

HEALTH CARE LAW: A SURVEY OF SIGNIFICANT 1998 DEVELOPMENTS

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INTRODUCTION

This Article reviews significant developments in the divergent field of health care law. The primary focus of this Article is on those areas which most likely impact client concerns, and therefore are of the most utility to practitioners in this field. This Article is not intended to be a comprehensive analysis of the most recent changes, but instead encapsulates several of the most important health care issues, including the new Stark II regulations, medical malpractice, Medicare and Medicaid issues, antitrust, labor and employment, fraud and abuse, and legislative health initiatives.

I. FEDERAL DEVELOPMENTS

A. *Federal Stark II Legislation*

On January 9, 1998, the Health Care Financing Administration (“HCFA”) issued proposed regulations¹ for sections 1877 and 1903(s) of the Social Security Act (“SSA”), better known as the Stark II Act.² Stark II restricts physician referrals for certain “designated health services” to entities with which they or immediate family members have a financial interest.³ The scope of Stark II is extremely comprehensive, applying to practically any financial arrangement involving a physician or immediate family member.⁴ However, HCFA’s interpretations of certain statutory terms, as well as the additional requirements imposed in certain definitions and exceptions, raise many issues for providers. The proposed regulations are extremely detailed and provide additional insight into the law’s referral prohibitions, specifically defining each designated health service.⁵

Stark II provides that if a physician or member of a physician’s immediate family has a financial relationship with a health care entity, “the physician may

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1. Health Care Financing Administration, 63 Fed. Reg. 1659 (1998) (to be codified at 42 C.F.R. pt. 411, 424, 435 & 455).

2. The Public Health & Welfare Act § 18, 42 U.S.C. § 1395nn (1994).

3. *Id.* § 1395nn(a).

4. *Id.*

5. 63 Fed. Reg. at 1663-64.

not make a referral to the entity for the furnishing of designated health services" for which payment may be made under the Medicare/Medicaid programs.⁶ Further, the entity may not present a claim to Medicare/Medicaid or bill any third party payor for services furnished pursuant to a prohibited referral.⁷

HCFA, in its proposed regulations, utilizes the Medicare definition of physician, which includes an M.D. or D.O., dentist or oral surgeon, podiatrist, optometrist, and chiropractor.⁸ "Immediate family member" means husband or wife; natural or adoptive parent, child or sibling; step relatives (parent, child, brother, sister); in-laws (father, mother, son, daughter, brother, sister); grandparent or grandchild; and spouse of a grandparent or grandchild.⁹

The term "financial relationship," whether direct or indirect, refers to ownership or investment interest in an entity or compensation arrangement with an entity.¹⁰ A "compensation arrangement" means any arrangement involving any remuneration between a physician (or immediate family member) and an entity.¹¹ The term "remuneration" includes any payment, discount, forgiveness of debt, or other benefit made directly or indirectly, in cash or in kind.¹²

The term "referral" is broadly worded to include a request for any designated health service payable under Medicare or Medicaid.¹³ A request by a pathologist for clinical diagnostic laboratory services, by a radiologist for radiology services, or by a radiation oncologist for radiation therapy services, is not deemed to be a referral if such request results from a consultation initiated by another physician and such tests or services are furnished by or under the supervision of such pathologist, radiologist, or radiation oncologist.¹⁴

In the proposed regulations, HCFA defines each of the statutory designated health services.¹⁵ Except for inpatient hospital services and home health services, these definitions are based upon how Medicare covers a service under Part B.¹⁶ For purposes of Medicaid, the Medicare definitions will still apply unless a state definition differs, in which case the state definition will apply.¹⁷

HCFA believes that a designated health service remains one, even if it is billed as something else or is subsumed within another service category by being bundled with other services for billing purposes.¹⁸ As an example, services performed by a skilled nursing facility ("SNF") are considered SNF services,

6. 42 U.S.C. § 1395nn(a).

7. *See id.*

8. 63 Fed. Reg. at 1704.

9. *Id.* at 1721-22.

10. *Id.* at 1721.

11. *Id.* at 1720.

12. *Id.* at 1723.

13. *Id.* at 1722-23.

14. *Id.*

15. *See* The Public Health & Welfare Act § 18, 42 U.S.C. § 1395nn (1994).

16. *See* 63 Fed. Reg. at 1673-74.

17. *See id.*

18. *See id.* at 1673.

which are not themselves designated health services.¹⁹ Nonetheless, SNF services can encompass a variety of designated health services, such as physical therapy or laboratory services.²⁰ In sum, HCFA interprets a designated health service as one provided regardless of the setting in which it is provided or payment category under which it is billed.²¹ This interpretation is thus very broad and includes both the professional and technical components of a service.²²

The proposed regulations contain clarification of the exceptions found in the Stark legislation as well as add new exceptions.²³ These exceptions apply to (i) both an ownership/investment interest and a compensation arrangement, (ii) only an ownership/investment interest, or (iii) only a compensation arrangement.²⁴ Providers must be careful to meet the correct exceptions under the law.

Exceptions for both ownership/investment interests and compensation arrangements include "physician" services, in-office ancillary services, services furnished through certain government prepaid plans, and services furnished under ambulatory surgery center, end stage renal disease, or hospice rates.²⁵ Exceptions solely for ownership/investment interests include ownership of certain publicly traded securities, certain rural providers, and hospitals.²⁶

Exceptions for compensation arrangements include space and equipment rentals, bona fide employment relationships, personal service arrangements, physician recruitment arrangements, isolated transactions, certain unrelated and group practice arrangements with hospitals, certain payments for items or services furnished, discounts, *de minimis* compensation, and fair market value compensation arrangements.²⁷ Each of these exceptions has numerous requirements which must be met in full to escape Stark's prohibitions.

The proposed regulations contain significant developments of which providers must be aware. HCFA's interpretations of the group practice definition are among the most significant developments in the proposed regulations. Highlights include a requirement that the group be a single legal entity; a group may have more than one billing number as long as such billing numbers are assigned to the group.²⁸ Further, physician owners and employees are only deemed "members of the group" if they meet the applicable seventy-five percent threshold standards for providing services through the group, as well as the group members providing at least seventy-five percent of the total patient case for the group.²⁹ In other words, independent contractors may not be utilized by a group

19. *See id.*

20. *See id.*

21. *See id.*

22. *See id.*

23. *See id.* at 1723-26.

24. *See id.*

25. *See id.* at 1723-24.

26. *See id.* at 1724.

27. *See id.* at 1724-26.

28. *See id.* at 1721.

29. *See id.* at 1722.

to meet the in-office ancillary services exception.

Group practices must also meet internal accounting and compensation requirements. Most notably, distribution of profits may not be based directly on referrals for designated health services—even self-referrals.³⁰ In addition, all compensation and overhead methodologies must be set in advance of the period in which the applicable services are performed and reflect a unified business as opposed to satellite offices acting as separate enterprises.³¹

The In-Office Ancillary Services for both ownership/investment interests and compensation arrangements includes three requirements that apply to the performance, location and billing of such services.³² Regarding the performance component, certain in-office ancillary services may be performed by an individual who is directly supervised by the referring physician or another physician in the same group practice as the referring physician.³³ The regulations define “direct supervision” as supervision by a physician who is actually present in the office suite and immediately available to provide assistance and direction throughout the time services are performed.³⁴

Regarding the location component, the services must be provided in the same office in which a physician provides actual physician services, a building used by a group for the provision of some or all of the group’s clinical laboratory services, or a building used by a group for the centralized provision of the group’s designated health services (other than clinical laboratory services).³⁵ Finally, although the in-office ancillary services exception does not apply to durable medical equipment (“DME”), a physician may provide crutches as long as no direct or indirect profit is realized.³⁶

HCFA defines “fair market value” to mean the value in arm’s length transactions, consistent with general market value.³⁷ “General market value” is an asset price or service compensation which is the result of bona fide bargaining between well-informed buyers and sellers or parties to an agreement.³⁸ According to HCFA, the fair market price is usually the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement.³⁹ With respect to rentals and leases, fair market value includes that for general commercial purposes (not taking into account its intended use) which may not be adjusted to reflect the additional value with respect to

30. *See id.* at 1721.

31. *See id.*

32. *See id.* at 1723.

33. *See id.*

34. *Id.* at 1720.

35. *See id.* at 1723.

36. *See id.*

37. *Id.* at 1721.

38. *Id.*

39. *Id.*

proximity or convenience of referrals.⁴⁰

The proposed regulations reiterate that compensation may not fluctuate in a manner that reflects referrals,⁴¹ including situations where a physician's payments are stable but predicated, *either expressly or otherwise*, on the physician's referrals to a particular provider.⁴² For example, if a physician is required to refer to an entity as a condition of employment, such compensation is deemed to impermissibly take into account the volume or value of referrals, even if the compensation is otherwise stable.⁴³ This interpretation is potentially problematic and seems to ignore many standard health care contracts, such as exclusive relationships, employee/contractor covenants not to compete, and other managed care initiatives.

HCFA proposes to create a compensation arrangement exception for *de minimis* compensation.⁴⁴ This exception places limits on compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed \$50 per gift and an aggregate of \$300 per year.⁴⁵ Such compensation must be provided to all similarly situated individuals, regardless of whether these individuals refer patients, and cannot be based in any way upon referrals.⁴⁶

A proposed exception covering other written contracts at fair market value also exists. However, among other requirements, this exception requires that the arrangement meet a safe harbor regulation under the Anti-Kickback Statute⁴⁷ or otherwise be in compliance with the Anti-Kickback law.⁴⁸ Because it is difficult to meet a safe harbor regulation⁴⁹ under the Anti-Kickback Statute, it remains unclear whether this exception will be truly beneficial.

The proposed regulations require all entities furnishing items or services for which payment may be made under Medicare to submit information to HCFA concerning their financial relationships as defined under Stark II.⁵⁰ This information must be submitted on a HCFA-prescribed form within the time period specified by the servicing carrier or intermediary.⁵¹ Thereafter, an entity must report annually to HCFA all changes that occurred in the previous year.⁵² The sanctions for failure to meet this reporting requirement include civil penalties of up to \$10,000 for each day after the provider's application deadline

40. *See id.*

41. *Id.* at 1699-1700.

42. *Id.* at 1700.

43. *See id.*

44. *Id.* at 1725.

45. *Id.*

46. *See id.*

47. *Id.* at 1725-26; *see* 42 C.F.R. § 1001.952 (1998).

48. 63 Fed. Reg. at 1725-26; *see* 42 C.F.R. § 1001.952.

49. *See* 42 C.F.R. § 1001.952.

50. 63 Fed. Reg. at 1726-27.

51. *See id.*

52. *See id.*

that a report is not properly made.⁵³

In sum, every financial arrangement involving physicians and their immediate family members should be separately scrutinized under Stark II. Sanctions for violating the statute include civil penalties of up to \$15,000 for submitting an illegal claim or not refunding such a claim on a timely basis (within sixty days) and up to \$100,000 for each circumvention arrangement or scheme.⁵⁴

On the same day that the Stark II proposed regulations were issued, HCFA also issued final regulations outlining a process for advisory opinions.⁵⁵ This process allows any individual or entity to request a written advisory opinion from HCFA concerning whether a physician's referrals for designated health services (other than clinical laboratory services) to an entity is or would be prohibited under Stark II and whether an exception applies.⁵⁶ However, HCFA will not advise whether an arrangement is at fair market value or whether an individual is a bona fide employee under the Internal Revenue Code.⁵⁷

B. Federal Anti-Kickback Statute Advisory Opinions

On July 16, 1998, the Department of Health and Human Services Office of Inspector General ("OIG") issued a final rule for the issuance of Anti-Kickback Statute advisory opinions.⁵⁸ Several advisory opinions have already been issued.

1. *Advisory Opinion 97-4*.⁵⁹—This opinion addresses whether the decision by an ambulatory surgery center ("ASC") to decline to pursue collection of copayments from patients with employer-sponsored Medicare complementary coverage constitutes grounds for imposition of sanctions under the Health Insurance Portability and Accountability Act ("HIPAA")⁶⁰ or the Anti-Kickback Statute.⁶¹ Based on the OIG's review, any waiver of the copayment obligation constitutes remuneration to the beneficiary. Further, the ASC's proposal to refrain from pursuing collection of the Medicare copayment from beneficiaries is intended, at least in part, to encourage covered beneficiaries to obtain services at the ASC. The proposed arrangement would therefore potentially be subject to sanction under HIPAA.⁶²

The OIG noted that when providers forgive financial obligations for reasons

53. *Id.*

54. The Public Health & Welfare Act § 18, 42 U.S.C. § 1395nn(g) (1994).

55. 63 Fed. Reg. at 1646.

56. *See id.* at 1655.

57. *See id.*

58. Advisory Ops. by the Off. of Inspector Gen., 42 C.F.R. §§ 1008.1-.59 (1998). This final rule follows an interim final rule published February 19, 1997. *See id.*

59. 97 Op. Off. of Inspector Gen. No. 97-4 (Sept. 25, 1997) [hereinafter No. 97-4].

60. Health Insurance Portability & Accountability Act of 1996, 42 U.S.C. §§ 1320a-7a(a), -7(a)(5) (1994 & Supp. II 1996).

61. 42 U.S.C. § 1320a-7b(b) (1994 & Supp. II 1996).

62. *See* No. 97-4, *supra* note 59.

other than genuine financial hardship of the particular patient, they may be unlawfully inducing the patient to purchase items or services in violation of the Anti-Kickback Statute's proscription against offering or paying something of value as an inducement to generate business payable by a federal health care program. Thus, except in those special cases of financial hardship, providers must make a good faith effort to collect Medicare copayments.⁶³

2. *Advisory Opinion 97-6*.⁶⁴—The OIG considered whether a proposed arrangement for restocking ambulance supplies and medications at no charge to ambulance services operated by a governmental entity constitutes illegal remuneration as defined in the Anti-Kickback Statute.⁶⁵ The OIG concluded that the hospitals' proposed provision of free supplies and medications to a municipal ambulance services fits squarely within the meaning of remuneration for purposes of the Anti-Kickback Statute.⁶⁶ An inference may be drawn that at least one purpose of this remuneration may be to induce the ambulance services to bring patients to the hospitals. To the extent those patients include beneficiaries of federal health care programs who require covered hospital services, the Anti-Kickback Statute may be implicated.

This proposed arrangement poses a risk of improper steering of patients and unfair competition. Patients in need of ambulance services are often in a vulnerable state, and their choice of emergency room may be influenced by ambulance service personnel. In these circumstances, where the payments relate directly to the delivery of patients, remuneration paid by a hospital to an ambulance service, including the provision of free goods, would be highly suspect. Although there may be no intent to induce referrals by such a practice (and such a practice may be fairly common), the OIG has decided that the parties may be at high risk for violating the Anti-Kickback Statute for such acts.⁶⁷ Hospitals that have relationships with ambulance services should review such relationships accordingly.

This Advisory Opinion has been the subject of much debate in the health care industry, and the concept of restocking and offering items to ambulance providers has been the subject of other Advisory Opinions. In Advisory Opinion 98-3,⁶⁸ the OIG approved the donation of an ambulance to a municipal fire department. In Advisory Opinion 98-7,⁶⁹ the OIG approved of a coordinated effort by a city council to restock ambulances with supplies and medications. This council had representation from the provider community and was responsible for oversight of the program. Finally, in Advisory Opinion 98-13,⁷⁰ the OIG approved of an ambulance restocking program coordinated through a

63. *See id.*

64. 97 Op. Off. of Inspector Gen. No. 6 (Oct. 8, 1997) [hereinafter No. 97-6].

65. 42 U.S.C. § 1320a-7b(b).

66. No. 97-6, *supra* note 64.

67. *Id.*

68. 98 Op. Off. of Inspector Gen. No. 3 (April 14, 1998).

69. 98 Op. Off. of Inspector Gen. No. 7 (June 16, 1998).

70. 98 Op. Off. of Inspector Gen. No. 13 (Sept. 23, 1998).

local emergency medical services council. In approving these initiatives, the OIG takes comfort in the increased quality of care to the respective communities and the minimal risk of abuse.

C. Internal Revenue Service Intermediate Sanction Regulations

In July 1998, the Internal Revenue Service ("IRS") proposed intermediate sanction regulations that impose penalties on "disqualified persons" engaging in "excess benefit transactions" with organizations exempt from federal income taxation under Internal Revenue Code § 501(c)(3) or (c)(4) as well as the "organization managers" who consent to such transactions.⁷¹ Prior to the September 1995 enforcement of Internal Revenue Code § 4958, the only legal remedy available to the IRS when an exempt entity engaged in a prohibited transaction was to revoke the entity's tax-exempt status.⁷² The IRS was historically hesitant to impose such a drastic sanction.

The intermediate sanction regulations (the "Rules") that proposed to alter Internal Revenue Code § 4958 broaden the tax penalty remedies and the definition of a "disqualified person."⁷³ The Rules allow for the imposition of a two-tiered penalty tax upon any "disqualified person" who engages in an excess benefit transaction with a § 501(c)(3) or (c)(4) tax-exempt organization.⁷⁴

An "excess benefit transaction" is defined as any deal in which a § 501(c)(3) or (c)(4) tax-exempt organization provides, either directly or indirectly, an economic benefit to a disqualified person where the value of such benefit exceeds the value received by the organization in return.⁷⁵

A "disqualified person" is defined by statute as any person involved in a transaction in a position to exercise substantial influence over the exempt entity's affairs at any time during the prior five year period ending on the date of the transaction.⁷⁶ The Rules extend this definition to apply to the family members of a disqualified person, as well as any entity in which a disqualified person either directly or indirectly owns more than a thirty-five percent interest.⁷⁷

The first-tier tax imposed by the Rules is an excise tax equal to twenty-five percent of any excess benefit a disqualified person receives from an improper economic benefit.⁷⁸ If the excess benefit transaction is not timely corrected, the disqualified person is subject to a second-tier tax of two hundred percent of the excess benefit received.⁷⁹ In addition to the excise taxes imposed on the

71. Department of Treasury, 63 Fed. Reg. 41,486 (1998) (to be codified at 26 U.S.C. § 4958)).

72. 26 U.S.C. § 4958 (Supp. II 1996).

73. 63 Fed. Reg. at 41,486.

74. *Id.* at 41,489.

75. 26 U.S.C. § 4958(c)(1)(A); 63 Fed. Reg. at 41,491.

76. 26 U.S.C. § 4958(f)(1).

77. 63 Fed. Reg. at 41,490.

78. *Id.* at 41,489.

79. *See id.*

disqualified person taking part in the excess benefit transaction, any exempt organization manager who approved the excess benefit transaction knowing it to be improper may be subject to a separate tax of ten percent of the excess benefit, not to exceed \$10,000 for each separate transaction.⁸⁰

Of significant interest are the comments from the House Report, which state that physicians are not intended to be treated as “per se” disqualified persons, looking instead to the facts and circumstances of each situation to make this determination.⁸¹ This departs from the prior guidance in this area, where the IRS took the position that physicians were insiders with regard to exempt entities where they render professional medical services, and therefore, all transactions between such organizations and these physicians were traditionally subject to an inference of private inurement.⁸²

Examples of “disqualified persons” include any voting member of an exempt entity’s governing body, as well as the president, chief executive officer, chief operating officer, treasurer and chief financial officer of the organization.⁸³ However, in determining who is a disqualified person, the IRS will look to the individual’s actual responsibilities and authority rather than his title.⁸⁴ If a person does not fall directly within the definition of “disqualified persons,” the IRS will apply a facts and circumstances test to make this determination.⁸⁵ The Rules set out a series of non-exclusive facts and circumstances which the IRS believes tend to reflect that an individual has substantial influence over an exempt organization.⁸⁶ Additionally, the IRS has listed facts and circumstances which reflect that an individual is not a disqualified person.⁸⁷

These Rules offer significant guidance in the area of hospital-physician transactions, particularly with regard to the reasonableness of compensation paid to physicians.⁸⁸ The Rules specify that compensation will be deemed reasonable if it is an amount which would customarily be paid for similar services “by like enterprises under like circumstances.”⁸⁹ The parties can establish a rebuttable presumption of reasonableness by having a compensation package approved by an independent board or board subcommittee unrelated to the subject or control of the disqualified person provided that the board or subcommittee obtains and relies upon appropriate compensation comparability data and adequately

80. *See id.*

81. H.R. REP. NO. 506 at 43 n.12 (1998).

82. IRS Gen. Couns. Mem. 39862 (Nov. 22, 1991); IRS Gen. Couns. Mem. 39498 (April 24, 1986); IRS Announcement 92-83, *Exempt Organizations; Examination Guidelines for Hospitals* § 33.2(2) (June 1, 1992).

83. 63 Fed. Reg. at 41,490.

84. *See id.*

85. *See id.*

86. *Id.*

87. *Id.*

88. *See id.* at 41,191-92.

89. *Id.*

documents the basis for any determinations it makes.⁹⁰

D. IRS Revenue Ruling 98-15

On March 4, 1998 the IRS provided significant guidance in the area of tax-exempt organizations.⁹¹ In Revenue Ruling 98-15, the IRS addressed two scenarios in which a tax-exempt hospital, by contributing all of its operating assets to a joint venture, forms a limited liability company (LLC) with a for-profit corporation. In the first hypothetical situation, the LLC's governing documents provide for a five person governing board, with three of the five directors selected by the nonprofit hospital. The governing documents could only be amended with the approval of both owners, and a majority of directors was required to approve key decisions related to the LLC's operations.⁹² Also, the governing documents specifically required that the LLC operate any hospital it owns in a manner that furthers charitable purposes. This structure was treated as a "safe harbor" by the IRS.⁹³

In contrast, the LLC's governing documents in the second hypothetical situation provided for a six person board, with three directors selected by each member. The governing documents could only be amended with approval of both members, and a majority of the entire board was required for a more limited list of operating decisions. The governing documents did not provide that the LLC operate any healthcare facilities it owns in a manner to further their charitable purposes. This approach was deemed violative of IRS statute and would jeopardize the tax-exempt entity's exempt status.⁹⁴

The IRS reiterated that a section 501(c)(3) organization may enter into a partnership-like venture, including an LLC, so long as the venture furthers a charitable purpose and allows the exempt organization to act exclusively in furtherance of its exempt purpose.⁹⁵ In addition to the "purpose test," Revenue Ruling 98-15 focused on the "control test"—whether the exempt hospital retains sufficient control over the activities of the venture as to prevent more than an incidental private benefit to the for-profit entity.⁹⁶

Through Revenue Ruling 98-15, the IRS identified key factors in deciding whether activities related to a joint venture between exempt and non-exempt entities are in furtherance of the exempt organization's charitable purposes. With regard to the "purpose test," the governing documents should require the new

90. See H.R. REP. NO. 506 at 41 (1998).

91. Rev. Rul. 98-15 (Mar. 4, 1998).

92. The decisions related to the following topics: the LLC's annual capital and operating budgets, distributions of the LLC's earnings, selection of key executives, acquisition or disposition of health care facilities, contracts in excess of a certain dollar amount, changes to the types of services offered by the hospital, and renewal or termination of management agreements. See *id.*

93. *Id.*

94. See *id.*

95. *Id.* (citing *Plumstead Theatre Society, Inc. v. Commissioner*, 74 T.C. 1324 (1980)).

96. *Id.*

entity to serve charitable purposes or provide health care services to the community as a whole. Moreover, furtherance of charitable purposes must override any duty to provide financial benefit to the owners. However, by emphasizing the factors of control in both hypotheticals, the IRS clearly indicated the importance of the nonprofit hospital owner retaining sufficient control over the joint venture to ensure that its assets and activities are used primarily for charitable purposes.⁹⁷

According to Revenue Ruling 98-15, the key powers should be reserved to the exempt organization or to a majority vote of the nonprofit owner's representatives on the board. In addition to the board's structure and voting control, the exempt organization should ensure that the joint venture be managed by an unrelated party, or that the powers of the management entity not be so broad as to effectively shift control from the board to the management company.⁹⁸

It remains to be seen how Revenue Ruling 98-15 will affect joint ventures beyond the "whole hospital" examples discussed in the ruling. The impact could be dramatic if the same analysis is applied to physician-hospital joint ventures. Even so, the hypothetical examples presented in Revenue Ruling 98-15 represent rather extreme fact patterns and do not provide indications as to what, if any, arrangements between the two extremes might be acceptable.⁹⁹

E. Organ Procurement Regulations

The centerpiece of the Department of Health and Human Services' 1998 initiative to increase organ, tissue, and eye donation was a set of regulations which established new organ procurement guidelines for hospitals.¹⁰⁰ The federal regulations became effective on August 21, 1998.¹⁰¹ Hospital compliance with these new regulations is a condition for participating in the Medicare and Medicaid programs.¹⁰²

The regulations principally address three key topics. First, responsibility for determining an individual's medical suitability for organ donation will shift from hospitals to organ procurement organizations ("OPO").¹⁰³ The new rule requires

97. *Id.*

98. *See id.*

99. *Id.*

100. Department of Health & Human Servs., 63 Fed. Reg. 33,856 (1998) (to be codified at 42 C.F.R. pt. 482).

101. *Id.* The final rule was published on June 22, 1998. Hospitals have one full year from the date the final rule took effect to come into compliance. Enforcement will begin on August 21, 1999. *See id.*

102. *See id.* An example of a compliance regulation is section 1320b-8 of the Public Health & Welfare Act. It requires Medicare and Medicaid participating hospitals that perform transplants to be members of the Organ Procurement and Transplantation Network and abide by its rules and requirements. 42 U.S.C. § 1320b-8(B) (1994).

103. *See* 63 Fed. Reg. at 33,856.

hospitals to have a written agreement with an OPO, under which the hospital will provide the OPO, or a third party designated by the OPO, with routine referrals of all deaths that occur in the hospitals.¹⁰⁴ The hospital must also have a written agreement with at least one tissue bank and at least one eye bank.¹⁰⁵ Finally, the regulations strengthen the consent and education process by requiring that only OPO personnel or other properly trained individuals consult with the families of potential donors.¹⁰⁶

The final rule adopts "routine referral language," which requires timely hospital referral of all patient deaths, as well as information about individuals whose deaths are imminent, to the designated OPO.¹⁰⁷ This provision is intended to relieve the hospital of its responsibility to keep current with changing donor criteria and determine the medical suitability of potential organ donors. However, the Health Care Financing Administration ("HCFA") declined to establish federal criteria defining medically suitable donors. Instead, the OPOs have the authority under the law to conduct testing, review medical records, and gather other medical information needed to determine the medical suitability of potential donors.¹⁰⁸

The final rule also shifts responsibility from the hospitals to OPOs to obtain consent from the families of potential donors.¹⁰⁹ HCFA found that rates of consent for organ donation are much higher when the request is made by the OPO in conjunction with the hospital staff.¹¹⁰ Consequently, the final rule requires that only OPO representatives or individuals trained by the OPO may approach families to explain their donation options and make the actual request for donation.¹¹¹ The rule also allows the hospital to choose the individual who will initiate the request for donation, provided that individual has been properly educated in the consent process.¹¹² Hospitals are required to work cooperatively with the OPO, tissue bank and eye bank in educating staff on donation issues, as well as reviewing death records to improve identification of potential donors.¹¹³

104. *See id.*

105. *See id.*

106. *Id.*

107. *Id.* at 33,858-59. The regulations do not define at what point death is "imminent," but do provide that the requirement for timely referral at death or when death is imminent means that hospitals must make referrals both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. *See id.* at 33,866.

108. *See id.* at 33,862.

109. *Id.* at 33,856.

110. *See id.* at 33,860. According to the study cited, there was a 67% consent rate when the OPO coordinator approached the family alone, a 9% rate when hospital staff approached the family alone, and a 75% consent rate when the approach was made by the OPO coordinator and hospital staff together. *See id.* (citing J. Klieger et al., *Analysis of Factors Influencing Organ Donation Consent Rates*, J. TRANSPLANT COORDINATION (1994)).

111. 63 Fed. Reg. at 33,856.

112. *Id.*

113. *See id.*

F. Antitrust

Antitrust enforcement activity maintained an aggressive pace during the 1998 fiscal year, especially in the area of mergers and acquisitions. The merger wave, which began in 1991, continued with a record 4640 Premerger Notification filings submitted to the Federal Trade Commission ("FTC") Premerger Notification Office during the fiscal year 1998.¹¹⁴ Of particular interest to healthcare attorneys was the FTC's challenge of a hospital merger in Poplar Bluff, Missouri¹¹⁵ and its successful effort to block two mergers of prescription drug wholesale distributors.¹¹⁶ In addition, two "virtual mergers" were challenged in the fiscal year 1998.¹¹⁷

1. *Federal Trade Commission v. Tenet Healthcare Corp.*—In July, a federal district court in Missouri preliminarily enjoined Tenet Healthcare Corporation, which owned 201-bed Lucy Lee Hospital in Poplar Bluff, from acquiring the only other hospital in town, 230-bed Doctors Regional Medical Center, for \$40.5 million.¹¹⁸ The merging hospitals were each other's primary competitor in their relatively isolated service areas.

As with many antitrust merger cases, a determinative issue before the *Tenet* court was the definition of a relevant geographic market.¹¹⁹ It was undisputed that Lucy Lee and Doctors Regional drew ninety percent of their patients from a service area radiating approximately fifty miles from Poplar Bluff. This service area, proffered by the FTC, included the merging hospitals and five small, rural hospitals, one of which was also owned by Tenet. The defendants, on the other hand, asserted a geographic market radiating sixty-five air miles (up to ninety-five driving miles) from Poplar Bluff, which encompassed an additional fifteen hospitals. However, the court found that statistical evidence could not, by itself, clearly define a relevant geographic market.¹²⁰

The *Tenet* court considered anecdotal evidence from third party payors and employers within the Poplar Bluff area. The court noted that the merging hospitals had a history of negotiating deeper discounts with payors that excluded

114. See Joseph G. Krauss, *New Developments in the Premerger Notification Program* (presented before the District of Columbia Bar Association, Antitrust, Trade Regulation and Consumer Affairs Section, Antitrust Committee on October 7, 1998, available at <<http://www.ftc.gov/os/1998/9810/dcbar.htm>> (last modified Oct. 29, 1998)).

115. *Federal Trade Comm'n v. Tenet Healthcare Corp.*, 17 F. Supp. 2d 937 (E.D. Mo. 1998).

116. *Federal Trade Comm'n v. Cardinal Health, Inc.*, 12 F.Supp. 2d 34 (D.D.C. 1998).

117. *New York v. St. Francis Hosps.*, No. 98-0939 (S.D.N.Y. Feb. 10, 1998); Christine Ngeo, *Partners Try Two-Step: FTC Investigates Second Phase of N.Y. Hospital Deal*, MODERN HEALTHCARE, Feb. 16, 1998, at 24.

118. *Tenet Healthcare Corp.*, 17 F. Supp. 2d at 939.

119. *Id.* at 941-42. The parties agreed that the relevant product market encompassed general acute care inpatient hospital services, including primary and secondary services, but excluding tertiary and quaternary care hospital services. See *id.* at 942.

120. *Id.*

the other local hospital from their managed care networks, and that payors believed they would be unable to negotiate the same discounts after the merger in the absence of such competition.¹²¹ The court concluded that the more restrictive market asserted by the FTC was appropriate and that the defendants' proposed market was "inconsistent with the economic realities of Southeast Missouri."¹²²

Tenet exemplifies the need to carefully balance subjective, anecdotal payor evidence against quantitative patient migration statistics.¹²³ Patient flow statistics do not clearly show where patients could turn in the face of competitive pricing.

2. *Federal Trade Commission v. Cardinal Health, Inc.*—On July 31, 1998, the U.S. District Court for the District of Columbia issued a preliminary injunction blocking the proposed mergers of the four largest drug wholesalers in the country.¹²⁴ In this case, the FTC sought to enjoin the merger of Cardinal Health, Inc. and Bergen-Brunswig Corporation (the second and third largest pharmaceutical wholesalers), and the merger of McKesson Corporation and AmeriSource Health Corporation (the largest and fourth largest pharmaceutical wholesalers). The proposed mergers would have reduced the number of national pharmaceutical wholesalers from four to two, creating a duopoly that "clearly would dominate the competition with close to eighty percent of the pharmaceutical wholesale market."¹²⁵

One of the pivotal issues in the court's analysis was the relevant product market.¹²⁶ The parties conceded that pharmaceutical products are sold through four distribution channels, including national wholesale distributors, manufacturers selling directly on an as-needed basis, manufacturers buying directly coupled with self-warehousing, and mail order distributors. The FTC contended that the national wholesaler distribution channel was a distinct product market, accounting for \$54 billion of the \$94 billion in pharmaceutical sales in the United States during 1997.¹²⁷ The defendant drug wholesalers asserted that the relevant market encompassed all four distribution channels.¹²⁸

The court sought to determine whether it would be reasonable for customers to switch to alternative sources of supply if the defendants were to raise prices after the proposed mergers. The court concluded that there was sufficient

121. *Id.* at 943.

122. *Id.* at 945.

123. *Compare* Federal Trade Comm'n v. Freeman Hosp., 69 F.3d 260 (8th Cir. 1995) (supporting dynamic market analysis), *with* United States v. Long Island Jewish Med. Ctr., 983 F.Supp. 121 (E.D.N.Y. 1997) (relying heavily on patient migration statistics).

124. Federal Trade Comm'n v. Cardinal Health, Inc., 12 F. Supp. 2d 34, 34 (D.D.C. 1998).

125. *Id.* at 53.

126. *See id.* at 49-50. The parties agreed, and the court found, that the wholesale pharmaceutical industry is largely driven by competition on a national level. Although the FTC attempted to show a national market for large customers and regional markets for smaller customers, the court found that the regional markets were not sufficiently defined at trial. *Id.*

127. *See id.* at 45-46.

128. *See id.* at 47.

differentiation between the four distribution channels and that the wholesale distribution market was the relevant product market in which to assess the likely competitive effects of the proposed mergers.¹²⁹

Once the relevant market was defined as pharmaceutical wholesalers in the United States, defendants' market dominance allowed the court to find that the FTC had made a *prima facie* case that the proposed merger would have noncompetitive effects in the relevant market.¹³⁰ Although this case represents a second recent enforcement victory for the FTC, the court's analysis of the relevant product market is particularly instructive for antitrust practitioners.

3. *Virtual Mergers.*—In early 1998, the FTC commenced an antitrust investigation of a joint operating agreement between the recently merged two-hospital system—Cross River HealthCare in Kingston, New York and Northern Dutchess Hospital in Reinbeck, New York.¹³¹ Additionally, on February 10, 1998, New York Attorney General Dennis Vacco challenged a joint operating agreement between 317-bed St. Francis Hospital and 257-bed Vassar Brothers Hospital, the only acute care facilities in Poughkeepsie, New York.¹³² The question of economic integration was raised in both situations.

The U.S. Supreme Court had analyzed economic integration for purposes of antitrust violations and focused on the unity of economic interest of a parent and its wholly owned subsidiary and the inherent control a parent has over subsidiaries.¹³³ As a general rule, antitrust risks are minimized when (a) the purpose and effect of the joint venture is to facilitate procompetitive efficiencies, (b) the competitive restrictions within the venture are necessary to achieve those efficiencies, and (c) the restraints do not “spill over” to competitor activities outside of the joint venture.¹³⁴

129. *Id.* at 53-54.

130. *Id.* at 61.

131. *Id.* at 41 n.4.

132. *See id.*

133. *Copperweld Corp. v. Independence Tube Co.*, 467 U.S. 752, 771 (1984). The *Copperweld* doctrine has been expanded to cover agreements between wholly owned subsidiaries of a common parent corporation, *see, e.g.*, *Advanced Health-Care Servs., Inc. v. Radford Community Hosp.*, 910 F.2d 139, 146 (4th Cir. 1990), and to associations of independent entities that exemplify a sufficient unity of economic interest, *see, e.g.*, *City of Mount Pleasant, Iowa v. Associated Elec. Coop., Inc.*, 838 F.2d 268, 275 (8th Cir. 1988) (finding that an electric cooperative and constituent members were single entity); *Proctor v. General Conference of Seventh-Day Adventists*, 651 F. Supp. 1505, 1523 (N.D. Ill. 1986) (applying the *Copperweld* doctrine to unincorporated church associations that had unity of interest with centralized unified church). For an excellent article summarizing the scope of the *Copperweld* doctrine, *see* Stephen Calkins, *Copperweld in the Courts; The Road to Caribe*, 63 ANTITRUST L.J. 345 (1995).

134. *Compare Broadcast Music, Inc. v. Columbia Broadcasting Sys.*, 441 U.S. 1 (1979) (blanket copyright license for musical compositions was not a per se violation of antitrust laws because the price-fixing was necessary to market the product), *with Arizona v. Maricopa County Med. Society*, 457 U.S. 332 (1982) (price fixing of maximum prices for health services was per se illegal).

Competitor collaborations such as virtual mergers, joint operating agreements, and other affiliations raise significant antitrust concerns if not structured properly. It is likely that the government enforcement agencies will continue to give close scrutiny to merger-like affiliations among healthcare providers.

G. Labor/Employment

The U.S. Supreme Court recently expanded the reach of the Americans with Disabilities Act of 1990 ("ADA")¹³⁵ by holding that the human immunodeficiency virus ("HIV") can be a disability under the ADA even when the infection has not yet progressed to the so-called symptomatic phase.¹³⁶ The logical outreach of this holding is that employers must reasonably accommodate HIV-infected employees under most circumstances.

In *Bragdon v. Abbott*,¹³⁷ the Court utilized a three-step analysis to reach this conclusion.¹³⁸ First, the Court concluded that HIV infection is a physical impairment from the moment of infection.¹³⁹ In making this determination, the Court largely considered the predictable and unalterable course of the disease, and the immediacy with which the disease begins its course.¹⁴⁰ Second, the Supreme Court concluded that reproduction is a major life activity.¹⁴¹ To arrive at this conclusion, the Court utilized a common-sensical approach, concluding that reproduction and the sexual dynamic surrounding reproduction are "central to the life process itself."¹⁴² Finally, the Court concluded that a person's HIV infection substantially limits the major life activity of reproduction.¹⁴³ The Court pointed to the relative risks of transmitting the virus to sexual partners during conception and the risk to unborn children.¹⁴⁴

135. 42 U.S.C. §§ 12101-213 (1994 & Supp. II 1996).

136. *Bragdon v. Abbott*, 118 S. Ct. 2196 (1998). While this case was actually decided with particular emphasis placed on Title III of the ADA, which prohibits disability in the provision of public accommodations, the implication of the Supreme Court decision also applies to Title I of the ADA, which prevents disability discrimination in employment. The definition of "disability" is the same under both titles. *See id.* at 2209; *see also* 42 U.S.C. § 12102(2) (1994). The ADA defines "disability" as "(A) a physical or mental impairment that substantially limits one or more of the major life activities of such individual; (B) a record of such an impairment; or (C) being regarded as having such an impairment." 42 U.S.C. § 12102(2).

137. 118 S. Ct. 2196 (1998).

138. *Id.* at 2209-10.

139. *Id.* at 2204.

140. *Id.* at 2203-04.

141. *Id.* at 2205. The federal regulations implementing the ADA define "major life activity" as "functions such as caring for oneself, performing manual tasks, walking, seeing, hearing, speaking, breathing, learning and working." 29 C.F.R. § 1630.2(f) (1998).

142. *Bragdon*, 118 S. Ct. at 2205.

143. *Id.* at 2209.

144. *Id.* at 2206.

The Court did not determine whether HIV infection is a per se disability under the ADA.¹⁴⁵ Rather, each individual plaintiff must show that HIV infection substantially limited a major life activity.¹⁴⁶ Favoring a case-by-case approach, the Court left open the scope of "major life activity."¹⁴⁷ The expansive implications of this decision have not yet been analyzed in determining the future interpretation of the definition of a disability under the ADA.

II. INDIANA DEVELOPMENTS

A. *Judicial Opinions*

In *Creasy v. Rusk*,¹⁴⁸ the Indiana Court of Appeals examined the issue of whether a patient institutionalized in a long-term care facility for the treatment of Alzheimer's disease owes a duty to refrain from conduct which will injure his or her caregivers.

Mr. Rusk was admitted to Brethren Healthcare Center ("BHC") in July 1992 with a primary diagnosis of Alzheimer's disease. At the time of his admission, Mr. Rusk's symptoms included memory loss and confusion, and his wife was unable to care for him at home. Mr. Rusk was known to hit staff members while they attempted to care for him.¹⁴⁹

Ms. Creasy was a certified nursing assistant, employed by BHC, whose duties required her to care for patients with Alzheimer's disease. Ms. Creasy was aware of the pathological effects of Alzheimer's and had worked with Alzheimer's patients on a regular basis for a number of years prior to the incident in question.¹⁵⁰ On May 16, 1995, Nurse Creasy sustained personal injuries when she was kicked several times by Mr. Rusk while attempting to put the patient to bed. The trial court granted Mr. Rusk's motion for summary judgment, concluding that the patient did not owe a duty to his caretaker, the caretaker incurred the risk of her injuries, the caretaker's comparative fault exceeded all other fault proximately contributing to her injuries, and the caretaker had failed to bring forth evidence that the patient had breached any duty owed to her.¹⁵¹

The Indiana Court of Appeals reversed the trial court's decision concluding that "a person's mental capacity, whether that person is a child or an adult, must be factored into the determination of whether a legal duty exists."¹⁵² In its analysis of whether a person institutionalized with a mental disability owes a duty to his caregiver to refrain from conduct that results in injury to the caregiver, the appellate court declined to adopt the general rule which provides

145. *Id.* at 2207.

146. *Id.*

147. *Id.* at 2205.

148. 696 N.E.2d 442 (Ind. Ct. App. 1998).

149. *See id.* at 443.

150. *See id.* at 444.

151. *See id.*

152. *Id.* at 446.

for a different standard of care for adults than for children. Instead, the court reasoned that a person cannot be drawn into a legal relationship with another unless such person is capable of apprehending and appreciating the peril of the situation; thus, a person's mental capacity, whether that person is a child or an adult, must be factored in the determination of whether a legal duty exists.¹⁵³ The court further found that while the determination of the existence of a legal duty is generally a question of law, there may be instances in which there are genuine issues of material fact regarding the relationship and foreseeability factors, which "[make] the existence of duty a mixed question of law and fact, ultimately to be decided by the finder of fact."¹⁵⁴

The appellate court held that "[i]n the absence of extenuating circumstances, the relationship between a patient in a healthcare facility and the caregivers working in the facility is sufficient upon which to base a legal duty."¹⁵⁵ However, the patient's mental capacity to control his actions and understand the consequences thereof may serve to alter the patient-caregiver relationship.¹⁵⁶ "The greater the degree of the patient's impairment, the less weight to be given to the relationship factor in determining legal duty."¹⁵⁷ Furthermore, the court held that "[i]t is foreseeable that when an Alzheimer's patient becomes combative in the presence of his caregiver, the caregiver will be injured."¹⁵⁸

In *McConnell v. Porter Memorial Hospital*,¹⁵⁹ the Indiana Court of Appeals addressed whether an incident report filed by an employee of a hospital provides sufficient notice to comply with the state's statute governing notice of tort claims against a political subdivision.¹⁶⁰ Dr. McConnell, an emergency room physician, injured his left knee when he slipped and fell on a wet floor in the emergency room. Dr. McConnell was employed by the defendant hospital and filed an incident report regarding the fall. This incident report contained information concerning "the identity of the injured party, the date, a description of the event, diagnostic studies and treatment, and witnesses to the event."¹⁶¹ Approximately two years after this incident occurred, Dr. McConnell filed a lawsuit against the defendant hospital. The trial court granted the hospital's motion for summary judgment on the basis that Dr. McConnell had not complied with the statutory notice requirements of the Indiana Tort Claims Act.¹⁶²

Upon appeal, Dr. McConnell argued that he had substantially complied with the provisions of the Tort Claims Act by his filing of the incident report with the hospital. The court disagreed, stating that "[n]othing in either the Incident

153. *Id.*

154. *Id.* (citing *State v. Cornelius*, 637 N.E.2d 195, 198 (Ind. Ct. App. 1994)).

155. *Id.*

156. *See id.*

157. *Id.*

158. *Id.*

159. 698 N.E.2d 865 (Ind. Ct. App. 1998).

160. *Id.* at 867.

161. *Id.*

162. *See id.*

Report or the Incident Analysis Report placed the hospital on notice that the McConnells intended to present a tort claim."¹⁶³ The court also rejected the McConnells' argument of substantial compliance, reiterating the long-standing principle "that negligence will not be presumed or inferred from the mere fact of an accident or injury."¹⁶⁴ The requisite notice to a political subdivision must include not only the fact that an accident has occurred, but also notice that the accident victim intends to assert a tort claim.¹⁶⁵

In *Doe v. Methodist Hospital*,¹⁶⁶ the Indiana Supreme Court declined to recognize a distinct tort for the public disclosure of private facts or allow such a claim to form the basis of a civil action in Indiana.¹⁶⁷ Mr. Doe was a letter carrier for the United States Postal Service. In early 1990, he was rushed from his workplace to a local hospital via ambulance due to a suspected heart attack. During this transfer, Mr. Doe informed the emergency personnel that he had tested positive for the human immunodeficiency virus ("HIV"). This information was then recorded in Mr. Doe's medical records.¹⁶⁸

During Mr. Doe's hospitalization, a coworker's wife who was employed by the hospital discovered Mr. Doe's HIV-positive status and disclosed this information to her husband. The coworker then relayed this information to other coworkers, and Mr. Doe alleged that he suffered "embarrassment, humiliation and mental distress" as a result.¹⁶⁹

The trial court granted defendant's motion for summary judgment. The plaintiff appealed and the court of appeals affirmed.¹⁷⁰ The Supreme Court thereafter granted plaintiff's petition for transfer. Chief Justice Shepard wrote a lengthy history regarding the invasion of privacy tort and its evolution, which is now codified in the Restatement (Second) of Torts.¹⁷¹ Under the Restatement view, there is a complex of four distinct injuries resulting from the invasion of privacy: (1) intrusion upon seclusion, (2) appropriation of likeness, (3) public disclosure of private facts, and (4) false-light publicity.¹⁷² The court clarified that, although it has generally recognized breach of privacy as an actionable offense, it has never specifically addressed whether the public disclosure of private facts will be a sufficient basis for such an action in Indiana.¹⁷³

In its analysis, the court held that the truth-in-libel provision of the Indiana Constitution suggests "a very strong policy" against the imposition of civil

163. *Id.* at 868.

164. *Id.* at 869.

165. *See id.*

166. 690 N.E.2d 681 (Ind. 1997).

167. *Id.* at 682.

168. *See id.* at 683.

169. *Id.*

170. *See id.* at 684.

171. *Id.*

172. *Id.* (quoting RESTATEMENT (SECOND) OF TORTS § 652a (1965)).

173. *Id.* at 685.

liability based upon the dissemination of truthful information.¹⁷⁴ Additionally, Chief Justice Shepard reasoned that Indiana law already provides a remedy for the intentional infliction of emotional distress (“outrage”) and that emotional injuries sustained by reason of the public disclosure of private facts should not be treated differently from other emotional injuries.¹⁷⁵

Chief Justice Shepard applied the Restatement’s disclosure analysis.¹⁷⁶ Under this analysis, a person is subject to liability for public disclosure of private facts if he or she: “(1) gives ‘publicity,’ (2) to a matter that (a) concerns the ‘private life’ of another; (b) would be ‘highly offensive’ to a reasonable person; and (c) is not of legitimate public concern.”¹⁷⁷ The court determined that the coworker’s disclosures to a small group of people did not constitute “publicity” as required under the analysis, stating that “[t]he Restatement explicitly observes that communication to a single person or even a small group of persons is not actionable.”¹⁷⁸ Instead, “publicity” requires either the communication of the private information to “the public at large, or to so many persons that the matter must be regarded as substantially certain to become one of public knowledge.”¹⁷⁹

In *Ley v. Blose*,¹⁸⁰ the Indiana Court of Appeals held that medical records maintained by hospitals regarding a defendant physician’s alcoholism were not protected from discovery in a medical malpractice action.¹⁸¹ Between 1980 and 1993, Mr. Blose sought and received medical treatment from Dr. Ley for various urological problems and conditions. The plaintiff subsequently filed his complaint against Dr. Ley alleging that, as a result of the defendant physician’s negligence, he was denied the benefit of early diagnosis and prompt intervention of a cancerous condition. Both prior and subsequent to the events in dispute, Dr. Ley received treatment for alcoholism and depression. Moreover, in 1995, Dr. Ley surrendered his license to practice medicine.¹⁸²

174. *Id.* at 687. The Indiana Bill of Rights contains the following provision: “In all prosecutions for libel, the truth of the matters alleged to be libelous may be given in justification.” *Id.* (quoting IND. CONST. art. I, § 10).

175. “To establish liability for outrage, a plaintiff must prove that a defendant (1) engaged in ‘extreme and outrageous’ conduct that (2) intentionally or recklessly (3) caused (4) severe emotional distress.” *Id.* at 691 (quoting RESTATEMENT (SECOND) OF TORTS §§ 46 (1965)).

176. *Id.* at 692.

177. *Id.* (quoting RESTATEMENT (SECOND) OF TORTS § 652D & cmt.a (1965)).

178. *Id.*

179. *Id.* In a concurring opinion, Justice Dickson criticized the majority for raising the constitutionality issue sua sponte and stated that Indiana courts have long recognized the tort of public disclosure of private facts in the past, and thus disagreed with the plurality’s conclusion that the Indiana Constitution presents a considerable obstacle to the recognition of this tort. However, Justice Dickson agreed that the facts of this case did not establish the requisite “publicity” element of the tort, and thus believed that the transfer should have been denied or the decision of the court of appeals summarily affirmed. *Id.* at 693-95 (Dickson, J., dissenting).

180. 698 N.E.2d 381 (Ind. Ct. App. 1998).

181. *Id.* at 384-85.

182. *See id.* at 382.

During the course of the litigation, Mr. Blöse's attorney obtained an order from the trial court directing certain third-party health care providers to release medical records relating to Dr. Ley's treatment for alcohol abuse.¹⁸³ Dr. Ley presented an interlocutory appeal, challenging the trial court's order requiring disclosure.

Dr. Ley further contended that his treatment records were protected from disclosure pursuant to the physician-patient privilege as codified in section 34-1-14-5(3) of the Indiana Code.¹⁸⁴ The court confirmed that the Indiana physician-patient privilege normally extends solely to physicians and does not apply to hospitals and other health care facilities, and thus affirmed the trial court's order requiring the disclosure of patient records by various institutional health care providers.¹⁸⁵ However, the court went on to reverse the trial court's decision requiring the disclosure of medical records by the defendant's treating physician, reasoning that "[u]nlike a personal injury plaintiff, Ley did not voluntarily place his physical or mental condition at issue."¹⁸⁶ Furthermore, the defendant physician neither asserted alcoholism as an affirmative defense nor disclosed any specific details about his communications with his treating physician; but instead, he affirmatively opposed disclosure of the medical records. Accordingly, the court concluded that Dr. Ley had not waived his patient-physician privilege, and thus, disclosure of the treating physician's records was prohibited.¹⁸⁷

Finally, Dr. Ley claimed that certain health care facilities treated him for both alcoholism and depression; thus, he argued, the medical records regarding his treatment at such facilities should be protected as "mental health records."¹⁸⁸ The court agreed that the medical records from these facilities were privileged "to the extent that they pertain[ed to the defendant's] depression," but were not privileged "to the extent that they relat[ed to the diagnosis and treatment of the defendant's] alcoholism."¹⁸⁹

In *Sanders v. State Family and Social Services Administration*,¹⁹⁰ the Indiana Court of Appeals determined that an applicant for Medicaid assistance must meet the eligibility standards for supplemental security income ("SSI") benefits before she is allowed to "spend-down" her resources to become eligible for Medicaid

183. *See id.*

184. *See id.* at 383. Indiana Code section 34-1-14-5(3) provides that physicians are not competent witnesses "as to matters communicated to them, as such, by patients, in the course of their professional business, or advice given in such cases." *Id.* (citing IND. CODE § 34-1-14-5(3) (recodified at IND. CODE § 34-46-3-1 (1998))).

185. *Id.*

186. *Id.* at 384.

187. *Id.*

188. *See id.*

189. *Id.* "[I]f the portions of the records pertaining to depression are not facially distinguishable from the portions regarding alcoholism, the records may not be disclosed." *Id.* at 384 n.3.

190. 696 N.E.2d 69 (Ind. Ct. App. 1998).

benefits.¹⁹¹ Ms. Sanders filed an application for Medicaid benefits with the Wabash County Department of Family and Children requesting Medicaid coverage from August 1995. After examining Ms. Sanders' resources and income, the Family and Social Services Administration ("FSSA") concluded that her resources exceeded the Medicaid eligibility limits. The FSSA further determined that Ms. Sanders did not meet the eligibility requirements for the SSI program and, therefore, could not use the "spend-down" provision to apply her incurred medical expenses to offset her excess resources. Consequently, the FSSA denied Ms. Sanders' application for Medicaid for the reason that her resources exceeded the allowable Medicaid resource limit.¹⁹² Ms. Sanders contended the FSSA's requirement that she first meet SSI eligibility standards before "spending down" her excess income as permitted under Indiana's Medicaid Regulations was unreasonable, arbitrary and capricious, and not otherwise in accordance with federal and Indiana law.

To qualify for Medicaid in Indiana, an applicant must meet both an income eligibility test and a resource eligibility test. Under certain circumstances, an applicant may be allowed to "apply his incurred medical expenses as a setoff against his excess resources for the relevant period. . . . However, 'Indiana did not intend to extend Medicaid eligibility to those who would not even qualify for benefits under SSI's more liberal requirements, because it did not endorse the more restrictive eligibility requirements by opting for 209(b).'"¹⁹³ Consequently, the resource spend-down component enabling eligibility for Medicaid "applies only after [the less restrictive] SSI eligibility requirements have been met."¹⁹⁴ The court thus concluded that because Ms. Sanders did not meet the eligibility criteria for SSI benefits, FSSA properly determined that she was not entitled to apply her incurred medical expenses as a setoff against her excess resources in order to become eligible for Medicaid assistance.¹⁹⁵

In *State Family & Social Services Administration v. Thrush*,¹⁹⁶ the Indiana Court of Appeals considered whether the "first day of the month" rule for calculating a Medicaid applicant's resources is arbitrary and capricious in situations where the applicant's unliquidated assets have already been applied to offset the applicant's unpaid medical bills in prior months.¹⁹⁷ Mrs. Thrush was hospitalized for approximately five months before her death. As a result of this hospitalization, her husband filed an application seeking Medicaid assistance for the payment of her medical bills which exceeded \$180,000. Mr. Thrush was advised that his assets exceeded the Medicaid eligibility limits and thus, he was required to "spend down" his excess resources in order to qualify for Medicaid

191. *Id.* at 72.

192. *See id.* at 70.

193. *Id.* at 71 (quoting *Department of Pub. Welfare v. Payne*, 622 N.E.2d 461, 463 n.1, 468 (Ind. 1993)).

194. *Id.* at 71-72.

195. *Id.* at 72.

196. 690 N.E.2d 769 (Ind. Ct. App. 1998).

197. *Id.* at 770.

assistance. Mr. Thrush acknowledged that his assets exceeded the eligibility limit; however, he disputed the county's calculation of his required spend-down amounts.¹⁹⁸

Mr. Thrush appealed the county's decision to an administrative law judge ("ALJ") and, following an evidentiary hearing, the ALJ affirmed the agency's decision, which was later adopted by FSSA. Mr. Thrush filed a petition for judicial review, whereupon the trial court affirmed FSSA's determination with regard to one month but concluded that FSSA erred in its calculation of the spend-down amount for three subsequent months and remanded the matter for further proceedings. The FSSA appealed.¹⁹⁹

Medicaid applicants must meet both an income eligibility test and a resources eligibility test. In Indiana, an applicant's financial resources are evaluated on the first day of each month for which Medicaid assistance is sought.²⁰⁰ "If the applicant's financial resources exceed the eligibility limit on the first day of the month, then the applicant is not eligible for that month."²⁰¹ However, an applicant whose financial resources exceed the eligibility limit on the first day of the month may still qualify for Medicaid assistance by "spending down" or off-setting his excess resources against incurred but unpaid medical bills.²⁰²

The Indiana Court of Appeals clarified that the purpose of the spend-down provision is to encourage Medicaid applicants to use available resources to pay their outstanding medical obligations. Medicaid is not responsible for the portion of an applicant's medical expenses that the applicant could have paid through his own income and resources had he chosen to do so. Accordingly, the court concluded that the first day of the month rule is consistent with the underlying purposes of the Medicaid program and is not inherently unreasonable, nor was the rule applied to *Thrush* in a manner that was arbitrary, capricious, an abuse of discretion, or otherwise contrary to law.²⁰³

In *Board of Trustees of Knox County Hospital v. Shalala*,²⁰⁴ the Seventh Circuit upheld the Health and Human Services ("HHS") policy of relying exclusively on the agency's own published data to determine the case mix index ("CMI") of a provider seeking to qualify as a rural referral center ("RRC").²⁰⁵ Good Samaritan Hospital is a 342-bed acute care facility which offers many services comparable to major urban hospitals and therefore sought to be

198. *See id.* at 771.

199. *See id.*

200. *See id.* at 772. "[T]he 'first day of the month' rule . . . which provides in relevant part: (a) [a]n applicant or recipient is ineligible for medical assistance for any month in which the total equity value of all nonexempt personal property exceeds the applicable limitation set forth below, on the first day of the month . . ." *Id.* *See* IND. CODE § 12-15-2-1 (1998).

201. *Thrush*, 690 N.E.2d at 772 (citing *Glaser v. Department of Pub. Welfare*, 512 N.E.2d 1128, 1132 (Ind. Ct. App. 1987)).

202. *See id.* (citing *Department of Pub. Welfare v. Payne*, 622 N.E.2d 461 (Ind. 1993)).

203. *Id.*

204. 135 F.3d 493 (7th Cir. 1998).

205. *Id.*

designated as a RRC beginning in the 1985 fiscal year for services rendered to Medicare beneficiaries, the Board of Trustees of Knox County Hospital d/b/a Good Samaritan Hospital ("Good Samaritan"). Under such a designation, the hospital would be entitled to reimbursement at the higher payment rate for urban areas despite its rural location.²⁰⁶ It is undisputed that Good Samaritan met three of the four requirements required for RRC statutes provided at 42 CFR sections 405 and 476(a)(1)(iii). However, the parties dispute whether Good Samaritan satisfied the remaining requirement based upon the hospital's 1981 CMI.²⁰⁷

Specifically, a provider is eligible for RRC status if its 1981 CMI equals or exceeds 1.1053.²⁰⁸ The Secretary of HHS (the "Secretary") had calculated Good Samaritan's 1981 CMI based upon CMI's own statistical file that consisted of information concerning only twenty percent of Good Samaritan's 1981 Medicare discharges. Good Samaritan had retained a nationally-recognized consulting firm, the Commission of Professional Hospital Activities ("CPHA"), to recalculate its 1981 CMI. CPHA's recalculation, based upon a study of one hundred percent of Good Samaritan's 1981 Medicare discharges, determined that the provider's 1981 CMI was actually 1.0637. Good Samaritan appealed the agency's decision to the Provider Reimbursement Review Board ("PRRB"), which ruled that the hospital had satisfied the eligibility criteria to qualify for RRC status.²⁰⁹ The Secretary, acting through the administrator of HCFA, thereafter reversed the PRRB's decision and Good Samaritan then appealed the Secretary's decision to the U.S. District Court. The court entered summary judgment in favor of the Secretary, holding that the Secretary "did not act in a manner which was arbitrary and capricious, an abuse of discretion, or contrary to law when she determined that Good Samaritan's CMI did not satisfy the regulatory requirement."²¹⁰ This appeal ensued.

Good Samaritan contended that the Secretary's interpretation of the RRC statute is inconsistent with its statutory language and basic purpose because the RRC statute grants a health care provider the right to challenge the Secretary's CMI calculation. The hospital thus argued that the Secretary's refusal to allow the substitution of CPHA data in lieu of its own published 1981 case mix index is arbitrary, capricious, and contrary to law. The Seventh Circuit agreed that the

206. *See id.* at 496-97.

207. There are actually three alternate sets of criteria under which a provider could qualify as a RRC. Good Samaritan sought eligibility based upon the third test, which requires that the provider be located in a rural area, meet or exceed certain mandatory discharge criteria, and satisfy certain criteria pertaining to the composition of the hospital's medical staff and inpatient population. Additionally, the hospital is required to satisfy any one of four CMI criteria; one of which provides that "a hospital is eligible for RRC status if its 1981 CMI was equal to or exceeded 1.03." Good Samaritan argued that it met all criteria as set forth in the aforesaid test. *See id.* at 496 (citing 42 C.F.R. § 405.476(g)(1)(iii)(A)(1),(2),(3) &(4)).

208. *See id.*

209. *See id.*

210. *Id.* at 408 (quoting *Board of Trustees of Knox County Hosp. v. Shalala*, 959 F. Supp. 1026, 1028 (S.D. Ind. 1997)).

Secretary has a substantial interest in using her own published calculations of a provider's 1981 CMI as a basis for determining eligibility for RRC status; and concluded that the Secretary's policy was not arbitrary and capricious.²¹¹

B. Statutory Developments

1. *Creation of Children's Health Insurance Program ("CHIP").*—Effective September 1, 1998, the Indiana General Assembly authorized a new program for health insurance coverage for children meeting certain family income eligibility standards. Senate Enrolled Act 19,²¹² which established an Indiana program in accordance with provisions of the federal Balanced Budget Act of 1997,²¹³ enables the state to use up to \$70 million in federal funds with approximately \$26 million in state funds,²¹⁴ to provide health insurance coverage for children whose family's income does not exceed one hundred and fifty percent of federal poverty standards.²¹⁵ An expansion of eligibility in the existing Indiana Medicaid Program provides such coverage. The statute also requires the Office of Medicaid Planning and Policy ("OMPP") to expend the maximum amount of authorized federally provided funds in outreach activities designed to inform and enroll eligible beneficiaries.²¹⁶ Family and Social Services Administration ("FSSA") is required to develop and implement a presumptive eligibility program consistent with federal guidelines for CHIP programs.²¹⁷ Presumptive eligibility allows a child or pregnant woman to begin to receive services based on an analysis of preliminary information that indicates eligibility prior to formal determination of eligibility.²¹⁸ To ensure reasonable access to enrollment and services, a disproportionate share provider, a federally qualified health center, or a rural clinic are acceptable entities to determine presumptive eligibility.²¹⁹ Effective July 1, 1999, an Office of the Children's Health Insurance Program within the Office of the Secretary of FSSA will oversee the provision of health services for eligible children.²²⁰

The act also provides twelve months of continuous Medicaid coverage to all Medicaid-eligible children on September 1, 1998 regardless of whether the child's family's income exceeds one hundred and fifty percent of the federal poverty level during the succeeding twelve month period.²²¹ This provision will allow beneficiaries to receive appropriate continuity of care irrespective of

211. *Id.* at 499-500.

212. S. 19, 110th Legis., 2d Sess. (Ind. 1998).

213. 42 U.S.C. § 1396d(u) (1994 & Supp. II 1996).

214. *See id.*

215. *See* IND. CODE § 12-15-2-15.6(a)(1) (1998).

216. *Id.* § 12-15-1-18.

217. *See id.* § 12-15-2.2-1.

218. *See id.*

219. *See id.*

220. *See id.* § 12-17-18-1.

221. *Id.* § 12-15-2-15.7(a).

fluctuations in income. Senate Enrolled Act 19, in creating the Indiana CHIP program, is a significant program for identifying and providing health care services to children.

2. *Changes in Indiana Medicaid Disproportionate Share ("DSH") Hospital Payment Program.*—House Enrolled Act 1349 ("Act 1349")²²² substantially restructures the Indiana Medicaid DSH Program and creates additional programs allowing increased Medicaid payments to eligible municipal hospitals, government-owned hospitals that have "Medicaid shortfalls,"²²³ and community mental health centers.²²⁴ Further, the Act modifies the existing Hospital Care for the Indigent Program ("HCI") by permitting increased Medicaid payments to hospitals located in counties whose county HCI tax levies paid to the state exceed payments made to providers of HCI services within the county.

The basic DSH program is continued and Act 1349 allows a hospital to obtain Medicaid basic DSH payments if the hospital's Medicaid inpatient utilization rate is at least one standard deviation above the mean Medicaid inpatient utilization rate for all Indiana hospitals, or if a hospital's low-income utilization rate exceeds twenty-five percent of total utilization.²²⁵ Payment to eligible basic DSH hospitals is based on a formula involving calculation of Medicaid day utilization, discharge rates, and total patient days based on the type of eligible hospital and on information from the most recent year for which audited data is available.²²⁶

The enhanced DSH program is extended in Act 1349 and eligibility is modified.²²⁷ This program is dependent upon intergovernmental transfers of money from certain government-owned hospitals to the state, which allows the state through the OMPP to obtain a federal match for the funds if expended as Medicaid payments.²²⁸ The program permits additional hospitals to receive enhanced DSH payments in state fiscal year 1998 and thereafter based on annual updates of Medicaid inpatient utilization rates and low-income utilization rates.²²⁹ Payments to eligible hospitals will be based upon a formula that limits total payments to the sum of a hospital's total expenditure for charity care and Medicaid shortfall.

Municipal hospitals are now specifically eligible to participate in a new DSH program if the hospital meets a minimum standard of Medicaid utilization²³⁰ and voluntarily makes an intergovernmental transfer of money to the state, allowing OMPP to obtain a federal match of the funds if expended as Medicaid

222. H. 1349, 110th Legis., 2d Sess. (Ind. 1998).

223. IND. CODE §12-15-18-5.1 (1998).

224. *Id.* § 12-15-19-9.

225. *Id.* § 12-15-16-1(a).

226. *See id.* §§ 12-15-16-1(f), 2.

227. *Id.* § 12-15-19-1.

228. *See id.* § 12-15-19-8.

229. *See id.* §12-15-18-5.1(a).

230. *See id.* § 12-15-19-8.

payments.²³¹ Participating hospitals will receive additional Medicaid payments equaling amounts transferred to the state plus an additional amount to partially offset charity care expenditures of the hospital. OMPP will retain part of the money obtained from the federal match and will transfer the remainder to the Medicaid indigent care trust fund to be paid out to basic and enhanced DSH eligible hospitals.²³²

Act 1349 states that, effective state fiscal year 1998, government-owned hospitals that have Medicaid shortfalls, which is the difference between its Medicaid payments and its Medicare upper payment limit, may receive additional Medicaid payments if the hospital voluntarily makes an intergovernmental transfer of money to the state.²³³ This allows OMPP to obtain a federal match of the funds if expended as Medicaid payments.²³⁴ Participating hospitals will receive additional Medicaid payments equaling amounts transferred to the state plus an additional amount to partially offset the hospital's Medicaid shortfall. OMPP will retain part of the money obtained from the federal match and transfer the remainder to the Medicaid indigent care trust fund to be paid out to basic and enhanced DSH eligible hospitals.²³⁵

Act 1349 also established a program authorizing additional Medicaid payments for eligible community mental health centers ("CMHC").²³⁶ To be eligible, a CMHC must own and operate an inpatient care unit, must receive payments from a political subdivision, and have a Medicaid inpatient utilization rate of at least one percent during the most recent state fiscal year.²³⁷ In counties with CMHCs meeting the eligibility requirements, the county treasurer must certify that funds were paid to the eligible CMHC.²³⁸ The certification then serves as the equivalent of the state's share of a Medicaid payment, which permits a federal match of the certified amounts.²³⁹ OMPP, upon receipt of the federal match, will make an additional Medicaid payment to the eligible CMHC equal to the federal match.²⁴⁰

3. *Managed Care Consumer Protection.*—In response to constituent complaints and consumer activism, the legislature enacted Senate Enrolled Act 364 ("Act 364").²⁴¹ Act 364 requires health maintenance organizations ("HMO"s) to make annual reports to the Indiana Department of Insurance specifying the number of providers credentialed by the HMO that meet current standards of the National Committee on Quality Assurance and providing

231. *See id.* § 12-15-15-1.1.

232. *See id.* § 12-15-19-8.

233. *Id.* § 12-15-18-5.1.

234. *See id.*

235. *See id.* § 12-15-15-1.1.

236. *Id.* § 12-15-18-5.1.

237. *See id.* § 12-15-16-1(d).

238. *See id.* § 12-15-18-5.1(e).

239. *See id.*

240. *See id.* § 12-29-1-7.

241. S. 364, 110th Legis., 2d Sess. (Ind. 1998).

information on the HMO's Health Plan Employer Data and Information Set.²⁴² It also requires HMOs to provide coverage and payment for services provided in hospital emergency rooms, irrespective of prior authorization or an existing contractual relationship between the HMO and provider if a prudent lay person could reasonably believe the enrolled patient's condition required immediate medical attention.²⁴³ HMOs must pay for these services at the usual, customary and reasonable charge for the same services in the HMO's service area or an amount agreed to between the HMO and provider.²⁴⁴ HMOs are also required to appoint medical directors who are licensed physicians²⁴⁵ and to stipulate in contracts with providers that if the contract is terminated for reasons other than inadequate quality, the provider must continue to care for assigned enrollees up to sixty days following termination of the contract.²⁴⁶ Act 364 further requires that the HMO have sufficient providers to meet enrollee needs and afford a choice of providers.²⁴⁷ In addition, HMOs must also maintain telephone access during business hours for routine care and twenty-four hour access for required prior authorization of care.²⁴⁸ Enrollees are entitled to reasonable access to appointment schedules in accord with HMO guidelines.²⁴⁹

If an HMO enrollee requires a covered service not available through the HMO's existing providers, the HMO must refer the enrollee to another provider and pay for the services rendered.²⁵⁰ An HMO must offer another choice of provider,²⁵¹ point-of-service option to purchasers,²⁵² and second opinion option for enrollees.²⁵³ Any HMO formulary for drugs and Medicaid devices must be developed by a committee composed of a majority of licensed physicians, must be disseminated to participating providers and pharmacists, and must provide for an expeditious process for enrollees to obtain non-formulary drugs.²⁵⁴ Every HMO must also establish and maintain a drug utilization review program.²⁵⁵ HMOs are required to develop and implement procedures to evaluate provision of coverage to an enrollee for new technologies, treatments, procedures, drugs, and devices.²⁵⁶

242. IND. CODE § 27-13-8-2(a)(4), (5) (effective Jan. 1, 2000).

243. *Id.* § 27-13-36-9(c) (1998).

244. *See id.* § 27-13-36-9(d).

245. *See id.* § 27-13-36-1(a).

246. *See id.* § 27-13-36-6.

247. *Id.* § 27-13-36-2.

248. *See id.* § 27-13-36-7.

249. *See id.* § 27-13-36-8.

250. *See id.* § 27-13-36-5.

251. *See id.* § 27-13-37-2.

252. *See id.* § 27-13-37-4.

253. *See id.* § 27-13-37-5.

254. *See id.* § 27-13-38-1.

255. *See id.* § 27-13-38-3.

256. *See id.* § 27-13-39-1(a).

4. *Newborn HIV Testing.*—Senate Enrolled Act 261²⁵⁷ permits a physician to order a confidential newborn HIV test if a mother of a newborn has not had the test, the mother refuses to consent to the test, and the physician reasonably believes the test is medically necessary.²⁵⁸ If a physician orders a test, the mother must be notified and provided with appropriate medical information and counseling.²⁵⁹ Results of an HIV test on a newborn must be provided to the mother.²⁶⁰ If a parent of the newborn objects in writing to an HIV test on his or her newborn and the objections are based on religious beliefs, the newborn is not required to have the test.²⁶¹

5. *Payments to Mental Health Providers.*—The Division of Mental Health (“DMH”) of the Indiana Family and Social Services Administration (“FSSA”) is authorized by Senate Enrolled Act 461 (“Act 461”)²⁶² to develop per diem or prospective payment mechanisms for community mental health centers (“CMHC”) for some eligible mentally ill and substance abuse patients.²⁶³ Act 461 requires DMH to continue implementation of a specific payment program for CMHCs for the care of seriously mentally ill adults.²⁶⁴ In developing payment programs, DMH is required to use actuarial principles and generally accepted accounting principles in determining appropriate payment based on efficiently and effectively operated treatment programs for mental health patients.²⁶⁵

6. *The Indiana Medical Malpractice Act.*—The 1998 legislative session saw substantial changes to the Indiana Medical Malpractice Act. On March 16, 1998, after unanimously passing in both the House and the Senate, Senate Enrolled Act 390 (“Act 390”)²⁶⁶ was signed into law. Act 390 amended the minimum insurance requirements for health care providers and changed the way in which the health care provider surcharge is calculated. After July 1, 1999, health care providers must have a per occurrence insurance policy which insures to at least \$250,000.²⁶⁷ Similarly, annual aggregates for hospitals and other health care providers will increase and range from \$750,000 and \$7.5 million.²⁶⁸

Act 390 also amended the way in which a provider’s surcharge is calculated. Prior to the passage of Act 390, the annual surcharge that insured hospitals paid into the Patient Compensation Fund (“PCF”) could not exceed two hundred

257. S. 261, 100th Legis., 2d Sess. (Ind. 1998).

258. IND. CODE § 16-41-6-4(a).

259. *See id.* § 16-41-6-4(b).

260. *See id.* § 16-41-6-4(d).

261. *See id.* § 16-41-6-4(e).

262. S. 461 Legis., 2d Sess. (Ind. 1998).

263. IND. CODE § 12-21-2-7.

264. *Id.*

265. *See id.*

266. S. 390, 110th Legis., 2d Sess. (Ind. 1998).

267. *See id.* This is a change from a per-occurrence amount of at least \$100,000. *See* IND. CODE § 34-18-4-1.

268. *See* IND. CODE § 34-18-4-1. This is an increase from \$300,000 for other providers to up to \$3 million for hospitals with greater than 100 beds.

percent of its insurance premium.²⁶⁹ Self-insured hospitals were required to pay an amount equal to one hundred and fifty percent of the premium that would have been charged to the provider by the Residual Malpractice Insurance Authority.²⁷⁰

After July 1, 1999, the surcharge for hospitals will be determined by taking information generated by the hospital and feeding that information into an actuarial program created by the Indiana Department of Insurance, which will determine the actuarial risk posed to the patient compensation fund by a hospital.²⁷¹ The program must take into consideration risk management programs used by the hospital, be an efficient and accurate means of calculating a hospital's actuarial risk, be publicly identified by the Indiana Department of Insurance by July 1 of each year, and be made available to the hospital's malpractice carrier to calculate the hospital's surcharge.²⁷²

A new surcharge formula was also created for physicians, which de-couples the surcharge payment from the insurance premium. Now, each year the insurance commissioner must contract with an actuary to determine the risk physicians pose to the PCF.²⁷³ The actuary will calculate the average of the three leading malpractice insurers' actual rates for all physicians practicing in the same specialty class or discipline. Using that information, the actuary will establish a uniform charge for all physicians practicing in the same specialty.²⁷⁴ Other providers will be assessed an annual surcharge of one hundred percent of its insurance premium.²⁷⁵

In addition, the legislature passed House Enrolled Act 1011 ("Act 1101"),²⁷⁶ which repealed Indiana Code section 27-12 and re-enacted the Malpractice Act as Indiana Code section 34-18.²⁷⁷ The re-enactment brought several changes to Act 1011. What follows is not an exhaustive list of the changes made to the Act, but represents several of the more substantive changes. After July 1, 1999, an insurance policy issued in Indiana must contain a provision that authorizes an insurer to settle a case without the consent of the insured after a medical review panel has issued a unanimous decision finding that the provider deviated from the applicable standard of care.²⁷⁸ Nothing requires that the medical review panel also find against the healthcare provider on the issues of causation and injury.²⁷⁹

The Malpractice Act added Indiana Code section 34-18-8-8, which allows a

269. *See id.* § 27-12-5-2 (Supp. 1997) (amended 1998).

270. *See id.* § 27-12-5-4 (Supp. 1997) (amended 1998).

271. *See id.* § 34-18-5-2(c) (1998) (effective July 1, 1999).

272. *See id.* § 34-18-5-2(a)(1-4) (1998).

273. *See id.* § 34-18-5-2(f)(1). Under prior Indiana law, the amount of the surcharge paid by a physician was calculated at 150% of the premium paid under the physician's insurance policy.

274. *See id.*

275. *See id.* § 34-18-5-2(b).

276. H. 1011, 110th Legis., 2d Sess. (Ind. 1998).

277. IND. CODE §§ 34-18-1-1 to -18-18-2 (1998).

278. *See id.* § 27-1-13-7(b). Before July 1, 1999, an insurance contract could specify that a physician's consent was required prior to settling a malpractice claim. *Id.*

279. *See id.*

malpractice case filed before the Indiana Department of Insurance to be dismissed if there has been no action taken on the claim for two years or more.²⁸⁰ The proper forum for filing a dismissal action is the Marion Circuit Court.²⁸¹ In addition, after July 1, 1999, plaintiffs may initiate their malpractice claims both with Indiana Department of Insurance and in state court.²⁸² However, the state court action may not name the defendants, nor may the action be pursued until after a decision has been issued by a medical review panel.²⁸³ The purpose for this addition was simply to hold the plaintiff's place in line on the court docket.

One significant change in the 1998 amendments to the Malpractice Act includes the addition of a provision which requires medical review panels to issue a separate determination as to whether the health care provider in question should undergo a "fitness to practice" review by the appropriate licensing board.²⁸⁴ If a panel unanimously determines that the provider should undergo a fitness review, the Commissioner of the Department of Insurance must forward that provider's name to the appropriate licensing agency.²⁸⁵ However, the panel's determination on the fitness to practice issue is not admissible as evidence in a civil action.²⁸⁶

Finally, for acts of malpractice that occur prior to July 1, 1999, an injured party is allowed access to the PCF until the provider (or providers) involved have paid a settlement of at least \$75,000.²⁸⁷ For claims arising after June 30, 1999, this amount has been increased to \$187,000.²⁸⁸ This amendment may see more defendants named in the initial Proposed Complaint to increase the number of providers who could contribute to the potential settlement.

CONCLUSION

Practitioners in the area of health care law must continue to focus on the increased scrutiny by government agencies regarding compliance with the Anti-Kickback Statute, Stark II and other laws. These effects, along with increased pressures to attend to the needs of health care patients in an efficient manner while maintaining quality, will continue to present challenges to those practitioners advising health care clients.

280. *Id.* § 34-18-8-8. Prior to the addition of this statutory section, there was no provision allowing for the dismissal of a case where there had been no action taken.

281. *See id.*

282. *See id.* § 34-18-8-7.

283. *See id.* The provision does, however, allow a court to set a case for trial prior to the completion of the medical review panel process. *Id.*

284. *Id.* § 34-18-9-4. Prior to this amendment, the Commissioner of Insurance was required to forward a provider's name to the licensing board only when there was a settlement or judgment rendered against the provider.

285. *See id.*

286. *See id.*

287. *See id.* § 34-18-14-4.

288. *See id.*

