSPCA were not “mutually exclusive.”

The defendants in *Carlini* also argued that they did not engage in state action and therefore were not obligated to provide due process to Dr.

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142. *Id.* at 1183-84.
143. *Id.* at 1184.
144. *Id.*
145. *Id.*
146. *Id.*
148. *Id.* at 1186.
149. *Id.*
150. *Id.* at 1184.
151. *Id.* at 1186-87.
152. *Id.* at 1190.
Carlini during the credentialing process. The court rejected this argument and held that the hearing panel process used to evaluate Dr. Carlini’s credentials was analogous to a review committee formed pursuant to the PHSPCA and, as such, was a “creature of the state” that must follow due process standards. The court ultimately determined that Dr. Carlini’s due process rights were violated because he was not given an impartial forum.

Carlini is significant for physicians for three reasons. First, it highlights the importance of reviewing all state laws that may require HMOs and other MCOs to provide a hearing prior to termination. As illustrated in this case, MCOs may be governed by multiple statutory schemes as a result of their corporate structure and affiliations. Second, the court treated Highmark as a state agency because it was required to adhere to a certain statutory scheme. Finally, the court required the MCO to provide due process beyond mere adherence to statutory provisions.

In addition to due process rights and statutory protections, providers should review their agreements with MCOs regarding termination and performance scoring issues. These agreements often provide for a hearing process in the event of termination due to competency or utilization issues. However, most of these contracts also allow for termination without cause. In most contracts, if the MCO terminates the provider without cause, there is no provision for a hearing. Several cases have involved physicians who requested judicial review of termination decisions based on a “no cause” contract provision.

In Pannozzo v. Anthem Blue Cross and Blue Shield, a physician challenged a no cause termination provision. The physician had maintained medical provider agreements with the defendant for ten years until he was notified that he was being removed from the defendant’s preferred provider list pursuant to the no cause contract provision. The physician sued for breach of express and implied contract and for violation of the duty of good faith and fair dealing. The court ruled in favor of the defendant and rejected the physician’s argument that he had a right to due process based on public policy or common law principles.

154. Id.
155. Id. (relying on Rudolph v. Pa. Blue Shield, 717 A.2d 508 (Pa. 1998) in which the Pennsylvania Supreme Court held that a medical review committee formed pursuant to the PHSPCA was a “creature of the state”).
156. Id. at 1188.
158. Id. at 92-93.
159. Id.
160. Id. at 98.
In contrast, the California Supreme Court extended its common law right to fair procedure to a situation in which a physician was removed from an insured’s provider list without cause.\textsuperscript{161} In \textit{Potvin v. Metropolitan Life Insurance Co.}, the court held that where an insurer has such substantial power that a physician’s removal from the preferred provider list would significantly impair the physician from practicing in a particular geographic area, an insurer must comply with the common law right to fair procedure.\textsuperscript{162} Moreover, the court explained that “fair procedure” means that the insurer’s decision should be substantively rational and procedurally fair.\textsuperscript{163}

The Supreme Court of New Hampshire has also accepted the public policy argument. In \textit{Harper v. Healthsource New Hampshire}, a physician was terminated without cause after he was initially notified that his contract was being terminated because he did not meet “recredentialing criteria.”\textsuperscript{164} The court held that an HMO’s decision to terminate a physician must comply with the covenant of good faith and fair dealing and cannot be made for a reason that contravenes public policy.\textsuperscript{165} A physician who has been terminated without cause can challenge the decision in the courts if he or she believes that the decision to terminate was really based on some factor contrary to public policy or that the decision to terminate was made in bad faith.\textsuperscript{166}

As the cases demonstrate, providers will have a difficult time invoking due process rights with respect to performance scores and plan termination. For this reason, it behooves providers to review applicable state statutes and contracts. Proper contract provisions are essential for providers. Providers who participate in P4P should insist on including the following provisions in their contracts: (1) a description of how performance will be measured; (2) a process for challenging the results of the performance evaluation; (3) a description of the MCO’s policy for addressing low performance scores; and (4) a description of the hearing process for termination decisions.

\textbf{C. Discoverability of P4P Information}

Pay for performance will generate more information regarding the performance and practice history of providers. Plaintiffs will likely seek to discover information generated as a result of P4P. The most obvious targets

\begin{itemize}
  \item 162. \textit{Id.} at 1161.
  \item 163. \textit{Id.} at 1159-60.
  \item 164. 674 A.2d 962, 965 (N.H. 1996).
  \item 165. \textit{Id.} at 966.
  \item 166. \textit{Id.}
of discovery include clinical guidelines relevant to the standard of care at issue and all documents relating to the provider’s performance. This section addresses whether information obtained as part of the P4P program will be discoverable.

Analysis of any discovery issue should begin with the applicable scope of discovery. Most state discovery rules mirror Rule 26(b) of the Federal Rules of Civil Procedure, which allows discovery regarding any matter if the material is not privileged and is relevant to the claim or defense of the parties.\textsuperscript{167} Relevancy, for purposes of discovery, is not limited to information that will be admissible at trial as long as the discovery appears to be reasonably calculated to lead to the discovery of admissible evidence.\textsuperscript{168} Therefore, the two main discovery arguments are privilege and relevancy.

1. Peer Review

Privileged materials should be the first consideration because discovery of such is prohibited. For cases brought in state court, the peer review privilege is based upon individual state statutory provisions, so the ultimate conclusion regarding discoverability will depend upon the statutory and case law in each particular state. However, a few universal principles guide the analysis as the privilege is reviewed in the context of clinical guidelines and provider performance results.

a. Clinical Guidelines

One of the central components of P4P is that providers must follow certain clinical guidelines or evidence-based medicine guidelines.\textsuperscript{169} In order to fully appreciate all of the issues regarding clinical guidelines, counsel should have a good understanding of guidelines and how they are created. Clinical guidelines have been around for approximately sixty years and began as an attempt to standardize the practice of medicine.\textsuperscript{170} In recent years, the number of guidelines has increased significantly. Guidelines are used frequently in litigation because they have become increasingly available to the public.\textsuperscript{171} The Agency for Health Care Policy

\begin{footnotesize}
\begin{enumerate}
\item FED. R. CIV. P. 26(b)(1).
\item Id.
\item Clinical guidelines have also been referred to as performance standards, practice parameters, practice guidelines, and clinical indicators.
\item John D. Ayers, The Use And Abuse of Medical Practice Guidelines, 15 J. LEGAL MED. 421, 421 (1994).
\item Id. See also Jodi M. Finder, The Future of Practice Guidelines Should They Constitute Conclusive Evidence of The Standard of Care?, 10 HEALTH MATRIX 67 (2000) (discussing the history and use of clinical guidelines).
\end{enumerate}
\end{footnotesize}
and Research defined clinical guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical conditions." Clinical guidelines may or may not differ from evidence-based medicine, which one physician described as follows:

Evidence-based medicine is a way of doing medicine that takes into consideration the scientific information that is available . . . [I]f there is good evidence that one particular method should be used, then it is [the physician’s] responsibility to use that method, but where that evidence is lacking or inadequate, then we use our best clinical judgment to render the safest care possible for our patients.

By this definition, the term "evidence-based medicine" connotes actual standard of care, as opposed to a guideline, which is not mandatory. Naturally, this distinction can be very important.

The origin of the guideline may also be an important issue. Many entities, including specialty practice organizations, local and federal medical societies, insurance companies, peer review organizations, and state and federal governments create guidelines. The origin of the guideline may reflect its purpose. An insurance company may create practice guidelines for the purpose of containing costs. On the other hand, most specialty practice organizations, such as the American Association of Clinical Endocrinologists, create guidelines to establish professional treatment standards.


174. See generally Williams, supra note 8 (discussing the differences between clinical guidelines and evidence-based medicine).


176. See also American Association of Clinical Endocrinologists, American Association of Clinical Endocrinologists Protocol For Standardized Production of Clinical Practice Guidelines, ENDOCRINE PRAC., Vol. 10 No. 4, July/Aug. 2004, at 353 (noting that the American Association of Clinical Endocrinologists aims to produce clinical guidelines to promote the dissemination of information about endocrinology to specialists and non-specialists and to “provide a consensus opinion about the appropriate management of certain clinical problems facing the practicing endocrinologist”), available at http://www.aace.com/pub/pdf/guidelines/GLStandards.pdf.
In typical malpractice litigation, clinical guidelines are usually not an issue during discovery because the guidelines are found outside of a healthcare entity's peer review or quality improvement process. Attorneys may find potentially applicable guidelines by simply searching a multitude of sources on the Internet or seeking the assistance of an expert. Additionally, a plaintiff's attorney can depose the defendant and ask whether the defendant followed any guidelines in the diagnosis and treatment of the plaintiff, or whether the defendant was aware of any applicable guidelines regarding the particular diagnosis and treatment. If the plaintiff's counsel wants to use a particular guideline at trial, she can attempt to get the defendant to acknowledge the authority of the guideline, the applicability of the guideline, or at least the authority of the entity that issued the guideline.  

Pay for performance is significant here because it has the potential to make clinical guidelines subject to the peer review privilege. One might argue that the development of P4P clinical guidelines is a peer review function because guidelines are part of the process of reviewing and evaluating services delivered by healthcare providers. Several conditions must be present, but depending on the jurisdiction, it may be possible to make a cogent argument regarding the applicability of the privilege. If the privilege is found to apply, discovery will be limited and the admissibility of guidelines will also be prohibited because peer review is not discoverable or admissible as evidence. The two pivotal issues regarding the applicability of the privilege are: (1) whether the body that issued the guideline is included within the specific definition of a peer review entity; and (2) whether the issuance of a guideline falls within the definition of peer review activities or functions.  

The first inquiry is whether the entity that promulgated the guideline for the P4P program falls within the definition of a peer review entity. For example, a state statute might define a peer review entity to include an insurance company, HMO, or a corporation comprised of healthcare providers that evaluate health care or services. If an HMO creates a guideline, it may potentially meet this definition. However, it is also important to know exactly which HMO committee or department created the P4P clinical guideline. If the utilization committee creates the guideline, for example, then it may not qualify for the privilege.

177. See Finder, supra note 171, at 96.
179. See, e.g., id. § 65-4915(a)-(b) (2005).
180. See, e.g., id. § 65-4915(a) (2005).
In *State ex rel. Tennill v. Roper*, the court interpreted the definition of a peer review entity rather narrowly by ruling that a company, which contracted with a peer review entity to implement cost containment measures, did not fall within the definition.\(^{181}\) In this case, a physician reviewer from Sunderbruch, the cost containment company, limited the inpatient hospital stay of a patient who had been suffering from depression.\(^{182}\) The patient committed suicide on the day of discharge.\(^{183}\) The parents of the patient sued the hospital, a physician, and Sunderbruch.\(^{184}\) The parents sought to discover information about Sunderbruch's evaluation of the case, but the company argued that the peer review privilege prohibited discovery of the information.\(^{185}\) The court first noted that, under Missouri law, a peer review committee's responsibility did include healthcare utilization.\(^{186}\) However, the definition of a peer review committee was specifically limited to: (1) state, local, or county societies of healthcare professionals; (2) healthcare professionals of a professional healthcare corporation; (3) hospitals or health facilities; and (4) any other organization formed pursuant to state or federal law authorized to exercise the responsibilities of a peer review committee.\(^{187}\) Sunderbruch argued that it met the fourth category because it contracted with a state employee health plan formed pursuant to state law.\(^{188}\) The court ruled that the contractual relationship with a state organization was insufficient to meet the definition because, under the statute, the organization itself had to be formed pursuant to state law.\(^{189}\)

However, a Texas court has ruled that an HMO's quality assurance committee meets the definition of a peer review entity.\(^{190}\) In the case of *In re Humana Health Plan of Texas, Inc.*, the plaintiffs sued the health plan for negligence in medical case management, disease management, and quality assurance.\(^{191}\) During discovery, the plaintiffs sought health plan documents, including the quality assurance guidelines that the health plan issued to its physicians.\(^{192}\) Interestingly, Humana produced its quality

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182. *Id.* at 946.
183. *Id.*
184. *Id.*
185. *Id.* at 947.
186. *Id.*
188. *Id.*
189. *Id.*
191. *Id.*
192. *Id.*
assurance policies and procedures and stated they were not privileged, but claimed that the information gathered as part of the quality assurance program was privileged. The plaintiffs argued that quality improvement was a separate function from peer review and was not covered by the peer review privilege.

The court reviewed several applicable statutory provisions and definitions. First, the court noted that under Texas law, an HMO was required to establish a quality assurance program. The court further observed that under another statute, records and proceedings of “medical committees” are confidential and are not subject to subpoena. Furthermore, the definition of medical committee included “committees of HMOs.” The court also reviewed the peer review statutes and ruled that the health plan’s HMO quality assurance committee met the definition of a peer review committee.

If the entity that promulgated the guideline is considered a peer review entity, then the next question is whether the creation and/or issuance of the clinical guideline qualifies as a peer review activity or function. For example, in Fulton DeKalb Hospital Authority v. Dawson, the court held that peer review immunity would not be applied to the defendants, even though they met the definition of a peer review organization, because the acts in question were not peer review activities as defined by statute. Similarly, the court in Claypool v. Mladineo held that even though the statutory definition of a peer review committee was broad, the privilege would not be applied to “committees where peer review of quality assurance is a peripheral function.” It is important then for providers to inquire whether the issuance of clinical guidelines is part of the peer review process in a P4P program.

Parties seeking discovery may argue that a guideline resembles a policy or procedure as opposed to a peer review activity, which connotes the actual process of reviewing the quality of care. However, some courts consider internal process records to be included within the peer review function. In Zajac v. St. Mary of Nazareth Hospital Center, the court held that the nature and content of a hospital’s internal review process is included within peer

193. Id.
194. Id. at *2.
196. Id. at *5.
197. Id. at *4.
198. Id.
199. 509 S.E.2d 28, 31 (Ga. 1998).
200. 724 So.2d 373, 387 (Miss. 1998).
review functions. The court reasoned that the procedures were used for quality control and patient care improvement. In *Ekstrom v. Temple*, the plaintiff sued a hospital after developing toxic shock syndrome. The plaintiff sought to discover the hospital infection committee's internal guidelines and records regarding the hospital's compliance with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) guidelines and standards. The court ruled that the hospital infection committee's own guidelines were privileged. However, with respect to documents regarding JCAHO compliance, the court noted that the hospital failed to show the applicability of the privilege because it did not prove that a peer review committee would generate the compliance records.

If the clinical guideline is available from other sources, then the peer review privilege may not be applicable. *Stratienko v. Chattanooga-Hamilton County Hospital Authority* involved the analysis of a peer review statute that included a common exception for documents "otherwise available from original sources." The defendant argued that the statute should be interpreted to mean that the plaintiff could discover the information from the original source, but not from the peer review committee. The court disagreed and ruled that documents otherwise available from original sources were not privileged. Therefore, if a P4P program adopts a clinical guideline created by another entity, such as a specialty organization, then such a guideline will probably not be afforded a discovery privilege in states where the peer review statutes include an exception for original source documents.

Finally, the party seeking discovery may try to determine whether any of the parties have waived the privilege by providing the information outside of the peer review context. For example, if a P4P program publicizes its guidelines, then the privilege should not apply. However, P4P programs

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202. *Id.* at 846.
204. *Id.* at 426.
205. *Id.* at 429.
206. *Id.*
208. *Id.* at *5.
209. *Id.* at *6. *See also* Humana Hosp. Desert Valley v. Superior Court of Ariz., 742 P.2d 1382, 1386 (Ariz. Ct. App. 1987) (stating that information available from original sources is not immune from discovery or use at trial merely because it was used by a medical review committee).
will probably not waive the privilege by providing the guidelines to its participating providers. 211

b. Physician Performance Information

The same peer review privilege analysis applies to documents relating to a provider’s performance. Again, the first issue is whether the entity reviewing the performance meets the statutory definition of a peer review committee. For example, in the McClellan case, the plaintiffs sought to discover the application files and investigations that the HMO had performed with respect to the primary care physician. 212 The HMO argued that these materials were subject to the peer review privilege. The court reviewed the peer review statutes and noted that the privilege only applied to specific healthcare providers defined under the statute. The statutory definition of a peer review committee did not cover an HMO. 213

If the entity meets the definition of a peer review provider, it should follow that review of a physician’s performance falls within the definition of peer review activities. Most statutes include a rather broad definition of peer review activities. For example, in Kansas, peer review includes the evaluation and improvement of “the quality of healthcare services rendered by healthcare providers” and the evaluation of the performance of healthcare providers. 214 When a P4P program reviews and analyzes a provider’s performance, it evaluates the quality of health care. If the P4P program evaluates providers within another context, such as the utilization review process, the argument to include that evaluation as a peer review activity weakens.

Finally, if information is privileged, the provider needs to maintain the privilege. If a physician participates in the Medicare PVRP and receives performance results from CMS, that physician should not disclose those results to any outside sources; otherwise, she may compromise the privilege.


c. Federal Law Regarding Peer Review

In some instances, disputes between providers themselves, disputes between providers and P4P programs, or malpractice cases could make their way into federal court. In that situation, Federal Rule of Evidence 501 governs. This rule provides that if the claims are brought pursuant to federal law, the federal common law regarding privilege applies.215 Prior to 2005, no federal statutory medical peer review privilege provisions existed. Therefore, in most instances, the peer review privilege did not apply in federal court. In Tucker v. United States, for example, the district court found that federal law provides the rule of decision with respect to malpractice claims brought under the Federal Tort Claims Act and a pendent state law claim.216 The court then ruled that there was no federal medical peer review privilege.217 Similarly, in Atteberry v. Longmont United Hospital, the court held that federal law provided the rule of decision with respect to claims brought under the Emergency Medical Treatment and Active Labor Act (EMTALA).218 The court ruled that there was no federal statutory medical peer review privilege and declined to apply the state law privilege under the principle of comity, even though the evidence sought might have been relevant to the pendent malpractice claims that were brought against a physician under state law.219 Thus, a clever plaintiff’s attorney could have added an EMTALA claim to a state negligence case, filed in federal court, and consequently avoided the peer review privilege.

In 2005, Congress enacted the first federal medical peer review privilege in the Patient Safety & Quality Improvement Act of 2005 (PSQIA).220 The PSQIA establishes a mechanism for certain providers to report information regarding medical errors and patient safety. Reporting is voluntary, but Congress has included the peer review privilege as an incentive for reporting.221 The PSQIA privilege preempts less stringent state peer review laws and applies in all federal and state proceedings, including administrative proceedings.222

Generally, if a provider develops a patient safety work product and reports that work product to a patient safety organization, then such work

217. Id. at 626.
219. Id. at 647-49.
221. Id. § 299b-23(a) (2006).
product is subject to the federal peer review privilege.223 A patient safety organization can be a private or public entity, but it must be certified by the Department of Health and Human Services and must meet certain criteria.224 “Patient safety work product” is defined to include any data or records that a provider assembled or developed in order to conduct “patient safety activities” that could result in improved patient safety or healthcare quality.225 The term “patient safety activities” is defined fairly broadly and includes efforts to improve healthcare safety and quality as well as the development and dissemination of protocols or information regarding best practices.226 Arguably, many aspects of a P4P program meet the definition of patient safety activities. However, a number of other requirements must be met to invoke the privilege in the P4P context.

First, the statute specifically defines the term “provider,” but this definition does not include insurance companies or MCOs. The definition of provider is limited to certain individuals who actually provide care and to entities licensed to provide care, such as hospitals and long-term care facilities.227 Therefore, a P4P program itself could not claim the privilege. Secondly, the provider itself would have to take the initiative to create a safety evaluation system. Additionally, the provider must assemble or develop the patient safety work product information in order to report it to a patient safety organization, and it must actually report it to a safety patient organization. Finally, patient safety work product does not include “information that is collected, maintained, or developed separately, or exists separately, from the patient evaluation system.”228

If a healthcare provider who participates in a P4P program wants to take advantage of PSQIA and its privilege provision, the provider must develop a patient safety evaluation system pursuant to the statute and to all the P4P requirements, and data must be collected, maintained, and developed within the broader patient safety evaluation system. Even then, however, the party seeking discovery might argue that if certain data is reported to a P4P program, that data might not be subject to the privilege.

Representing providers that are contemplating a P4P program requires strict scrutiny of the peer review issue. If the proposed P4P program considers the evaluation of performance in conjunction with state peer review statutes, it should be able to protect performance results and possibly even specific clinical guidelines from discovery. Providers should

223. Id. § 299b-21(7) (2006).
know which entity will be issuing guidelines and reviewing performance, and whether that entity is covered under the peer review statute. Providers should also determine whether the requisite type of review falls within the peer review definition. Additionally, the type and content of the performance information released to the public is also relevant. Providers should be ready for a plaintiff to argue that the privilege does not apply to P4P performance information if much of the information is disclosed to the physician and the public through the report cards and awards systems.\(^{229}\) Moreover, both providers and their counselors should consider taking advantage of the new federal peer review privilege statute.

2. Relevancy

\textit{a. Clinical Guidelines}

If the peer review privilege does not apply, parties opposing discovery may object to the information’s relevancy. However, in all likelihood, relevancy will not be an issue with respect to clinical guidelines. The determination of the standard of care is a central issue in malpractice cases. If a plaintiff was covered by a plan that included a P4P program and the plaintiff requested copies of all P4P clinical guidelines applicable to the patient’s diagnosis or treatment, an objection to relevancy would likely fail.

\textit{b. Performance Results}

Unlike the triviality of a relevancy objection with respect to guidelines, relevancy is a more significant issue in the discovery of performance results. Arguably, information regarding a provider’s prior performance or practice with respect to other patients is not relevant in a malpractice action against a provider. The key to this issue is how a plaintiff frames the argument for relevancy. A plaintiff will likely lose if he argues that evidence of a physician’s poor performance history tends to prove negligence in a particular case. Generally, evidence of other acts is not admissible to establish a person’s character and propensity in order to infer conformity therewith.\(^{230}\) However, performance information may be relevant for other reasons, such as to demonstrate habit or custom, or for

\(^{229}\) For example, Medicare plans to provide physicians with performance feedback in the PVRP. If the physician does not treat this information in a confidential and privileged manner, a plaintiff may successfully argue that the privilege has been waived.

\(^{230}\) \textit{Fed. R. Evid.} 404(a).
impeachment. Further, the information may be relevant to impugn the physician's qualifications if the treating physician testifies as an expert.

The decision in *J. W. v. B. B.* provides an excellent analysis of relevancy of performance results in this context. In that case, two individuals brought malpractice claims against the defendant for performing unnecessary digital-rectal prostate exams during an employment physical. The plaintiffs requested information regarding the defendant's employment history and whether he previously had complaints against him for inappropriate touching or for performing unnecessary or inappropriate rectal or prostate exams.

The court held that while evidence of other allegations could not be used to show that the defendant acted in conformity in these instances, the information could be relevant for other purposes. In reaching its conclusion, the court explained that if the defendant physician testified that he performed these exams on all healthy males because he believed the standard of care required it, evidence that he has been fired for performing these exams could be used to impeach his testimony. Additionally, if the defendant denied performing the exams and testified that it was not his usual routine to perform these exams, then evidence of prior complaints could be used for impeachment and to show custom and habit.

In contrast, the plaintiff failed to articulate a sufficient basis for relevancy in the case of *Youle v. Ryan*. In that case, the plaintiff sued the defendant for malpractice after he transected the plaintiff's common bile duct during a cholecystectomy. During a subsequent deposition, the doctor disclosed that he had maintained a database of all of his surgeries. The database contained basic information about each surgery, including the type of surgery and whether there were any complications. The plaintiff requested the database, arguing that it would show evidence of a pattern of negligence. The trial court granted the plaintiff's motion and allowed the discovery, not because it might show a pattern of negligence, but because

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231. FED. R. EVID. 406, 407.
233. *Id.* at 280.
234. *Id.* at 279.
235. *Id.* at 282.
236. *Id.* at 284.
237. *Id.*
239. *Id.* at 1282.
240. *Id.*
241. *Id.*
242. *Id.* at 1282.
the defendant planned to testify as an expert about the standard of care.\textsuperscript{243} The court decided that information in the database could be relevant on the issue of the defendant’s qualifications as an expert.\textsuperscript{244}

The Illinois Court of Appeals reversed the decision in Youle, remanding the case to the trial court for an in camera review of the documents.\textsuperscript{245} However, it seems that the court of appeals never got past the plaintiff’s initial argument regarding a pattern of negligence. The court of appeals specifically questioned how records of hundreds of other patients could be relevant to the issue of whether the defendant was negligent with respect to the plaintiff.\textsuperscript{246} The court also noted that even though the defendant did not explicitly raise the issue of confidentiality, the information in the database could be confidential information covered by the physician-patient privilege.\textsuperscript{247}

Performance results may be sought in cases other than provider malpractice. In a case against an MCO for negligent credentialing, a plaintiff could have a strong argument that the provider’s performance results are not merely relevant, but they probably constitute the most relevant information in the case. Thus, counsel may be able to avoid the relevancy objection by adding the MCO as a defendant in the case.

If a court determines that a provider’s performance information is discoverable, then the party seeking to introduce the evidence has the burden to demonstrate that the evidence is admissible. The next two sections analyze the admissibility of clinical guidelines and performance ratings.

\textbf{D. Admissibility of Clinical Guidelines}

A plaintiff or provider may introduce evidence of a clinical guideline to establish the applicable standard of care.\textsuperscript{248} The admissibility of medical guidelines is clearly a significant factor in malpractice cases. The practice of medicine is a profession, so generally the only way to establish the

\textsuperscript{243} Id at 1282-83.
\textsuperscript{244} Youle v. Ryan, 811 N.E.2d 1281, 1282-83 (Ill. App. Ct. 2004).
\textsuperscript{245} Id at 1285.
\textsuperscript{246} Id at 1284.
\textsuperscript{247} Id. at 1284-85.
\textsuperscript{248} The admissibility of clinical standards is not a new issue but continues to be debated. One of the earliest cases is Stone v. Proctor, 131 S.E.2d 297 (N.C. 1963). In this case plaintiff sued a psychiatrist for negligence in administering electroshock therapy (“EST”). At trial, the court allowed plaintiff to introduce standards on EST promulgated by the American Psychiatric Association as evidence of the standard of care. The court noted that the standards reflected a consensus among these specialists regarding the use of EST and that they should be followed. Id. at 299.
standard of care is by presenting expert testimony.249 In many cases, determining the standard of care comes down to a battle of the experts. Clinical guidelines are valuable because they can provide the trier of fact with more tangible evidence of the standard of care. The admissibility of guidelines can be supported by various legal arguments, depending on the jurisdiction. However, before deciding which of the arguments should be advanced in a particular case, counsel should understand the particular clinical guideline at issue and how it was created.

The origin and purpose of a guideline is particularly important in relation to P4P programs. The fact that a guideline was created for a P4P program may be the determining factor with respect to admissibility. One clear example of this appears in Quigley v. Jobe.250 In Quigley, the plaintiff presented to her physician after discovering a lump in her right breast.251 The plaintiff claimed that although the defendant performed a breast exam, he failed to provide her with instructions to return for a follow-up exam and to instruct her to perform self-exams.252 The plaintiff was diagnosed with breast cancer one year after the defendant’s exam.253 At trial, the court excluded evidence of a practice guideline contained within the defendant’s malpractice liability policy.254 The guideline recommended that the physician instruct patients to return for a follow-up exam six weeks after discovery of a palpable lesion.255 The court of appeals upheld the trial court’s decision, ruling that the guideline was not relevant because it was established by an insurance company and did not reflect the applicable standard of care.256

As payors establish many P4P programs in an attempt to reduce costs, clinical guidelines in these programs may be susceptible to relevancy arguments like those set forth in Quigley. However, if a P4P program merely adopts a guideline from a professional organization, then the guideline could still be relevant even though it is used by a payor to reduce costs. The issue of relevancy becomes even further complicated because many P4P guidelines are developed by a consensus of several different groups. Insurers might create the P4P guidelines, but they will still

249. See id.
251. Id. at 237.
252. Id.
253. Id.
254. Id. at 238.
255. Id. at 237-38 (discussing the defendant’s agreement to incorporate the guideline into his practice. According to the policy, failure to comply with the guideline could result in an additional charge or non-renewal of the policy).
generally draw from input of medical professionals. The guidelines might be created with a dual purpose of establishing the standard of care and reducing costs.

After researching the background of a guideline, including its origin and use, the next step is to analyze the legal arguments for the admission or exclusion of the guideline. Admissibility depends, in part, on the jurisdiction. However, the available legal arguments can be categorized into four different areas: 1) learned treatise; 2) the expert's opinion regarding standard of care; 3) industry safety standards; and 4) impeachment on cross-examination.

First, pursuant to the Federal Rules of Evidence 803(18), learned treatises are admissible as an exception to the hearsay rule if certain conditions are met. Rule 803(18) states as follows:

The following are not excluded by the hearsay rule, even though the declarant is available as a witness:

To the extent called to the attention of an expert witness upon cross-examination or relied upon by the expert witness in direct examination, statements contained in published treatises, periodicals, or pamphlets on a subject of history, medicine, or other science or art, established as a reliable authority by the testimony or admission of the witness or by other expert testimony or by judicial notice. If admitted, the statements may be read into evidence but may not be received as exhibits.\(^ {257}\)

This rule provides a solid basis for the admissibility of guidelines in federal court. Arguably, some clinical guidelines should be considered learned treatises and should therefore be admissible under this rule during direct or cross-examination. Several states have also adopted the learned treatises hearsay exception.\(^ {258}\) Under this rule, admissibility may again depend on the origin of the guideline. A clinical guideline promulgated by the American Association of Clinical Endocrinologists would likely meet the definition of a learned treatise, but a guideline promulgated by an MCO probably would not. Additionally, the learned treatise rule does impose an important limitation in that the guidelines may not be received as actual exhibits.

\(^{257}\) Fed. R. Evid. 803(18).

\(^{258}\) See, e.g., Scott v. Grimes, 2003 WL 1251975 (Ky. Ct. App. 2003) (holding that an American College of Obstetricians Gynecologists publication was admissible as learned treatise under KRE 803(18)); Wilson v. Knight, 982 P.2d 400, 403 (Kan. Ct. App. 1999) (holding that medical journal articles were properly admitted as independent substantive evidence under learned treatise exception to the hearsay rule KAN. STAT. ANN. §60-460(cc)); and Flanagan v. Wesselhoeft, 712 A.2d 365, 369 (R.I. 1998) (holding that medical text should have been admitted under learned treatise rule of evidence).
Second, another common argument for admissibility is that a guideline may be admissible if an expert testifies that the guideline represents the actual standard of care. This testimony can be elicited when an expert is asked to define the applicable standard of care. However, to maintain admissibility, it is crucial to ensure that the expert does not diverge from this point. If an expert waives even a small amount in stating that the guideline is the standard of care, then the basis for admissibility is lost. Courts view a guideline as a recommendation differently than a guideline as an evidence-based practice that represents the actual mandated standard of care. If an expert testifies that a guideline represents only one way to approach treatment, then that guideline is insufficient. Additionally, some states prohibit using learned treatises to bolster expert witness opinions. In these states, it is much more difficult to admit evidence of guidelines as the standard of care on direct examination.

The case of Frakes v. Cardiology Consultants provides a good example of expert testimony and its influence on a guideline as the standard of care. In Frakes, the plaintiff presented to the defendant in the emergency room with complaints of chest pain for several days. Results of a resting EKG and X-ray were normal. The defendant ordered a treadmill EKG, which was ended before completion due to the patient’s complaints of severe chest pain. The defendant dismissed the patient, who died several hours after returning home.

During the trial, defense counsel cross-examined the plaintiff’s expert regarding the results of the treadmill EKG. Counsel used a table published by the American College of Cardiology and American Heart Association entitled, “Exercise Test Parameters Associated With Poor Prognosis and/or Increased Severity of [Coronary Artery Disease].” The plaintiff’s expert agreed that this table represented a consensus statement on

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259. See, e.g., Campbell v. Hosp. Serv. Dist. No. 1, 768 So.2d 803, 811 (La. Ct. App. 2000) (observing that, when asked about standard of care, the expert testified that applicable clinical guidelines mandated certain treatments). Note that this approach is different from admitting the guideline under the argument that it forms the basis of the expert’s opinion. Although this is a fine line, there is a distinction between these arguments. See FED. R. EVID. 703. Some jurisdictions do not allow hearsay evidence even though it forms the basis of the expert’s opinion.
260. FED. R. EVID. 803 note to Paragraph (18).
261. Id.
263. Id. at *1.
264. Id.
265. Id.
266. Id.
267. Id. at *2.
the interpretation of treadmill EKG tests. The expert also agreed that even though the test had not been completely finished, none of the results obtained were abnormal according to the table. During the plaintiff's case, the defendant was called as a witness, and during his testimony he stated that the guidelines included within the table represented the applicable standard of care at the time he treated the plaintiff.

After the plaintiff rested, counsel for the plaintiff moved the court to prohibit the defendant from using the table with his expert during his case. The plaintiff cited the applicable Tennessee rule of evidence that learned treatises may only be used for impeachment and not for substantive purposes. The trial court denied the motion and even allowed the chart to be viewed by the jury over a hearsay objection, ruling that the experts had adopted the chart as the standard of care.

On appeal, the plaintiff argued that the chart was improperly admitted because it was hearsay and should have only been used for impeachment purposes. The Tennessee Court of Appeals disagreed with the plaintiff. The court provided the following explanation for its decision:

As the trial judge pointed out in ruling on the motion to admit the document, the result was exactly the same as if one of the experts had been asked to go to the board and list the standards to be applied in interpreting the stress test. By the end of the trial the exhibit was simply a statement of what at least two experts testified was the standard of care with respect to reading the test results.

In this case, the party seeking to introduce the guideline was successful despite the rule on learned treatises. The success was largely due to the fact that the defense attorney emphasized the guideline as a consensus statement, which is another expression for the standard of care. The testimony of the experts supported the argument of the defense.

A concurring opinion in *Frakes* emphasized that medical guidelines could be helpful to juries because they are more than just a sampling of professional opinions. The concurring judge specifically opined that

269. *Id.*
270. *Id. at *2-3.*
271. *Id.*
272. *Id.*
273. *Id.*
275. *Id.*
276. *See also Ensor v. Wilson*, 519 So.2d 1244, 1265-66 (Ala. 1987) (stating that the publication “Standards for Obstetrics and Gynecologists” published three years after the alleged negligent act was admissible because an expert testified that the publication reflected the actual standard of care at the time).
relevant and properly authenticated medical guidelines are pertinent to the issue of standard of care and should not be considered as learned treaties, but should instead be admitted as substantive evidence. 277

The decision in Frakes contrasts with that of Liberatore v. Kaufman. 278 In Liberatore, the plaintiff sued a physician and hospital as a result of complications that ensued following a vaginal birth after cesarean (VBAC). 279 On direct examination, experts for the defendants testified about a bulletin published by the American College of Gynecologists (ACOG bulletin). 280 The first expert testified generally about the ACOG bulletin and stated that the physician’s treatment met the guidelines in the ACOG bulletin. 281 The second expert testified that the ACOG bulletins “don’t represent the standard of care, that is, they don’t represent the only way people can do it, but they do represent one appropriate standard of care.” 282 The second expert testified that if the physician provided treatment according to an ACOG bulletin, no one could claim a violation of the standard of care. 283 Finally, the physician was specifically asked whether the ACOG bulletin represented the standard of care, and, in response, the defendant testified: “the . . . ACOG said, hey, it’s safe to do this.” 284 Following a jury verdict for the defendants, the plaintiff appealed. The Florida Court of Appeals held that it was reversible error to introduce the ACOG bulletin during direct examination of the defendant’s experts. 285 The court cited the Florida statute, which allows learned treatises only on cross-examination of experts, and held that experts cannot bolster their opinions through the use of a treatise. 286

The learned treatise statute in Liberatore was similar to the Tennessee statute in Frakes. However, the courts reached different conclusions. The important distinction was the testimony of the experts regarding the standard of care. The court in Liberatore clearly did not view the ACOG bulletin as representing the standard of care because of the expert testimony. In its opinion, the court described the ACOG bulletins as containing “suggested treatment regimens, current trends, and other issues

279. Id. at 406.
280. Id.
281. Id.
282. Id. at 407.
283. Id. at 406-07.
285. Id. at 407.
286. Id. See Jeffrey S. Badgley, Using Medical Literature on Direct Examination To Win The “Battle of The Experts” 77 FLA. B.J. 39 (2003) (discussing the admissibility of medical literature with experts in Florida).
of concern to the practicing obstetrician." Liberatore also highlights the importance of distinguishing guidelines from learned treatises in states that prohibit such treatises on direct examination.

Another challenge to admitting clinical guidelines under the standard of care argument is that clinical guidelines are not always a good representation of the actual standard of care. Clinical guidelines simply cannot address every situation. Symptoms and diseases do not always cooperate and follow the same patterns. Furthermore, some patients have competing conditions. For example, a patient may take medication for a cardiac condition that may induce hypertension. If a provider treats the heart condition, he may not be able to meet the guidelines or expected outcomes for hypertension.

A recent study performed at Johns Hopkins emphasizes the limitations of clinical guidelines. The study evaluated clinical guidelines for the treatment of an elderly woman with multiple conditions, including osteoporosis, diabetes, and arthritis. According to the study, if all clinical guidelines were followed, the patient would require twelve medications daily at nineteen doses, five times per day. Researchers noted that the problem is not just the expense and logistics of taking all the medicine, but that each medicine increases the risk of medication error. Additionally, most medications have some adverse affects and can lead to negative interactions. The guidelines also recommended multiple activities for the patient, such as exercise, education, and further monitoring. These recommendations did not always coincide. For example, the clinical guideline for osteoporosis prescribed weight-bearing exercise, but the guideline for diabetes recommended avoidance of such exercise.

The lead author for the study noted that specialty groups usually create clinical guidelines, and those groups do not typically account for patients

287. Liberatore, 835 So.2d at 406.
288. News Release, John Hopkins Medicine, Clinical Guidelines May Not Apply to Older Patients With Several Chronic Illnesses (August 9, 2005), available at http://www.hopkinsmedicine.org/Press_releases/2005/08_09a_05.html [hereinafter Johns Hopkins]; Cynthia M. Boyd et al., Clinical Practice Guidelines and Quality of Care for Older Patients with Multiple Comorbid Diseases: Implications for Pay for Performance, 294 JAMA 716, 716 (2005).
289. Id.
290. Id.
291. Id.
292. Id.
293. Id.
295. Id.
with multiple conditions. According to the author, half of the population over the age of sixty-five has three or more chronic diseases. The study highlights the need, in many cases, for a physician’s clinical judgment and flexibility to formulate treatment plans specifically tailored to the patient and her particular circumstances. Therefore, as a practical matter, one of the major considerations for admissibility is how easily a clinical guideline can be applied to the patient’s condition. The more judgment that a treatment requires, the less persuasive is the argument that a clinical guideline represents the standard of care.

Currently, most of the clinical guidelines that P4P programs adopt are relatively basic, universally accepted guidelines. This makes it easier to argue that the guidelines represent the actual standard of care. In addition, unless a patient has multiple diagnoses, the standard conditions covered by the guidelines should not require considerable physician judgment. This may change if P4P programs incorporate more guidelines or if P4P programs expand to more specialty practices.

Furthermore, if the guidelines that a party seeks to introduce come across as mere recommendations rather than as the standard of care, there may be a valid objection to relevancy. In *Shuford v. McIntosh*, the North Carolina Court of Appeals held that the trial court properly excluded an ACOG guideline, noting that there was no showing of relevancy for the documents “which on their face appear to be recommendations, rather than standards applicable to either of the defendants.” In contrast, the District of Columbia court in *Washington v. Washington Hospital Center* held that guidelines that are not mandatory, but recommend or encourage certain practices, are directly relevant to the issue of standard of care. That court held that such guidelines are relevant as evidence of emerging or developing standards.

Finally, if a court does not find that a guideline represents the standard of care, then evidence of adherence to the guideline will not preclude

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296. *Id.*
297. *Id.*
298. *Id.*
299. 408 S.E.2d. 747, 750 (N.C. Ct. App. 1991). It appears that plaintiff was able to introduce the evidence at some other point in the trial.
300. 579 A.2d 177 (D.C. Cir. 1990).
301. *Id.* at 182. *See also* Hinlicky v. Dreyfuss, 791 N.Y.S.2d 221, 224-25 (N.Y. App. Div. 2005) (holding that a guideline for evaluation for noncardiac surgery published by the American College of Cardiology and the American Heart Association was properly admitted where the document was not admitted as hearsay since it was not offered for the truth of the matter, nor was it offered to establish the per se standard of care, but it was evidence of defendant’s decision-making process).
liability. Such was the case in *Bankert by Bankert v. United States*, a malpractice case brought under the Federal Tort Claims Act for a delivery at an Air Force hospital. In that case, the mother was scheduled for a VBAC. Despite many ominous signs, including failed labor, pitocin administration, and early signs of fetal distress, the physicians refused the mother's request for a C-section. Finally, when the family practice physician noted serious signs of fetal distress, she paged the surgeon. The C-section was performed within approximately thirty minutes of the page to the surgeon. The defendants argued that they were not negligent because they followed an applicable ACOG guideline.

The court noted that the ACOG guidelines in question required delivery within thirty minutes of the decision to perform a C-section. However, the court explained that the ACOG guideline was merely a guideline and actually represented the maximum period of time delay allowed. The court also noted that a guideline "cannot blindly address every situation of emergency cesarean delivery." The court held that, given the circumstances of the case, the physician should have issued a stat page and that there was an unreasonable delay in the delivery that constituted a breach of the standard of care.

Providers are in a precarious position if a court finds that a P4P guideline does not represent the standard of care. Physicians experienced this firsthand in the case of *Wickline v. California*. In that case, the plaintiff, a Medicaid recipient, underwent vascular surgery and experienced some postoperative complications. As the scheduled discharge date approached, the surgeon requested that the plaintiff's hospital stay be

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302. Conversely, deviation from a guideline may not be negligence. See, e.g., Even v. Bohle, 2002 WL 31640613 (Iowa Ct. App. 2002) (finding that deviation from a guideline may not be negligence where the court held that ACOG guidelines were recommendations, and the jury could find for defendant despite defendant's failure to adhere to ACOG guidelines regarding forceps delivery).
304. *Id.* at 1173.
305. *Id.* at 1175.
306. *Id.* at 1177-78.
307. *Id.* at 1178.
308. *Id.* at 1181.
309. This guideline is described by many physicians as "thirty minutes from decision to incision."
311. *Id.* at 1181.
312. *Id.* at 1182.
314. *Id.* at 1634-35.
extended by eight days. The request was taken through the Medicaid utilization review process. The request for an additional eight days was denied, but the plaintiff was allowed an additional four days. The surgeon dismissed the plaintiff according to the utilization review decision. After discharge, the plaintiff experienced more complications, which ultimately resulted in an above-the-knee amputation. The plaintiff sued the State of California for negligence in its decision to discharge her prematurely. The jury found for the plaintiff.

The Court of Appeals reversed the Wickline decision, however, and held that the state was not liable because the Medicaid program did not override the judgment of physicians. The court explained that a physician who complies, without protest, with treatment limitations that a third-party payor imposes could not avoid ultimate responsibility to the patient. Therefore, according to Wickline, a physician should not blindly follow a P4P guideline if the physician does not believe it represents the applicable standard of care in that particular situation. However, failure to follow the guidelines will result in lower performance ratings.

The third argument for admissibility of a guideline is admission as an industry safety standard. For example, in Davenport ex rel. Davenport v. Ephraim McDowell Memorial Hospital, the appellants argued that the trial court erred by admitting clinical guidelines published by the American Society of Post Anesthesia Nurses. The Kentucky Court of Appeals rejected the argument, noting that the guidelines should not be considered as a learned treatise, but should be considered as safety standards that are "helpful as a guide for measuring care." Furthermore, in a physician malpractice case, the Oklahoma Supreme Court determined that evidence of a hospital policy should be treated as a non-legislative safety standard.

315. Id. at 1636.
316. Id.
317. Id. at 1637-38.
318. Id. at 1640.
320. Id. at 1632-33.
321. Id. at 1645.
322. Id.
323. For liability purposes a physician would be well advised to document knowledge of the applicability of the guideline and the reasons why the physician chose not to adhere to the guideline in the particular case.
324. 769 S.W.2d 56 (Ky. Ct. App. 1988).
325. Id. at 62. If a hospital formally adopts P4P standards, the same argument applies. See, e.g., Lockwood v. Baptist Reg'l Health Serv., 541 So.2d 731 (Fla. Dist. Ct. App. 1988) (holding that hospital policy and procedure manuals and books establishing industry standards are admissible in negligence case against hospital).
The court ruled that a safety standard is material and relevant on the issue of standard of care, but that "it does not establish the degree of care that is legally due." 327

Finally, the last legal argument for guideline admissibility deals with impeachment on cross-examination. In states that have statutes limiting the admissibility of learned treatises to cross-examination, some courts have already equated practice guidelines to learned treatises. Thus, the use of guidelines is much more limited in these states. For example, courts in Michigan and Florida have ruled that ACOG guidelines should be treated as learned treatises and are only admissible on cross-examination or for impeachment purposes. 328 While it may be difficult to use guidelines in this manner, it can still be effective. Additionally, it may still be worthwhile to argue that a particular guideline is not a learned treatise, but rather that it is evidence of the actual standard of care.

As this section demonstrates, it is important to be prepared before arguing either for or against admissibility of a P4P guideline. Pay for performance will only add to the trend of increased use and knowledge of clinical guidelines, which means that courts will continue to face this issue. Courts are not likely to establish one guiding principle for admissibility because of the nature of guidelines and because parties tend to take opposing positions with respect to admissibility. Counsel for parties can anticipate that P4P will only expand and complicate the issue. For example, if one aspect of a P4P program performance evaluation includes whether a physician has the technology to track test results and issue alerts and reminders to patients, a plaintiff may argue that the performance criteria represents the standard of care, or at the very least, is akin to a practice guideline, and should be admissible as such.

**E. Admissibility of Performance Results**

The purpose of P4P is to evaluate providers, and thus P4P will create potential new evidence in the form of performance results. Some of the results will be made public, for example, in the form of report cards or provider ratings. 329 Other programs may give providers "star" or "blue

327. Id. See also Michelle M. Mello, Of Swords and Shields: The Role of Clinical Practice Guidelines in Medical Malpractice Litigation, 49 U. PA. L. REV. 645, 660 (2001) (noting that a large number of cases follow these decisions regarding the admissibility of safety or industry standards in malpractice cases).
329. Public reporting is still in its infancy. The State of California Office of the Patient Advocate has a website with a report card that provides an overall rating of medical groups in the state. State of California, Office of the Patient Advocate,
ribbon" status. This type of public information will be general, but will be available to anyone without having to resort to the discovery process. More detailed performance results, however, will still require discovery proceedings. Regardless of the level of detail, in some cases plaintiffs or providers may want to introduce performance results as evidence.

The main objections to admission of this type of evidence are relevancy and the rules prohibiting character evidence. The federal rules distinguish between general character evidence and evidence of prior specific acts. Evidence of a provider's overall performance status will be considered as general character evidence under Rule 404(a) and will generally not be admitted. For example, in McCaffrey v. Puckett, the defendant's expert witness, a member of the State Board of Chiropractic Examiners, testified that during his tenure on the Board, the plaintiff had never been the subject of a complaint or disciplinary action. The Mississippi Supreme Court held that this evidence was improper character evidence because it was not relevant to the issue of whether the defendant was negligent in his treatment of the plaintiff. In its decision, the court in

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331. FED. R. EVID. 404.


333. 784 So.2d 197, 203 (Miss. 1997).

334. Id. at 204.
McCaffrey quoted the reasoning set forth in a similar decision by the North Carolina Supreme Court:

[...]he character of a defendant physician in a medical malpractice action is irrelevant to the ultimate issue of whether the physician acted negligently. Such evidence tempts the jury to base its decision on emotion and to reward good people or punish bad people, rather than to render a verdict based upon the facts before them. 335

The Liberatore case also dealt with evidence very similar to a provider's performance rating. In Liberatore, the Florida Court of Appeals ruled that it was reversible error to allow the defendant to testify that he was included on the list of "top doctors" in a local survey. 336

Detailed performance history may be addressed by Rule 404(b), which prohibits evidence of prior acts to prove character in order to show conformity therewith. 337 The rule does allow admission if the evidence is admissible for other purposes, such as to show proof of plan, motive, knowledge, or absence of mistake or accident. 338 For both sections of Rule 404, the key to admissibility is whether the evidence is offered to show the character of the defendant. Miller ex rel. Miller v. Phillips provides a good example of how prior acts or conduct can be successfully distinguished from character evidence. 339 In Phillips, the plaintiff sued a midwife, alleging that when the defendant became aware of fetal distress and shoulder dystocia during the delivery, the defendant panicked and mishandled the baby. 340 The plaintiff presented witnesses who testified that the defendant panicked. 341 The plaintiff also called the defendant during its case-in-chief and questioned her about her reactions during previous deliveries. The defendant denied panicking. 342 The defendant then asked the court's permission to offer evidence that she had not panicked during previous deliveries. 343 The trial court allowed the testimony, ruling that the plaintiff had opened the door to the issue. 344
On appeal, the plaintiff argued that the trial court improperly admitted evidence of the defendant's character. However, the Alaska Supreme Court ruled that the evidence was properly admitted. The court explained that because of the plaintiff's theory in the case, the evidence related more to the defendant's knowledge and experience than to character evidence. The court noted that the plaintiff's counsel extensively questioned the defendant about her knowledge and experience in handling these deliveries. In fact, the plaintiff's counsel's line of questioning suggested that the defendant was not aware of the proper method for handling shoulder dystocia prior to the delivery in question. The court ruled that because the plaintiff called into question the defendant's knowledge, experience, and ability to deal with these deliveries, the defendant could present witnesses with knowledge of her capability of handling such deliveries.

The court further explained that evidence of the defendant's knowledge, experience, and capability should not be considered as character evidence. Yet the court acknowledged that some of the testimony was more like character evidence because it dealt with her emotional response. The court noted that in this particular case, as the evidence was so closely tied to evidence of the defendant's experience and knowledge, it created little likelihood that the jury would treat it as character evidence. Additionally, the court stated that even if the jury considered the evidence as character evidence, admission was justified because the plaintiff's counsel "all but invited this testimony" when he asked the following question: "Do you panic on all deliveries?"

When a patient brings suit against a health plan or MCO for negligent credentialing, the admissibility of a provider's performance history tends to be much less complicated. A plaintiff should not have any difficulty demonstrating that the provider's performance results are relevant to a claim against an MCO for negligent credentialing. However, the difficulty will arise in cases where the provider and the MCO are both named as defendants and tried in the same case.

346. Id. at 1253.
347. Id. at 1253.
348. Id.
349. Id.
350. Id. at 1252.
351. Miller, 959 P.2d at 1252-53.
352. Id.
353. Id.
354. Id. at 1253.
Overall, P4P performance ratings are not generally admissible in malpractice cases against individual providers. Specific performance information may be admissible if the moving party can make a compelling argument that the information is not offered as character evidence but is relevant for some other reason.

V. CONCLUSION

The success and future of P4P remains to be seen. The magnitude of P4P’s effects depends on its pervasiveness and endurance. No long-term studies have been conducted to predict the future of P4P programs. However, providers should be prepared for expansion of P4P programs because they are already a reality. Major healthcare payors, such as large employers and Medicare, continue to pursue P4P seriously and may pursue implementation in the near future.

While providers may initially focus on the economic aspects of P4P, they should also be aware of P4P’s other implications. Providers should be cognizant that P4P may affect certain aspects of their relationship with health plans and MCOs because of the likelihood of increased liability exposure for credentialing decisions. Additionally, providers who participate in P4P programs should insist upon contractual terms that allow fair review of performance scores and that grant hearing rights for termination decisions.

In malpractice cases, parties can anticipate more discovery disputes because P4P programs aim to collect and analyze a broad range of information regarding the practice of providers. The good news for providers, though, is that P4P may offer a cogent argument for the application of the peer review privilege. Such a privilege could significantly limit and shorten the discovery process. Providers and their counsel should take an active role to ensure that P4P programs issue guidelines and review and analyze performance data within the structure of the peer review statutes.

Courts will continue to struggle with the admissibility of clinical guidelines. The crucial factors for admissibility include both the nature and purpose of the clinical guideline as well as the particular approach chosen by the party seeking to admit the guideline. On one hand, P4P will add to the struggle by increasing consumer familiarity with guidelines. On the other, P4P may limit the admissibility of guidelines. Courts may be persuaded that P4P guidelines are meant to reduce costs and not to establish the standard of care. Finally, while P4P ratings may help providers advertise services, it is unlikely that they will be allowed in the courtroom as part of a defense in a malpractice case.
Overall, many of the potentially detrimental effects of P4P can be minimized by foresight and provider involvement. Provider liability will mainly be affected by the creation of additional practice history data and the fact that this data will be more widely known and available. Currently, it is unclear whether P4P will evolve into a common set of programs or whether payors will create more individualized incentive programs. The more homogenous the programs, the more accessible the information will be to consumers and litigants.

The influences that P4P may have on liability should be weighed against other considerations for providers, such as the overall costs and benefits of the program. As one physician noted, even though performance evaluation may have its drawbacks, the overall approach of focusing on preventative care and using standardized practices to contain costs may be much more appealing than the previous managed care approach of limiting patient care. As long as providers remain involved in the development of P4P programs, they can continue to shape the development of P4P programs to protect their interests.

Although many issues remain, the fact that P4P programs have developed demonstrates that we as a society have changed our view of the quality and value of medical services. Even if incentive programs similar to P4P cease to exist, it is unlikely that we will ever completely abandon the association of provider performance and payment. The focus on provider performance will no doubt continue to make its way into the courtroom in one form or another.