

HEALTH CARE LAW: A SURVEY OF 1994 DEVELOPMENTS

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INTRODUCTION

This Survey highlights several notable developments during the 1994 Survey period in the rapidly expanding and diverse field of health care law.

While numerous profound changes frequently occur in this area of law, this Survey focuses on those areas most likely to be of use to practitioners, emphasizing aspects of health care law that impact broadly on numerous client interests. The Survey is, however, by no means a comprehensive or complete discussion of all or even most of the significant developments in the field, but is a summary of several important changes in the areas of medical malpractice, products liability, Medicare and Medicaid reimbursement, patient dumping, legislative and regulatory initiatives, peer review, antitrust and patient consent.

I. MEDICAL MALPRACTICE

Medical malpractice cases dealt with the running of the statute of limitations, expert witness qualifications, the impact rule, the medical review panel and standard of care.

A. *Judicial Opinions*

1. *Statute of Limitations.*—In *Follett v. Davis*,¹ the Indiana Court of Appeals dealt with the doctrine of a “continuing wrong.” A continuing wrong in a medical malpractice action allows a plaintiff to bring an action after the two-year statute of limitations has expired based on a physician’s failure to properly diagnose and treat a patient’s medical condition.

After discovering a lump in her right breast, Ms. Follett, the plaintiff, went to see her physician, Dr. Davis. However, Dr. Davis was unavailable to see her on that day. Dr. Davis’s office staff directed Ms. Follett to a radiology department for a mammogram. Contrary to office procedure, Dr. Davis’s staff did not schedule Ms. Follett for a follow-up visit to review the details of the mammogram. The office staff told Ms. Follett that when they received the mammogram results, Dr. Davis would contact her if there was any problem. Otherwise, she could assume everything was normal.

The radiology report, which accompanied Ms. Follett’s mammogram, stated that the breast lump was not normal and recommended follow-up tests. Dr. Davis reviewed the report and considered it negative for breast cancer. Ms. Follett was not contacted. Two

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1. 636 N.E.2d 1282 (Ind. Ct. App. 1994).

years later, Ms. Follett began to experience pain with the same lump. An examination at that time revealed the lump was cancerous.

In her suit, Ms. Follett claimed she suffered a continuing wrong based upon Dr. Davis's failure to diagnose her condition and implement timely treatment.² Because she did not discover the failure to diagnose until after the two-year statute of limitations³ had expired, Ms. Follett argued that the statute of limitations on her action did not begin to run until the end of the wrongful act, which was the continuous omission to act.⁴ Thus, the wrongful act would not end until proper diagnosis and treatment began.

The court found for Ms. Follett, holding that had the physician's office procedures been properly followed, Dr. Davis would have had occasion to diagnose Ms. Follett's condition sooner.⁵ The court of appeals reversed the trial court's summary judgment for the physician.⁶

This case is noteworthy because it suggests that a failure to follow normal patient procedures may toll a statute of limitation and form the basis of a continuing wrong by the intentional withholding of information. Providers are well advised to follow procedures that they themselves have developed because courts may infer that a departure from self-imposed standards is tantamount to a failure to adhere to an appropriate standard of care.

In *Hughes v. Glaese*,⁷ also relevant to Indiana's statute of limitations for medical malpractice, Dr. Hughes informed the plaintiff, Ms. Glaese, after her abdominal repair surgery that she was "okay" without disclosing to her the results of a chest X-ray that revealed a potentially cancerous growth. Almost three years later, Ms. Glaese was diagnosed with Hodgkin's disease.⁸ Ms. Glaese asserted that Dr. Hughes' failure to diagnose and fully disclose the results of her earlier chest X-ray caused her to lose valuable time in her fight against the disease. Ms. Glaese did not assert that Dr. Hughes intentionally misrepresented her condition to her; instead she based her malpractice claim on his failure to diagnose her condition. She claimed that the doctor's failure to disclose this condition was fraudulent concealment, which tolled the statute of limitations.

The court ruled that the physician-patient relationship ended after the initial abdominal repair surgery when Dr. Hughes released Ms. Glaese to the care of her regular family physician.⁹ Since the two-year statute of limitations began to run at that point, Ms. Glaese failed to file her medical malpractice action within the two-year period.

Indiana courts have recognized two variants of fraudulent concealment, active and constructive, that espouse an equitable doctrine tolling the statute of limitations in certain cases.¹⁰ Where fraudulent concealment is active, the statute is tolled until discovery, or opportunity for discovery. However, where failure to disclose is incident to a confidential

2. *Id.* at 1284.

3. IND. CODE § 27-12-7-1 (1993).

4. *Follett*, 636 N.E.2d at 1284.

5. *Id.* at 1283.

6. *Id.* at 1284.

7. 637 N.E.2d 822 (Ind. Ct. App. 1994).

8. A malignant disorder of unknown etiology producing enlargement of lymphoid tissue, spleen, and liver with invasion of other tissues.

9. *Id.* at 826.

10. See *Guy v. Schuldt*, 138 N.E.2d 891 (Ind. 1956).

relationship, such as the physician-patient relationship, and not active fraud, constructive fraudulent concealment terminates when the relationship terminates. Since there was nothing extraordinary about the termination of the physician-patient relationship between Ms. Glaese and Dr. Hughes other than a possible prior misdiagnosis, the court held that the normal application of the statute of limitations was appropriate. To hold otherwise would subject every instance of wrongful diagnosis and the termination of the physician-patient relationship to characterization as a possible case of constructive fraudulent concealment.¹¹ Judgment was reversed in favor of Dr. Hughes.¹²

In *Weinberg v. Bess*,¹³ the court of appeals again addressed the issue of the time at which the physician-patient relationship ends so as to commence the running of the statute of limitations for a claim of medical malpractice. More specifically, the court addressed the issue of when fraudulent concealment by a physician may toll the statute of limitations in a medical malpractice action. At issue was Dr. Weinberg's statement to Ms. Bess that she had received saline breast implants during plastic surgery when in fact Dr. Weinberg had used silicone implants.¹⁴

Prior to Ms. Bess's surgery in January 1985, Dr. Weinberg told Ms. Bess that he intended to use saline implants. After surgery, Ms. Bess saw Dr. Weinberg several times for follow-up care. Her final visit was on April 3, 1986. After a great deal of media attention concerning the risks of silicone breast implants, Ms. Bess contacted Dr. Weinberg's office by telephone in June 1991 to inquire about the type of implant she had received. Dr. Weinberg's office staff again told Ms. Bess she had received saline implants.

In May 1992, Ms. Bess went to the hospital and reviewed her medical records. As a result of this review, Ms. Bess learned for the first time that she had received silicone implants. She filed a malpractice action against Dr. Weinberg in July 1992, six years after her last visit to his office. At trial, Dr. Weinberg argued that because Indiana law requires a malpractice action be brought within two years from the date of the alleged act, omission or neglect,¹⁵ the plaintiff's action was not timely filed.¹⁶ Ms. Bess argued that the doctrine of fraudulent concealment estopped Dr. Weinberg from asserting a statute of limitations defense.¹⁷

As no appellee brief was filed in the case, a lesser standard of review was employed by the court wherein it sought only to determine if "prima facie error" had occurred at trial. The court agreed that Dr. Weinberg's conduct constituted fraudulent concealment.¹⁸ However, since such fraud was constructive, not active, it terminated at the conclusion of the physician-patient relationship. At that point, the malpractice statute of limitations began to run. The court concluded that the physician-patient relationship terminated and the statute of limitations began to run at the end of Ms. Bess's last office visit.

11. *Hughes*, 637 N.E.2d at 825-26.

12. *Id.* at 826.

13. 638 N.E.2d 841 (Ind. Ct. App. 1994) (Robertson, J., dissenting).

14. *Id.* at 843.

15. IND. CODE § 27-12-7-1 (1993).

16. *Weinberg*, 638 N.E.2d at 841.

17. *Id.* at 844.

18. *Id.*

The court stated that "fraudulent concealment tolls the running of the statute of limitations until either the physician-patient relationship is terminated, the patient discovers the malpractice or the patient learns information which in the exercise of due diligence would lead to the discovery of the malpractice."¹⁹ Ms. Bess's assertion that the physician-patient relationship continued beyond her final office visit because she relied upon the physician for treatment and counsel was insufficient as a matter of law to create a factual issue. Likewise, Ms. Bess could not resurrect the claim by scheduling an office appointment in March 1992 long after the statute had run. With one judge dissenting, the court found for Dr. Weinberg.²⁰

Here, the physician's initial misrepresentation as to the intended use of saline implants was insufficient to toll the statute of limitations indefinitely because the physician-patient relationship had terminated more than two years prior to suit being filed, and the fraudulent concealment was of a constructive, and not active, nature. Thus the statute began to run from the last occasion of an actual patient-physician relationship. Dr. Weinberg clearly benefited from the more expansive standard of review since there were ongoing instances of continuing misrepresentation that arguably could have been deemed active fraudulent concealment, which would have tolled the statute until discovery, or opportunity for discovery, of the malpractice.

2. *Expert Witnesses.*—In *Snyder v. Cobb*,²¹ the court addressed the issue of the qualifications of expert witnesses in medical malpractice actions. The defendants in this malpractice action included an obstetrician/gynecologist and an anesthesiologist. James and Patricia Snyder filed suit against the physicians and a hospital for their alleged negligence while attempting to resuscitate the Snyders' infant daughter after premature delivery. As a result of the alleged negligence, the infant suffered permanent brain damage, cerebral palsy and a hearing impairment.

Although the Snyders' expert witness was neither an obstetrician nor an anesthesiologist, he was a pediatrician with expertise in the resuscitation of newborns. The expert stated at trial that he was familiar with the applicable standard of care required of obstetricians and anesthesiologists in similar communities. The expert also testified that he knew such physicians' duties with respect to high-risk prenatal situations, delivery and the necessary medical care under such circumstances. Based on this knowledge, the expert testified that the defendants breached the applicable standard of care and that the infant's injuries were a direct result of the defendants' negligence. The trial court granted summary judgment for the defendants, and the plaintiffs appealed.²²

On appeal, the defendants argued that the plaintiffs' expert was not qualified to testify as to the appropriate standard of care since he did not have sufficient specific knowledge as would an anesthesiologist or an obstetrician and his opinion at trial should have been inadmissible.²³ The court disagreed, holding that the expert's general knowledge of the

19. *Id.*

20. *Id.* (Robertson, J., dissenting).

21. 638 N.E.2d 442 (Ind. Ct. App. 1994).

22. *Id.* at 445.

23. *Id.* at 446.

subject matter was sufficient.²⁴ The expert's "bare assertion that he was familiar with the standard of care was sufficient, and we find no error."²⁵

This case illustrates the breadth of the trial courts' discretion in determining whether certain physicians qualify as experts for the purpose of testifying in medical malpractice actions.

3. *Modification of Impact Rule in Claims for Damages for Emotional Distress.*—*J.L. v. Mortell*²⁶ concerns a modification of the so-called "impact rule." The impact rule generally does not allow a plaintiff to recover damages in claims of emotional distress unless such emotional distress is accompanied by or is the result of a physical injury.²⁷ In this case, after receiving a referral from her family physician, J.L. began receiving physical therapy for abductor muscle spasms in 1986.²⁸ After several therapy visits, the physical therapist began vaginal massage as part of the treatment for her abductor muscle spasms. In 1990, J.L. began seeing another physical therapist who informed J.L. that continuation of such treatment was contraindicated. Thereafter, J.L. was diagnosed with post-traumatic stress syndrome resulting from such allegedly inappropriate treatment. After filing a claim for malpractice against the first physical therapist, J.L. and the defendant physical therapist entered into a settlement agreement for \$100,000, the statutory limit of the physical therapist's liability under the Malpractice Act. J.L. then filed a claim for excess damages from the Patient's Compensation Fund.²⁹

At the close of J.L.'s case, Mr. Mortell, the Commissioner of Insurance, filed a motion to dismiss under Indiana Trial Rule 41(B).³⁰ The trial court granted the motion to dismiss and held that J.L. could not recover damages for emotional distress since the distress was not accompanied by, nor did it result from, a physical injury. Since the emotional distress experienced by J.L. was the result of the inappropriate treatment, it was a non-compensable injury under the Patient's Compensation Fund.

The court of appeals examined three issues regarding J.L.'s claim. The first issue discussed was whether Mr. Mortell waived his right to contest the determination of damages to J.L. for failure to timely file an objection contesting the award of damages. The court dismissed this contention out of hand.³¹

The second issue was whether the trial court exceeded its authority in making a determination as to whether J.L.'s injuries were compensable from the Patient's Compensation Fund. In support of this contention, J.L. relied upon *Dillon v. Glover*,³² which stated that the Commissioner of Insurance may not litigate liability of a health care provider after the issue of liability has been determined prior to submission to the Patient's Compensation Fund. The court agreed and stated that Mr. Mortell was not

24. *Id.*

25. *Id.*

26. 633 N.E.2d 300 (Ind. Ct. App. 1994). Mr. Mortell was the State Insurance Commissioner authorized to administer and defend claims against the Patient's Compensation Fund.

27. *Id.* at 304.

28. *Id.* at 301.

29. *Id.*

30. *Id.*

31. *Id.* at 303.

32. 597 N.E.2d 971 (Ind. Ct. App. 1992).

permitted to challenge either the liability or proximate cause issues that were deemed established by a settlement with the health care provider.³³ However, the court reasoned that the denial of J.L.'s claim was not the result of a re-examination of the therapist's liability. Instead, the trial court's denial of relief to J.L. was due to its conclusion that recovery for emotional distress without an accompanying physical injury could not be compensated under the Patient's Compensation Fund.

Finally, the court addressed whether damages for emotional distress could be awarded to J.L. without being accompanied by a physical injury pursuant to the impact rule. In determining that J.L. could recover for emotional distress suffered without an accompanying physical injury, the court relied upon a modified version of the impact rule as set out in *Shuamber v. Henderson*.³⁴ In *Shuamber*, the Indiana Supreme Court held:

When . . . a plaintiff sustains a direct impact by the negligence of another and, by virtue of that direct involvement sustains an emotional trauma which is serious in nature and of a kind and extent normally expected to occur in a reasonable person, . . . such a plaintiff is entitled to maintain an action to recover for that emotional trauma without regard to whether the emotional trauma arises out of or accompanies any physical injury to the plaintiff.³⁵

The court reasoned that the modified impact rule applied in the *Mortell* case.³⁶ J.L. had suffered a direct impact from the vaginal massage which was deemed to be a negligent form of treatment as evidenced by the settlement agreement. The negligent massage also resulted in severe emotional trauma that was serious in nature and likely to occur in a reasonable person. Therefore, the court reasoned, J.L. was entitled to maintain an action to recover excess damages from the Patient's Compensation Fund regardless of whether the trauma arose out of or was accompanied by any physical injury.³⁷ Accordingly, the court reversed the decision and remanded the case to the trial court on J.L.'s claim of emotional distress.³⁸

This case may represent a potential for additional damages in medical malpractice cases where proof of emotional injuries exists. Any negligent physical touching may be sufficient to apply the modified impact rule since physical injury to the claimant may not be required.

4. *Duty of Care*.—In *Hook's-SuperX, Inc. v. McLaughlin*,³⁹ the plaintiff, Mr. McLaughlin, sued a pharmacy for negligence because the pharmacist had refilled his prescription for propoxyphene salt, a Schedule IV narcotic drug under the Federal Controlled Substance Act. The pharmacist had called Mr. McLaughlin's physician regarding the propriety of the prescription and the physician authorized the continuing refill of the drug. Mr. McLaughlin had a chemical dependency problem with narcotic medications. He claimed that the defendant pharmacy had breached the duty of care it

33. *Mortell*, 633 N.E.2d at 303.

34. 579 N.E.2d 452 (Ind. 1991).

35. *Id.* at 456.

36. *Mortell*, 633 N.E.2d at 304.

37. *Id.*

38. *Id.*

39. 632 N.E.2d 365 (Ind. Ct. App. 1994).

owed to him when it filled the prescriptions ordered for him by his physician. It should have been obvious to the pharmacist, Mr. McLaughlin argued, based on the large volume of refills he had received for narcotic medication, that Mr. McLaughlin had a chemical dependency problem.

Mr. McLaughlin asserted three duties of care: a statutory duty, a gratuitously assumed duty, and a general duty. The court of appeals found against him on all three theories. In holding for the pharmacy, the court stated, "When a pharmacist calls a physician concerning a question about a patient's prescription, the pharmacist should be permitted to rely on the physician's instructions in good faith as a matter of law."⁴⁰

The supreme court granted transfer and vacated the opinion of the court of appeals, affirming the trial court in its denial of the defendant's motion for summary judgment.⁴¹ In so doing, the court found a direct relationship between pharmacists and customers that is independent of the relationship between physicians and patients and is sufficient to create a duty of care.⁴² Whether that duty has been breached will depend on the degree of care that an ordinarily prudent pharmacist would exercise in the same or similar circumstances. This determination is usually a question of fact.⁴³ Accordingly, the trier of fact should determine whether the duty was breached in the instant case. This case is important because the supreme court, while recognizing that physicians remain ultimately responsible for their orders, held that other professionals on the health care team must exercise their independent professional judgment in the fulfillment of their duty of care to the patient.

5. *Products Liability.*—*St. Mary Medical Center, Inc. v. Casco*⁴⁴ was a case of first impression in Indiana. Mr. Casco received a pacemaker while he was a patient at St. Mary Medical Center ("Hospital"). The pacemaker later failed and Mr. Casco brought an action against the Hospital, which included a products liability claim.

The Hospital argued that since it was not a dealer engaged in selling pacemakers, a products liability action was inappropriate. The Hospital contended that it was in the business of providing professional medical services to patients, which included the provision of certain medical equipment. The Hospital argued that when medical equipment is provided to patients, it is incidental to the overall primary purpose of providing health care. In finding for the Hospital, the court cited a California appellate opinion:

Unlike the products sold in a hospital gift shop, for which the hospital is strictly liable, the pacemaker provided to the patient is necessary to the patient's medical treatment. While the hospital itself does not use its own medical skill or knowledge in providing its services in connection with the provision of the pacemaker for the patient, the hospital still is engaged in the process of providing everything necessary to furnish the patient with a course of treatment.

40. *Id.* at 368.

41. 642 N.E.2d 514, 521 (Ind. 1994).

42. *Id.* at 517.

43. *Id.* at 519.

44. 639 N.E.2d 312 (Ind. Ct. App. 1994).

In this regard, the hospital's actions concerning the provision of the pacemaker are "integrally related to its primary function of providing medical services."⁴⁵

Under the Indiana Products Liability Act,⁴⁶ the Hospital could not be held strictly liable as a seller of pacemakers since the complaint addressed its actions as a health care provider.

This case apparently turned on the provision of medical equipment being only a part of the overall service component of hospitals. The result might have been different had the Hospital or a durable medical equipment subsidiary or affiliate been primarily in the business of acquiring and reselling medical equipment. It also appears that the court construed the patient to be the ultimate purchaser and the Hospital's liability may have been limited to an instance of an alteration or modification of the medical equipment.

II. MEDICAID/MEDICARE

Recently, the Indiana Medicaid program has been the focus of great change in the way it pays providers. New reimbursement regulations were promulgated for virtually all Medicaid providers. The courts also dealt with a Boren Amendment challenge to the nursing home Medicaid reimbursement system. Finally, the courts handed down an antidumping case and a class action case concerning Indiana's method of determining Medicaid eligibility.

A. Judicial Opinions

1. *Indiana Medicaid Is under No Obligation to Reimburse Long Term Pediatric Care Facility for Higher Levels of Care.*—In *Indiana State Department of Public Welfare v. Lifelines of Indianapolis, Limited Partnership*,⁴⁷ the court of appeals addressed whether federal or state law compels the Indiana State Department of Public Welfare (DPW)⁴⁸ to reimburse Lifelines of Indianapolis ("Lifelines") costs for providing pediatric subacute care.⁴⁹

Lifelines was licensed and certified as a long-term care nursing facility under the Indiana Medicaid Program. As a nursing facility, Lifelines received an initial Medicaid rate that reimbursed Lifelines for only 22.4% of its actual costs. In accordance with Medicaid regulations, Lifelines appealed the initial rate determination to an administrative law judge who determined that the rate was inadequate. The State Board of Public Welfare ("Board") reversed the decision of the administrative law judge and reinstated the initial rate as calculated by DPW. Lifelines appealed to the Hamilton County Circuit Court. The circuit court set aside the Board's decision and DPW appealed.

45. *Id.* at 314 (quoting *Hector v. Cedars-Sinai Medical Ctr.*, 180 Cal.App.3d 493, 506-07 (1986)).

46. IND. CODE §§ 33-1-1.5-1 to -8 (1993).

47. 637 N.E.2d 1349 (Ind. Ct. App. 1994).

48. The Indiana State Department of Public Welfare is now referred to as the Indiana Family and Social Services Administration.

49. Subacute care is a level of care requiring more intensive staffing and services than care normally rendered in nursing facilities, but less intensive than is provided in acute care hospitals.

To support its argument that the State was not required to compensate Lifelines for long-term pediatric subacute care, DPW cited *Lett v. Magnant*.⁵⁰ In *Lett*, a certified long-term care facility that provided services to the profoundly mentally retarded requested that the State reimburse it at a greater rate due to the higher level of services it provided. Determining that the State did not violate the federal Boren Amendment,⁵¹ the Seventh Circuit Court of Appeals reversed the district court's decision, which stated that the facility's costs for providing a higher level of care were reasonably necessary for a facility to provide such services and that the costs had to be "incurred in order to provide legally sufficient care and services."⁵² The court of appeals determined that the district court had misapplied the Boren Amendment: "[T]he Boren Amendment had been enacted to move the State away from the payment of the reasonable costs of services actually provided. Accordingly, the amendment was violated only when the rates in the aggregate were arbitrary and capricious."⁵³

Although the *Lifelines* court admitted that "there is imprecision in the State's reimbursement system,"⁵⁴ in that the State did not reimburse for pediatric subacute care, the court determined that DPW was not obligated to make an exception for "a facility providing a higher level of care than its certified counterparts."⁵⁵ Therefore, because the State's method of reimbursing skilled nursing facilities was reasonable in the "aggregate," the system was neither "arbitrary and capricious" nor unreasonable because DPW refused to "tailor" its reimbursement scheme to each participating facility. Further, although the Boren Amendment requires some uniformity among providers of long-term care services, it is not required to reimburse all facilities their costs due to the fact that some facilities may provide a specialized level of care.⁵⁶

The court ruled that because Lifelines chose to specialize in pediatric long term subacute care, with the knowledge that DPW did not reimburse these particular facilities at a higher rate, "the State need not pay for the care provided by Lifelines if a more efficient and economical option is available."⁵⁷ Once again referring to *Lett*, the court stated:

[I]f a facility can obtain reasonable and adequate reimbursement for the care and services it provides by meeting the licensing and/or certification standards of a higher recognized category of care, the State need not fine-tune its system for the anomaly. Hence, it is our conclusion that the State need not create an exception to its Medicaid reimbursement plan for Lifelines in order to comply with federal

50. 965 F.2d 251 (7th Cir. 1992).

51. The federal Boren Amendment requires Medicaid reimbursement to be provided in accordance with rates that are reasonable and adequate to meet the costs incurred by efficiently and economically operated facilities. 42 U.S.C. §1396a(a)(13)(A) (1988 & Supp. 1993).

52. *Lett*, 965 F.2d. at 257.

53. *Lifelines*, 637 N.E.2d at 1358 (citing *Lett*, 965 F.2d at 257).

54. *Id.* at 1357.

55. *Id.*

56. *Id.* at 1351.

57. *Id.* at 1358.

and state statutory law. Neither has the State misapplied its own regulations by comparing Lifelines to other "dissimilar" skilled [nursing] facilities.⁵⁸

This case holds that even though treatment rendered to Medicaid beneficiaries may be medically necessary and appropriate, the costs of such service need not be reimbursed if they exceed the established level of care and payment that the State has established by regulation. In essence, the State does not have an obligation to provide a higher level of care even if there may exist some need for the level of care. Parenthetically, to gain a higher reimbursement rate, Lifelines subsequently became licensed and certified as a hospital.⁵⁹

2. *Implementation of Medicaid Reimbursement Methodology Violative of the Boren Amendment.* *Indiana State Board of Public Welfare v. Tioga Pines Living Center, Inc.*⁶⁰—In January 1990, a plaintiff class of nursing homes filed an action against the State relating to its Medicaid reimbursement scheme, found at Title 470, Rule 5-4.1 of the Indiana Administrative Code ("Rule 4.1"), on the basis that it did not conform with certain federal or state statutory requirements.⁶¹ On February 26, 1991, after a trial had commenced on Rule 4.1, the State adopted a new Medicaid reimbursement scheme, found at Title 470, Rule 5-4.2 of the Indiana Administrative Code ("Rule 4.2"). The class moved to supplement its complaint to include a challenge to Rule 4.2 and to obtain a preliminary injunction barring the implementation of Rule 4.2. The trial court ruled in favor of the class regarding Rule 4.1 and an appeal was taken to the Indiana Supreme Court, which reversed the trial court's holding that Rule 4.1 was in compliance with the requirements of the Boren Amendment.⁶² The First District Court of Appeals withheld ruling on Rule 4.2 until a review of Rule 4.1 was completed. The issue before the court of appeals regarding Rule 4.2 was whether the trial court was correct in granting the preliminary injunction regarding Rule 4.2 pursuant to the Boren Amendment.

In determining whether the trial court had abused its discretion in granting the preliminary injunction regarding Rule 4.2, the court had to determine whether (1) the plaintiffs' remedies at law were inadequate; (2) irreparable harm would be inflicted if the injunction was not issued; (3) the plaintiffs had demonstrated a reasonable likelihood of success at trial by establishing a prima facie case; (4) the threatened injury to the plaintiffs outweighed the threatened harm that the grant of an injunction would occasion upon defendant; and (5) the preliminary injunction, if granted, would be against the public interest.⁶³

Regarding the plaintiffs' likelihood of success on the merits, the court of appeals undertook an analysis of the Federal Boren Amendment, which requires, in part, that a state Medicaid plan provide

for payment . . . of . . . nursing facility services, and services in an intermediate care facility for the mentally retarded provided under the plan through the use

58. *Id.*

59. *Id.* at 1353 n.4.

60. 637 N.E.2d 1306 (Ind. Ct. App. 1994).

61. *Id.* at 1310.

62. 42 U.S.C. § 1396(a)(13)(A) (1988 & Supp. 1993).

63. *Tioga Pines*, 637 N.E.2d at 1311.

of rates . . . which the State finds, and makes assurances satisfactory to the Secretary [of the Department of Health and Human Services], are reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities in order to provide care and services in conformity with applicable [s]tate and [f]ederal laws, regulations, and quality and safety standards.⁶⁴

In conducting this analysis, the State must make "findings" that the state plan reimburses costs that efficiently and economically operated facilities must incur in order to provide the level of care required by federal and state standards. "The requirement that the state make 'findings' is thus not a mere formality, but an entirely independent, necessary prerequisite to the requirement of assurances."⁶⁵

The court of appeals agreed with the trial court and determined that the state did not engage in an adequate findings process as required by the Boren Amendment. This was based on the fact that the findings conducted by the state's Medicaid rate-setting contractor excluded data from "better than half of the 744 providers in the class" due to a lack of historical data or because for relevant periods these providers had an occupancy rate of less than eighty percent.⁶⁶ Therefore, the findings could predict the extent of reimbursement that would be received by only forty-three percent of the class.⁶⁷ Additionally, the state did not supply the mandatory objective assessment of quality care and reasonable access required by the Boren Amendment.⁶⁸

The court then determined whether the plaintiffs had an adequate remedy at law and whether the plaintiffs would suffer irreparable harm if the injunction were not issued. Finding this condition satisfied, the court held that the plaintiffs had no adequate remedy at law "[b]ecause the implementation of the new regulations [would] result in a reduction of between Nine to Eleven Million Dollars in reimbursement being paid to the class."⁶⁹

Finally, the court determined that the public interest was served "by requiring [the state] to live up to the responsibilities with which [it is] charged under federal law without usurping [the state's] role in the rate setting process."⁷⁰ The court then reviewed the balance of the hardships and the public interest threatened by the grant of the preliminary injunction. The court determined that the state suffered no hardship because the injunction merely prohibited the state from a continuing violation of the Boren Amendment and that the state would suffer no particular injury in continuing reimbursement pursuant to Rule 4.1.⁷¹

Under *Tioga Pines*, large payment reductions potentially resulting in facility closures or fiscal insolvency may represent irreparable harm for which no adequate remedy at law exists since monetary damages subsequently awarded may be insufficient to rectify the

64. 42 U.S.C. § 1396a(a)(13)(A) (1988 & Supp. 1993).

65. *Tioga Pines*, 637 N.E.2d at 1312.

66. *Id.* at 1314.

67. *Id.*

68. *Id.*

69. *Id.* at 1316 n.5.

70. *Id.* at 1318 (quoting *Thomas v. Johnston*, 557 F. Supp. 879, 919 (W.D. Tx. 1983)).

71. *Id.* at 1317.

current unlawful activity of the state. *Tioga Pines* also reaffirms other Boren Amendment cases that require the state to conduct an adequate findings process before implementing a new Medicaid reimbursement system.

3. *Patient Dumping*.—In *Harris v. Health & Hospital Corp.*,⁷² an action was brought against defendant Hospital alleging that it had violated the Emergency Medical Treatment and Active Labor Act (“Act”)⁷³ by discharging Ms. Harris from its emergency room after an admission for severe chest pain. Within two hours of discharge, she was readmitted in cardiac arrest and died shortly thereafter. At the time of her first admission, the attending emergency room physician made a “differential diagnosis” of costochondritis and hyperventilation syndrome.⁷⁴ Plaintiff argued that because myocardial infarction and pulmonary embolus were within the range of possible diagnoses, defendant knew that Ms. Harris was suffering from an emergency medical condition and her subsequent discharge violated the Act.⁷⁵

The court ruled that because the plaintiff failed to present any evidence that the physician knew Ms. Harris was suffering from anything but the conditions he originally listed in her medical record, she was not in an emergency medical condition at the time of her first admission and, accordingly, the hospital did not violate the Act when she was discharged. Even if it could be argued that an inaccurate diagnosis occurred in this case, the pertinent finding of the court is that an appropriate screening and stabilization are the principal requirements of the Act and both were present in the instant case.

4. *Medicaid Eligibility*. *Cherry v. Sullivan*.⁷⁶—In May 1990, a class action suit was filed against the Secretary of the Indiana Family and Social Services Administration seeking declaratory and injunctive relief. The class consisted of all married Medicaid applicants who had lived in a nursing facility prior to September 1989, and who had further been determined to be ineligible for Medicaid because of the amount of assets held by spouses living at home. Additionally, the plaintiffs mounted a constitutional challenge under the Equal Protection Clause of the United States Constitution.⁷⁷

The court ruled that Indiana’s Medicaid eligibility rules were proper in considering a non-institutionalized spouse’s access to assets in making Medicaid eligibility determinations.⁷⁸ In support of this result, the court reviewed the state’s interest in limiting its Medicaid expenditures and allocating finite Medicaid funds to truly needy persons. The court also stated: “Indiana has the additional legitimate interest in recognizing the marital relationship for what it is, a relationship of interdependence wherein it is neither unfair nor unrealistic to require one spouse to support the other, in particular to help meet the obligation to pay for family medical bills.”⁷⁹

While non-institutionalized spouses require sufficient resources to care for themselves, this decision is supported by strong public policy considerations. If the

72. 852 F. Supp. 701 (S.D. Ind. 1994).

73. 42 U.S.C. §§ 1395dd (1988 & Supp. 1993).

74. A differential diagnosis is a broad diagnosis which includes several different possible diagnoses.

75. 852 F. Supp. at 702.

76. 30 F.3d 73 (7th Cir. 1994).

77. *Id.* at 75.

78. *Id.*

79. *Id.*

availability of assets to the spouse of a Medicaid recipient were not taken into consideration in making an eligibility determination, many persons of means could arrange their affairs so as to establish eligibility for a spouse requiring medical care. This could substantially impair the state's ability to provide Medicaid services for those most in need.

B. Legislative Action

House Enrolled Act 1298 empowers the Indiana Attorney General and an investigator of the Medicaid Fraud Control Unit to issue, serve and apply to a court for enforcement of subpoenas to compel an individual to produce books, papers, or other records, including records stored in electronic data systems, for inspection and examination.⁸⁰ Additionally, a subpoena may be issued and enforced compelling an individual to appear before the Attorney General in person.⁸¹ This Act also makes the knowing or intentional commission of Medicaid fraud a Class D felony, unless the fair market value of the claim or payment at issue exceeds \$50,000, in which case it is a Class C felony.⁸²

C. Administrative Action

1. Reimbursement.—In 1994, the Office of Medicaid Policy and Planning (OMPP) published a number of reimbursement regulations that substantially changed the way certain health care providers are reimbursed under the Indiana Medicaid program.

The new regulations revised hospital inpatient reimbursement procedures. Hospital reimbursement under the new Medicaid reimbursement system is based on a Diagnostic Related Group (DRG) system.⁸³ Each in-patient hospital stay is now reimbursed using a prospective system based upon DRGs.⁸⁴ These payments will constitute complete payment to hospitals, and there will no longer be any end-of-year adjustments.⁸⁵ Reimbursement for inpatient hospital stays using the DRG methodology will equal the sum of the DRG rate, the capital rate, the medical education rate, and, where applicable, the outlier payment amount.⁸⁶

The new regulations also revise hospital outpatient service reimbursement procedures. Reimbursement for outpatient services will be subject to the lower of submitted charges or the established fee schedule allowance for the particular procedure.⁸⁷ Surgical procedures are classified into groups corresponding to the Medicare Ambulatory Surgical Center (ASC) methodology and paid an established rate for each ASC group.⁸⁸ Payment is based upon a blended rate equal to fifty percent of the fiscal year 1992 Indiana statewide median allowed amount for that service and fifty percent of the Medicare ASC

80. IND. CODE § 4-6-10-3 (Supp. 1994).

81. *Id.*

82. IND. CODE §35-43-5-7.1 (Supp. 1994).

83. IND. ADMIN. CODE tit. 405, r. 1-10.5-2(h) (1994).

84. *Id.* at r. 1-10.5-3(a).

85. *Id.*

86. *Id.* at r. 1-10.5-3(b).

87. *Id.* at r. 1-8-3(a) (1995).

88. *Id.* at r. 1-8-3(b).

rate.⁸⁹ Emergency care reimbursement is based upon a state-wide fee schedule of HCPCS codes.⁹⁰ Reimbursement for laboratory procedures and the technical component of radiology procedures will be based on ninety-five percent of the Medicare allowance that was in effect prior to the adoption of the Resource Based Relative Value Scale for Medicare services.⁹¹

Medicaid recipients are to be charged a three dollar copayment for nonemergency services provided in an emergency room setting.⁹² The provider is responsible for collecting the copayment amount from Medicaid recipients.⁹³ However, providers may not deny services to any individual based on such individual's inability to pay the copayment amount.⁹⁴ Thus the provider's ability to collect copayments for nonemergency services seems improbable at best.

There is also a new Medicaid reimbursement system for physicians and non-physician practitioners. The OMPP is empowered to establish fee schedules providing maximum allowable payment amounts for services and procedures covered under the Indiana Medicaid program for physicians, limited license practitioners⁹⁵ and non-physician practitioner⁹⁶ services.⁹⁷ The reimbursement for physicians and limited license practitioners is equal to the lower of submitted charges or the established fee schedule for such procedure.⁹⁸ The fee schedule is based on the Medicare relative value unit for an Indiana urban locality multiplied by the procedure's conversion factor established by OMPP.⁹⁹ Assistant surgeons are reimbursed using a different formula whereby payment is equal to twenty percent of the state-wide fee schedule for physicians and limited license practitioners.¹⁰⁰

2. *Rate Setting Criteria for Nursing Facilities.*—On August 1, 1994, a new rate-setting criteria for nursing facilities went into effect as promulgated by the Indiana Family and Social Services Administration (IFSSA) at Indiana Administrative Code Title 405, Rule 1-14 ("Rule 14"). It has had a dramatic impact on certain providers of nursing facility services under the Indiana Medicaid program.

89. *Id.*

90. *Id.* at r. 1-8-3(c).

91. *Id.* at r. 1-8-3(e).

92. *Id.* at r. 1-8-4(b).

93. *Id.* at r. 1-8-4(c).

94. *Id.* at r. 1-8-4(d).

95. Physician and limited license practitioner means a doctor of medicine, doctor of osteopathy, a physician group practice, a primary care group practice, an optometrist, a podiatrist, a dentist who is an oral surgeon, a chiropractor and a health service provider in psychology. *Id.* at r. 1-11.5-1(c).

96. Nonphysician practitioner means a physical therapist, an occupational therapist, a respiratory therapist, an audiologist, a speech therapist, a licensed psychologist, an independent laboratory or radiology provider, a dentist who is not an oral surgeon, certain social workers and psychologists, advance practice nurses, physician's assistants, and certain mental health professionals. *Id.* at r. 1-11.5-1(d).

97. *Id.* at r. 1-11.5-2.

98. *Id.* at r. 1-11.5-2(b).

99. *Id.* at r. 1-11.5-2(b)(1)(B).

100. *Id.* at r. 1-11.5-2(b)(5). The specific reimbursement formula for nonphysician practitioners is articulated at IND. ADMIN. CODE tit. 405, r 1-11.5-2(c) (1994).

Some of the more significant changes regarding Rule 14 involve the administrative appeal process available to facilities that contest Medicaid rates as established by IFSSA. For example, Medicaid rates can be implemented and overpayments can be recovered without awaiting the outcome of the administrative appeal process.¹⁰¹ Additionally, when a provider seeks a request for administrative reconsideration of its Medicaid rate, Medicaid is under no obligation to respond to the provider's request. If the rate-setting contractor does not respond within forty-five days, the request is deemed denied.¹⁰²

The changes also involve the information that must be submitted to the Indiana Medicaid program in the form of financial reports. The annual financial report is to be submitted to the office "not later than ninety (90) days after the close of the provider's reporting year."¹⁰³ Additionally, the annual report must include a statement of all expenses and all income, a complete balance sheet, and a schedule of Medicaid and private pay rates in effect on the last day of the reporting period and the rate effective date. The private pay charges are the lowest usual and customary charge.¹⁰⁴

With respect to interim rates, upon a change of provider or establishment of a new service, interim rates will be set at the greater of the prior provider's then current rate, or the fiftieth percentile. The fiftieth percentile rate will be calculated on a state-wide basis by level of care.¹⁰⁵ A change in provider status can also be rescinded if any subsequent transaction by the provider "cause[s] a capital lease to be reclassified as an operating lease."¹⁰⁶

Rate reviews for new providers will be submitted once a year based on the annual report. Budgets will no longer be submitted by providers. When determining rates for active providers, the state may consider changes in federal law or regulations during a calendar year when determining whether a rate increase will be allowed.¹⁰⁷ The state is under no obligation to revise a rate regardless of the scope of the federal or state law or impact that such law or regulation may have on the provider.

Rate setting shall be prospective based on allowable costs that will be determined by using the provider's historical expense information, and inflating the expense by the HCFA/SNF index. Expenses that will not be inflated include mortgage interest on facilities and equipment, depreciation of facilities and equipment, rent or lease costs for facilities and equipment, and working capital interest expense. The inflation adjustment will be applied "from the midpoint of the annual or historical financial report period to the midpoint of the expected rate period."¹⁰⁸

Allowable costs for certain fixed costs for nursing facilities will be subjected to initial minimal occupancy levels of ninety percent and ninety-five percent effective April 1, 1995, or the actual occupancy rate if higher. Target occupancy under the previous rules was eighty percent. Fixed costs subject to the minimum occupancy rate calculation

101. *Id.* at r. 1-14.1-1(d).

102. *Id.* at r. 1-14.1-25(a).

103. *Id.* at r. 1-14.1-4(a).

104. *Id.* at r. 1-14.1-4(b).

105. *Id.* at r. 1-14.1-5(a).

106. *Id.* at r. 1-14.1-5(h).

107. *Id.* at r. 1-14.1-6(b).

108. *Id.* at r. 1-14.1-7(a).

include director of nursing wages, administrative wages, all costs in the ownership cost center except for repairs and maintenance, and the capital return factor allowance.¹⁰⁹ Advertising is an allowable expense only when "incurred in the recruitment of facility personnel necessary for compliance with facility certification requirements."¹¹⁰

The provider's rate is based on recognition of the provider's allowable costs, plus a potential profit add-on. The rate is established at the lowest of the four limitations listed as follows:

1. Average allowable cost of the median patient day, by level of care and geographic area times 115%.
2. The rate paid by the general public for the same type of service.
3. The rate requested by the provider.
4. Inflated allowable costs plus the allowed profit add-on payment. The profit add-on is equal to 50% of the difference between the allowable costs and 100% of the average inflated allowable costs of the median patient day, by level of care and geographic area, with the profit add-on limited to 5% of the average inflated allowable costs of the median patient day, by level of care and geographic area.¹¹¹

Rule 14 is also important in that the provider's per diem rate now includes the costs of "nonroutine supplies" and oxygen, for which the bill could have been sent separately under the previous Medicaid rate-setting criteria.¹¹² Therapy services provided to Medicaid recipients are also included in the established per diem rate. Provider's costs for therapy will be included in the calculation of the rate and subsequent rate calculations, if the services satisfy conditions provided in the Indiana Medicaid Provider Manual.¹¹³ Therapy services can be provided through facility staff, licensed and certified therapists, or through a contractual arrangement.¹¹⁴

III. HEALTH CARE PROVIDER LAW

Several changes in Indiana law affect the activities of specific health care providers. The courts have addressed the issue of confidentiality of information within a peer review committee under the Indiana Peer Review Act. The General Assembly passed new legislation concerning hospital charity care, full-time physicians in hospitals, and an amendment to the Living Will Act. Finally, new rules were promulgated that affect advance practice nurses.

109. *Id.* at r. 1-14.1-7(b).

110. *Id.* at r. 1-14.1-8(a).

111. *Id.* at r. 1-14.1-9(a).

112. *Id.* at r. 1-14.1-22(a).

113. *Id.* at r. 1-14.1-23(a).

114. *Id.* at r. 1-14.1-23(b).

A. Judicial Opinions

In *Mulder v. Vankersen*,¹¹⁵ Mr. Vankersen was a certified registered nurse anesthetist and a non-physician member of the medical staff employed by St. Joseph Hospital of Huntingburg, Inc. ("Hospital"). In February 1992, a surgical technician made several reports to the director of the operating room that Mr. Vankersen had reported to work smelling of marijuana and that he suffered from mood swings. Mr. Mulder, the Hospital's chief executive officer, was ultimately apprised of Mr. Vankersen's alleged marijuana use.¹¹⁶

On May 20, 1992, at the medical staff's executive committee meeting, Mr. Vankersen's alleged marijuana use was discussed. The Hospital's executive committee consisted of five physician members and Mr. Mulder, the only non-physician member of the executive committee. No minutes of the May 20, 1992 meeting were kept.¹¹⁷

After the May 20, 1992 meeting of the executive committee, Mr. Vankersen was notified that his alleged marijuana use was discussed at the executive committee meeting. In response, Mr. Vankersen's attorney sent Mr. Mulder "a cease and desist" letter asking Mr. Mulder to stop making these accusations.¹¹⁸ After receiving the cease and desist letter, Mr. Mulder drafted a memorandum that detailed his communications regarding Mr. Vankersen to the executive committee at the May 20, 1992 meeting. The memorandum drafted by Mr. Mulder was not shown to anyone except Mr. Mulder's attorneys.¹¹⁹ Mr. Vankersen also discovered that Mr. Mulder had communications with a physician who was not a member of the executive committee regarding Vankersen's alleged marijuana use.

Mr. Vankersen thereafter filed a defamation action. In the process of discovery, Mr. Vankersen sought information discussed at the May 20, 1992 executive committee meeting as well as the memorandum prepared by Mr. Mulder in response to the cease and desist letter. All of the members of the executive committee invoked the peer review privilege¹²⁰ under the Indiana Peer Review Act ("Act")¹²¹ and refused to testify. Mr. Mulder similarly relied on the privilege in refusing to produce the memorandum.¹²²

In response to the executive committee members' invocation of the privilege, Mr. Vankersen sought a motion to compel from the trial court. The motion to compel was granted on the basis that: (1) the executive committee meeting was not a meeting of a peer review committee; (2) even if the meeting of the executive committee was a meeting of a peer review committee, the communications made at the meeting were not protected by the statute since the requirements for confidentiality were breached; and (3) the memorandum drafted by Mr. Mulder in response to the cease and desist letter was outside the scope of the Act. Mr. Mulder appealed.

115. 637 N.E.2d 1335 (Ind. Ct. App. 1994).

116. *Id.* at 1336.

117. *Id.*

118. *Id.*

119. *Id.* at 1336-37.

120. IND. CODE § 34-4-12.6-2 (1993).

121. *Id.* §§ 34-4-12.6-1 to -4.

122. *Mulder*, 637 N.E.2d. at 1337.

The court of appeals first determined whether the statements regarding Mr. Vankersen's alleged marijuana use made to the executive committee were communications made to a peer review committee pursuant to the Act. Under Indiana Code section 34-4-12.6-1(c), a "peer review committee" is

[a] committee having responsibility of evaluation of qualifications of professional health care providers, or of patient health care rendered by professional health care providers, or of the merits of a complaint against a professional health care provider that includes a determination or recommendation concerning the complaint. The committee must meet the following criteria:

(1) The committee is organized:

. . . .

(B) by the professional staff of a hospital . . . ;

(2) At least fifty percent (50%) of the committee members are:

(A) individual professional health care providers, the governing board of a hospital or professional health care organization¹²³

The court of appeals determined that the Hospital's executive committee satisfied the requirements of a peer review committee since it had responsibility for evaluating the qualifications of the Hospital's health care providers and of the patient care rendered by professional health care providers as required by Indiana Code section 34-4-12.6-1(c).¹²⁴ Additionally, the executive committee met the requirement that it be organized by the professional staff of the Hospital with at least fifty percent of its members being individual professional health care providers. The court held that "the executive committee of the hospital was a peer review committee within the meaning of the statute and communications to the committee [were] within the scope of the peer review privilege and [were] entitled to protection."¹²⁵

The court then rejected Mr. Vankersen's arguments that: (1) the statements made to the executive committee were not within the scope of the Peer Review Act because they had no direct connection to an evaluation of patient care, and (2) because the executive committee did not take minutes at its May 20, 1992, meeting, the meeting was "stripped of the peer review privilege."¹²⁶ The court stated that because Mr. Vankersen was a registered nurse, the communications made to the executive committee regarding his alleged marijuana abuse had a direct effect on his ability to deliver patient care and, thus, were within the scope of the peer review privilege.¹²⁷ The court also stated that the failure to take minutes during the executive committee meeting did not change the peer review character of the communications and did not strip the communications of the privilege.¹²⁸

The court then briefly addressed whether Mr. Mulder's memorandum was protected by the peer review privilege. The court reasoned that the memorandum was protected on

123. *Id.* (quoting IND. CODE ANN. § 34-4-12.6-1(c) (West 1983 & Supp. 1994)).

124. *Mulder*, 637 N.E.2d at 1338-39.

125. *Id.* at 1339.

126. *Id.*

127. *Id.*

128. *Id.*

the basis that the "memorandum is simply a personal record of the communications in question, which we have determined are protected by the peer review privilege."¹²⁹ Therefore, the court held that the memorandum merely memorialized the privileged communications to the executive committee and was therefore protected under the Act.

Lastly, the court determined that Mr. Mulder's actions did not invalidate the privileges guaranteed under the Act by discussing Vankersen's alleged marijuana use with a physician who was not a member of the executive committee since that discussion related to the confidentiality provision of the statute and did not affect the privilege section. In holding that the privilege provisions had not been affected, the court relied upon the waiver provisions of the Act.¹³⁰ These provide that the peer review privilege may be waived only if the waiver is executed in writing. Without a written waiver, the peer review privilege is not waived even though some communications are outside of the peer review committee meeting.

The court rejected Mr. Vankersen's argument that the breach of the confidentiality provisions in the Act had caused a revocation of the privilege under the Act. Even though immunities under the Act shall be withheld from any person violating the confidentiality requirements therein, the same reasoning does not hold as to the privilege.¹³¹ Because the issue at hand revolved around waiver of the privilege as opposed to the immunities granted under the Act, the court found no waiver of the privilege because Mr. Mulder had not executed a written waiver.

B. Legislative Developments

1. *Charity Care*.—Effective July 1, 1994, Indiana requires that hospitals must document and report to the Indiana State Department of Health ("Department") the amount of charity care provided.¹³² Charity care is defined as the "unreimbursed cost to a hospital of providing, funding, or otherwise financially supporting health care services" to patients seeking medical services at such hospital.¹³³ Hospitals are required to file an annual community benefits report and a mission statement with the Department.¹³⁴

This statute could have considerable significance to Indiana nonprofit, tax-exempt hospitals as a measuring device to quantify whether such hospitals are continuing to satisfy their community and public service commitments through the provision of charitable care. This determination will be increasingly important as federal, state and local governments begin to examine the role of tax-exempt entities and the effect of those entities upon tax policy within various jurisdictions.

2. *Full-Time Physicians in Hospitals*.—Hospitals with at least 100 beds must have a physician on duty at all times.¹³⁵ The Department is authorized to promulgate rules that

129. *Id.*

130. *Id.* See IND. CODE § 34-4-12.6-2(g)-(i) (1993).

131. IND. CODE § 34-4-12.6-2(m) (1993).

132. The specific requirement is found at IND. CODE § 16-21-9-7(a) (1993 & Supp. 1994).

133. *Id.* § 16-18-2-52.5(a).

134. *Id.* § 16-21-9-7(a).

135. IND. CODE § 16-21-2-15 (1993 & Supp. 1994).

will establish procedures for hospital response to inpatient emergencies to ensure continuous coverage.¹³⁶

3. *Living Will Act.*—Effective July 1, 1994, the Living Will Act¹³⁷ no longer exempts the provision of appropriate nutrition and hydration from the term “life prolonging procedure.”¹³⁸ The living will declaration form¹³⁹ was also amended by the legislature to allow the patient to check one of the following three choices regarding the provision of artificially supplied nutrition or hydration:

- _____ I wish to receive artificially supplied nutrition and hydration, even if the effort to sustain life is futile or excessively burdensome to me.
- _____ I do not wish to receive artificially supplied nutrition and hydration, if the effort to sustain life is futile or excessively burdensome to me.
- _____ I intentionally make no decision concerning artificially supplied nutrition and hydration, leaving the decision to my health care representative appointed under IC 16-36-1-7 or my attorney in fact with health care powers under IC 30-5-5.¹⁴⁰

The amendments to the Living Will Act do not apply to living will declarations executed prior to July 1, 1994.

Although these amendments to the Indiana Living Will Act are limited in number, the import of the changes is significant in that the General Assembly explicitly recognized that artificially supplied nutrition or hydration is a form of medical care. These changes bring the Living Will Act into accord with other statutes¹⁴¹ and with applicable Indiana case law.¹⁴²

4. *Medical Claims Review.*—In amending Indiana Code section 27-8-16-4, the General Assembly expanded the definition of “medical claims review agent” to include review entities or individuals who review amounts charged for health care services.¹⁴³ Whenever a medical claims review agent reviews and adjusts a medical bill, such agent must provide an explanation of the determination made, the database relied upon by the review agent in reaching such decision, and the percentile limiter applied to the amount charged by the health care provider. This law is designed to prevent arbitrary decisions by medical claims review agents with regard to the payment of medical claims.

5. *Charges Permitted for Providing Copies of Medical Records.*—Pursuant to Indiana Code section 16-39-1-1, a health care provider, upon the written request and with reasonable notice from a patient, was required to provide *at the provider's actual total cost* a copy of the patient's health record to the patient or the patient's designee.

136. *Id.*

137. IND. CODE §§ 16-36-4-1 to -21 (1993 & Supp. 1994).

138. *Id.* § 16-36-4-1.

139. *Id.* § 16-36-4-10.

140. *Id.*

141. Indiana Health Care Consent Act, IND. CODE §§ 16-36-1-1 to -14 (1993); Indiana Powers of Attorney Act, IND. CODE §§ 30-5-5-1 to -10-4 (1993).

142. *See In re Lawrence*, 579 N.E.2d 32 (Ind. 1991).

143. IND. CODE § 27-8-16-4 (1993 & Supp. 1994).

Effective July 1, 1994, a provider is now limited with respect to the charges that can be assessed for providing copies of medical records. This new chapter states that "[a] provider may collect a charge of twenty-five cents (\$0.25) per page for making and providing copies of medical records."¹⁴⁴ The provider is also entitled to collect a retrieval charge of fifteen dollars.¹⁴⁵ However, if the fifteen dollar retrieval charge is assessed, the provider may not charge for making and providing copies of the first ten pages of the medical record.¹⁴⁶ The provider may charge an additional fee of ten dollars if the provider is required to supply the person requesting the medical record a copy within two working days.¹⁴⁷

C. Administrative Action

1. *Revised Hospital Licensure Regulations.*—In early 1995, the Indiana State Department of Health ("Department") issued new rules regarding the licensure of hospitals in Indiana.¹⁴⁸ These rules represent the first major state regulatory changes affecting hospital licensure in nearly two decades.

One of the most significant aspects of the new rules permits hospitals to establish policies and procedures for various hospital services. The Department will then confirm that the hospital's policies and procedures are in place and evaluate adequacy for the services provided. The rules depart from a previous regulation that specified standards by each service area.

The new hospital licensure rules also seek to make the regulatory process more consistent with requirements of the Joint Commission for Accreditation of Healthcare Organizations (JCAHO)¹⁴⁹ and the Medicare Conditions of Participation.¹⁵⁰ Consistency with the national standards will allow a more uniform survey process for the purposes of regulatory evaluation and comparison.

Another part of the licensure rules changes the physical plant requirements for hospitals. Current rules dictate compliance with very specific physical plant standards. The new hospital rules have incorporated the American Institute of Architecture Guidelines ("AIA Guidelines").¹⁵¹ The AIA Guidelines establish various building requirements for different types of hospital services, both inpatient and outpatient. The current rules have only one set of physical plant requirements that apply to all services and plant operations without regard to the type of service.

144. *Id.* § 16-39-9-3(a).

145. *Id.* § 16-39-9-3(b).

146. *Id.* § 16-39-9-3(a).

147. *Id.* § 16-39-9-3(d).

148. IND. ADMIN. CODE tit. 410, r. 15-1.1-1 to -1.7-1 (1994).

149. The JCAHO is a private accrediting organization that inspects hospitals for compliance with established accreditation guidelines for services provided by hospitals. Hospitals may voluntarily seek JCAHO accreditation. If a hospital is JCAHO-accredited, it is deemed to be in compliance with the Medicare Conditions of Participation.

150. 42 C.F.R. § 482 (1993).

151. IND. ADMIN. CODE tit. 410, r. 15-1.5-8 (1994).

The new rules also require twenty-four hour inpatient mandatory physician coverage in the hospital if it has more than 100 beds.¹⁵² The rules regarding the medical staff of hospitals require the staff to adopt and enforce bylaws and rules that include a provision of coverage for emergency care for all patients.¹⁵³ This provision of coverage for emergency care includes a definition of emergency care requiring a timely response by the on-duty physician.¹⁵⁴

These new rules afford Indiana hospitals the flexibility necessary to provide quality health care in a rapidly changing environment while remaining in compliance with licensure requirements.

2. *Advanced Practice Nurses.*—The new rules add to and clarify the definitions of “advanced practice nurse practitioner” and “clinical nurse specialist” and their standards of competent practice.¹⁵⁵ These definitions are based upon required additional skills and training. Most significant is the prescriptive authority given to an advanced practice nurse to prescribe legend drugs including controlled substances subject to certain requirements.

IV. FEDERAL DEVELOPMENTS

At the federal level, the Department of Justice and the Federal Trade Commission issued policy statements covering antitrust in the health care industry. A federal court in Virginia dealt with the issue of continuing medical treatment when such treatment is determined futile.

A. *Antitrust*

The rapid increase in health sector collaborative initiatives among competitors has been an integral part of the quiet revolution occurring in health care. Providers of health services require considerable guidance as to the permissible range of relationships and arrangements lawful under Federal antitrust law.

Some additional guidance is now forthcoming. On September 27, 1994, a year after their 1993 Policy Statements, the Department of Justice and the Federal Trade Commission (“Federal Agencies”) issued an enlarged set of Policy Statements on the health care industry and antitrust, entitled “Statements of Enforcement Policy and Analytical Principles Relating to Health Care and Antitrust” (“1994 Policy Statements”).¹⁵⁶

Although in some instances virtually no difference exists between the 1993 and 1994 Policy Statements, the latter pronouncements are important because the Federal Agencies appear to have responded to the plea of the health care field that additional direction and clarification was necessary in structuring business arrangements. The identification by

152. *Id.* at r. 15-1.4-1(d)(3)(A).

153. *Id.* at r. 15-1.5-5(b)(3)(L).

154. *Id.*

155. IND. ADMIN. CODE tit. 848, r. 5-1-1 (1994).

156. U.S. DEPARTMENT OF JUSTICE AND THE FEDERAL TRADE COMMISSION, STATEMENTS OF ENFORCEMENT POLICY AND ANALYTICAL PRINCIPLES RELATING TO HEALTH CARE AND ANTITRUST (1994) [hereinafter “1994 POLICY STATEMENTS”].

the federal agencies of certain safety zones in areas such as sharing of equipment and services, creation of multi-provider networks and the dissemination of fee-related information provides some encouragement that the complexities of the health care industry are being recognized and some accommodation of usual policy may occur.

The 1994 Policy Statements include guidance in the following areas: (1) mergers among hospitals; (2) hospital joint ventures utilizing high technology or other expensive health care equipment; (3) hospital joint ventures involving specialized clinical or other expensive health care services; (4) providers' collective provision of non-fee-related information to purchasers of health care services; (5) providers' collective provision of fee-related information to the purchasers of health care services; (6) provider participation in exchange of price and cost information; (7) joint purchasing arrangements among health care providers; (8) physician network joint ventures; and (9) analytical principles regarding multiprovider networks.¹⁵⁷

The 1994 Policy Statements appear to be particularly useful in the expansion of established safety zones. Hospital joint equipment ventures may now include existing equipment as well as newly purchased equipment, so long as "the joint venture includes only the number of hospitals whose participation is needed to support the equipment."¹⁵⁸ Interestingly, the federal agencies have never challenged a joint venture among hospitals to purchase health care equipment or services.¹⁵⁹ In developing physician network ventures, the Policy Statements allow a twenty percent market share threshold for exclusive ventures and thirty percent share for non-exclusive physician network joint ventures sharing meaningful financial risk.¹⁶⁰

In addition to the antitrust safety zones, the 1994 Policy Statements also provide insight into the analytical process used by the federal agencies in evaluating efficiencies created by joint ventures.¹⁶¹ The issuing agencies also renewed their commitment to reply to inquiries for guidance within ninety days of the provision of all necessary information and material related to the 1994 Policy Statements, except for mergers outside the safety zone and multi-provider networks, which will require 120 days response time.¹⁶²

The 1994 Policy Statements are important aids to providers as they structure their business affairs in the sometimes confusing and contradicting areas of competition and collaboration. Providers now have additional guideposts and an element of certainty that has eluded them in the past. There is a greater likelihood that most arrangements as described by the 1994 Policy Statements fostering competition and lower costs will be viewed favorably.

B. Consent

1. *Continuation of Treatment Determined Futile.*—Although the doctrine of informed consent was developed to ensure that patients had complete information prior

157. 1994 POLICY STATEMENTS, *supra* note 156, at 2-3.

158. 1994 POLICY STATEMENTS, *supra* note 156, at 17.

159. 1994 POLICY STATEMENTS, *supra* note 156, at 16.

160. 1994 POLICY STATEMENTS, *supra* note 156, at 68-69.

161. 1994 POLICY STATEMENTS, *supra* note 156, at 35-43.

162. 1994 POLICY STATEMENTS, *supra* note 156, at 106.

to making important decisions regarding medical care and treatment,¹⁶³ that doctrine has, through a recent Fourth Circuit Court of Appeals decision, evolved to the point that the clinical judgment of the physician may in certain cases be secondary to a patient's or a patient representative's demand for medically inappropriate care.

In *In re Baby K.*,¹⁶⁴ a hospital brought an action for declaratory and injunctive relief under four federal statutes and one state statute. The statutes were the Emergency Medical Treatment and Active Labor Act (EMTALA),¹⁶⁵ the Americans with Disabilities Act of 1990 (ADA),¹⁶⁶ the Rehabilitation Act of 1973 (RA),¹⁶⁷ the Child Abuse Amendments of 1984,¹⁶⁸ and the Virginia Medical Malpractice Act.¹⁶⁹

The plaintiff acute care hospital was a Medicare and Medicaid participating hospital under 42 U.S.C. § 1395cc, licensed in Virginia to provide full medical and hospital services, and staffed by a complete complement of physicians, including several pediatric specialists that frequently treated sick children.¹⁷⁰ Ms. H., the defendant, was a citizen of Virginia and the biological mother of Baby K. Baby K. was born on October 13, 1992, with anencephaly, a congenital defect in which the brain stem is formed but the cerebral cortex is absent or quite underdeveloped. No known treatment will reverse, modify, cure or otherwise improve this condition. Because the cerebral cortex contains centers of high brain function, Baby K. was unconscious, could neither see nor hear and probably could not feel pain. Baby K.'s primary functions were limited to reflex actions controlled by the brain stem such as feeding reflexes, respiratory reflexes and response to sound or touch. Most of Baby K.'s other organs and body functions appeared normal. Generally, most anencephalic infants die within a few days of birth.¹⁷¹

Because of breathing problems, immediately upon birth, Baby K. was placed on a mechanical ventilator to assist in breathing. Several days later, hospital personnel requested that Ms. H. authorize a "Do Not Resuscitate Order" for Baby K., which would include the discontinuation of ventilator treatment. The doctors informed Ms. H. that the ventilator treatment was "medically unnecessary and inappropriate"; however, she refused to authorize the Do Not Resuscitate Order and continued to request ventilator treatment for Baby K.¹⁷² With Ms. H.'s consent, the hospital thereafter transferred Baby K. to a nursing home during a period of respiratory stability for Baby K. Ms. H.'s consent was subject to the hospital's agreement to readmit Baby K. and provide ventilator treatment in the event Baby K. encountered future respiratory distress. Approximately six weeks later, Baby K. was returned to the hospital after experiencing respiratory distress. Ms. H. insisted on ventilator treatment even though hospital officials again sought to dissuade

163. See *Payne v. Marion Gen. Hosp.*, 549 N.E.2d 1043, 1046 (Ind. Ct. App. 1990).

164. 832 F. Supp. 1022 (E.D. Va. 1993), *aff'd*, 16 F.3d 590 (4th Cir. 1994), *cert. denied*, 115 S. Ct. 91 (1994).

165. 42 U.S.C. § 1395dd (1988 & Supp. 1993).

166. 42 U.S.C. § 12101 (Supp. 1993).

167. 29 U.S.C. § 794 (1988 & Supp. 1993).

168. The Child Abuse Prevention and Treatment Act, 42 U.S.C. §§ 5101-5106h (1988 & Supp. 1993).

169. VA. CODE §§ 8.01-581.1 to 581.20 (1992 & Supp. 1994).

170. *In re Baby K.*, 832 F. Supp. at 1024.

171. *Id.*

172. *Id.* at 1025.

her. After stabilization, Baby K. was again transferred to the nursing home where she continued to live at the time of trial.

The hospital, expecting future episodes of respiratory distress for Baby K., brought this action and made a motion for appointment of a guardian ad litem, which was granted by the court. The hospital also stipulated to the court that its request to deny ventilator treatments to Baby K. was not related to Ms. H.'s ability to pay. The guardian ad litem supported the position of the hospital as to withholding ventilator treatment from Baby K.¹⁷³

The district court held for Ms. H. in all respects, ruling that the hospital is required under EMTALA to provide necessary and appropriate emergency care to Baby K. and such stabilizing care as is necessary.¹⁷⁴ The district court also stated that the EMTALA had no "futile case" exception and, even if it did, providing ventilator care relieved the acute symptom of breathing difficulty, which is an emergency condition requiring treatment irrespective of the underlying medical condition.¹⁷⁵ The district court further found that the RA also required the hospital to provide emergency care in this case because Baby K. had a handicapping condition and was otherwise qualified to receive medical care.¹⁷⁶ Withholding of necessary ventilator treatment because of her handicap, anencephaly, would therefore violate the RA. The district court concluded that the ADA would also be violated by withholding ventilator treatment for Baby K. because the hospital was a place of public accommodation, and the plain language of the statute compels treatment in this case because an infant without an anencephalic condition in respiratory distress would receive ventilator treatment if consented to by the parent.¹⁷⁷

The Fourth Circuit Court of Appeals affirmed the district court by a two-to-one majority.¹⁷⁸ The majority held that the hospital had a duty to provide stabilizing treatment under EMTALA.¹⁷⁹ The majority had little difficulty in finding that EMTALA unequivocally obligated the hospital to provide emergency care to Baby K. while she was in respiratory distress. They did, however, acknowledge that the decision placed physicians in a dilemma since the plain language of EMTALA requires treatment in these types of cases even if it is contrary to accepted medical standards.¹⁸⁰ The majority concluded that the legislative branch of government must resolve this problem, not the judicial branch.¹⁸¹ The majority, because it was "bound to interpret federal statutes in accordance with their plain language,"¹⁸² apparently read literally the application of EMTALA and found no exception for independent medical judgment. It also failed to distinguish between the manifest medical emergency (respiratory distress) and the indisputable cause and related underlying medical condition (anencephaly).

173. *Id.* at 1025-26.

174. *Id.* at 1027.

175. *Id.*

176. *Id.* at 1028.

177. *Id.*

178. 16 F.3d 590, 598 (4th Cir. 1994), *cert. denied*, 115 S. Ct. 91 (1994).

179. *Id.* at 595.

180. *Id.* at 597.

181. *Id.* at 598.

182. *Id.*

If this Fourth Circuit decision gains currency, physicians in many jurisdictions could be compelled to provide medical treatment inconsistent with their best medical judgment because transferring such a patient will not always be an option. The welfare of the patient is not always well served by prolonging the patient's death by any and all means. Federal statutes seeking to ensure availability of emergency care, access to care for handicapped persons and the protection of children should be re-examined to determine whether modifications are necessary to restore the concept of providing all persons necessary care as determined primarily by medical judgment and appropriate consent. Indiana attorneys advising hospitals and physicians should be aware of this important development in the Fourth Circuit.

CONCLUSION

As the public becomes accustomed to the precept that only finite resources exist for all necessary services, including the delivery of health care, significant choices must be made as to the services to be provided, the populations to be served, and the most efficient and cost-effective methods of delivering care. This decision-making process will result in a confluence of fiscal, political, moral and legal forces. Members of the legal profession have an important role and opportunity to provide leadership in assuring that these difficult decisions affecting basic human needs are rooted in principles of fairness embodied in the rule of law.