

SURVEY OF RECENT DEVELOPMENTS IN HEALTH CARE LAW

JOHN C. RENDER*
STEVEN H. PRATT**

Health care in Indiana, as in the rest of the United States, is governed by an evolving and changing body of law, both state and federal, covering a vast number of topics. The 2004 survey article discusses disciplines ranging from Privacy and Security, Labor and Employment, and Fraud, demonstrating the complexities of the practice of health law today.

I. GENERAL HEALTH LAW

There have been several interesting cases impacting health law providers decided in 2004 by the Indiana Court of Appeals. These cases dealt with (a) what constitutes an “occurrence” under Indiana’s Medical Malpractice Statute; (b) whether an arbitration provision contained in a nursing home admission contract was valid and enforceable; and (c) what is required to show a person is suffering from a “grave disability” which would allow the courts to have a person involuntarily committed to a mental health facility.

A. Medical Assurance of Indiana v. McCarty

The Indiana Court of Appeals dealt with the issue of what constitutes an “occurrence of malpractice.” The issue before the court was whether Medical Assurance of Indiana (“MAI”), an insurance company, would be required to pay the statutory maximum for each of two acts of malpractice committed by Dr. Patel during one surgery.¹ Mary Barker had been diagnosed with a malignancy in her colon and had been referred to Dr. Patel for surgery. After the surgery it was found that Barker’s colon was leaking into her abdominal cavity. Dr. Patel performed a second surgery.² Barker continued to experience problems. Two surgeons performed a third operation on Barker to remove the hemoclip left on her ureter and to reverse the colonostomy.³

Barker filed suit for medical malpractice against Dr. Patel.⁴ At trial, Barker was successful in convincing a jury that Dr. Patel breached the standard of care in two ways.⁵ First, he breached the standard of care by suturing the colon in

* Partner, Hall, Render, Killian, Heath & Lyman, P.S.C., B.S., 1966, Butler University; J.D., 1971, Indiana University School of Law—Indianapolis.

** Partner, Hall, Render, Killian, Heath & Lyman, P.S.C., B.A., 1980, DePauw University; J.D., 1983, Indiana University School of Law—Indianapolis. The authors wish to thank Regan E. Tankersley, Karen D. Bolton, Juli K. Shields, Charise R. Frazier, Brian C. Betner, Dana E. Stutzman, Susan D. Bizzell, Gregg M. Wallander, James R. Willey, and Charles (Chad) P. Sukurs.

1. *Med. Assurance of Ind. v. McCarty*, 808 N.E.2d 737, 739 (Ind. Ct. App. 2004).

2. *Id.*

3. *Id.*

4. *Id.*

5. *Id.*

such a way that it leaked, and second by leaving a hemoclip on her ureter.⁶ Barker was awarded \$1.8 million, however, that amount was reduced by the trial court to the amount of \$1.5 million, in order to comply with the statutory maximum proscribed by the Indiana Medical Malpractice Act (“Act”).⁷ The Act allows for \$750,000 per act of malpractice.⁸ In the first appeal the court of appeals upheld the trial court’s finding that Barker was entitled to recover for each “act” of malpractice committed by Dr. Patel.⁹

After the Indiana Supreme Court denied transfer from the initial appeal in this case, MAI filed a declaratory judgment action against the Indiana Patient’s Compensation Fund.¹⁰ MAI asserted that although the court of appeals had determined that Barker was entitled to two maximum \$750,000 recoveries, the Act only required MAI to pay the health care provider \$100,000, the malpractice liability maximum in effect at the time of the surgery, rather than \$200,000.¹¹ The trial court disagreed and required MAI to pay two payments of \$100,000.¹² MAI and Dr. Patel appealed.¹³ On appeal MAI asked the court of appeals to shift the entire cost of the second act of malpractice committed by Dr. Patel to the Fund by only making MAI pay one \$100,000 payment.¹⁴ MAI further argued that the surgery Dr. Patel performed was a single “occurrence of malpractice,” regardless of the number of injuries inflicted and negligent acts committed during the surgery.¹⁵

The Indiana Court of Appeals began its review of this case by analyzing the language contained in Indiana Code section 34-18-14-3, which is a portion of the Medical Malpractice Act for the State of Indiana.¹⁶ The court of appeals noted that it had just recently reviewed the Act in the case of *McCarty v. Sanders*¹⁷ and found that the Act was unambiguous.¹⁸ However, when reviewing this case, the court of appeals noted that there was an ambiguity in the statute concerning the use of the word “act” used in paragraph (a) of section 34-18-14-3 and the word “occurrence” contained in (b) of 34-18-14-3.¹⁹ The court of appeals noted that paragraph (a) of section 34-18-14-3 discusses the total amount a patient may recover from all sources for an injury or death and refers to the amount recoverable for “an act of malpractice.”²⁰ Paragraph (b) of section 34-18-14-3,

6. *Id.*

7. *Id.*

8. *Id.* at 740.

9. *Id.*

10. *Id.*

11. *Id.*

12. *Id.*

13. *Id.*

14. *Id.* at 742.

15. *Id.*

16. *Id.*

17. 805 N.E.2d 894, 898 (Ind. Ct. App. 2004).

18. *Med. Assurance*, 808 N.E.2d at 742.

19. *Id.*

20. *Id.*

however, refers to the total amount for which a health care provider may be liable and refers to "an occurrence of malpractice."²¹ In examining the use of the two different words, "act" versus "occurrence," the court of appeals concluded that the legislature never would have intended that a health care provider/insurer would be allowed to shift its costs to the Fund.²² After examining fundamental tort law principles relating to injuries and the proximate cause of those injuries, the court of appeals concluded that the phrase "an occurrence of malpractice" to be the functional equivalent of "an act of malpractice" for purposes of determining a health care provider's maximum liability.²³ Further, the court noted that this interpretation was consistent with the case law addressing Indiana Code section 34-18-14-3.1.²⁴

The court then reviewed several key decisions made by the court of appeals and the Indiana Supreme Court concerning the interpretation of Indiana Code section 34-18-14-3.²⁵ The court reviewed the Indiana Supreme Court's decision in *Miller ex rel Miller v. Memorial Hospital of South Bend*.²⁶ The court also reviewed the decisions in *St. Anthony Medical Center v. Smith*,²⁷ *Bova v. Roig*,²⁸ and *McCarty v. Sanders*.²⁹

The court summarized these decisions concerning the interpretation of Indiana Code section 34-18-14-3 as follows:

Smith, Bova, Miller, Patel, and McCarty have established the following: (1) a patient who suffers only one compensable injury, regardless of the number of negligent acts causing that injury, is entitled to only one maximum statutory recovery; (2) a doctor who commits more than one negligent act in treating a patient is only liable for one maximum statutory payment if only one compensable injury results; (3) a patient who suffers two or more distinct injuries from two or more negligent acts by one or more health care providers is entitled to the maximum statutory recovery for each injury; and (4) a doctor who commits only one act of malpractice, yet causes more than one compensable injury to more than one patient, is still only liable for one maximum statutory payment.³⁰

The court noted that "the most logical extension of these holdings is that a doctor who commits two or more negligent acts in treating a patient and thereby causes two or more distinct injuries is liable for the maximum statutory payment

21. *Id.* at 743.

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.* at 744.

26. 679 N.E.2d 1329 (Ind. 1997).

27. 592 N.E.2d 732, 739 (Ind. Ct. App. 1992).

28. 604 N.E.2d 1, 3 (Ind. Ct. App. 1992).

29. 805 N.E.2d 894 (Ind. Ct. App. 2004).

30. *Med. Assurance*, 808 N.E.2d at 744.

for each compensable injury.”³¹ Each distinct act of malpractice resulting in a distinct injury is “an occurrence of malpractice” under section 34-18-14-3(b) for which a health care provider is liable up to the maximum amount.³² The court of appeals concluded that:

We can conceive of no reason in this case to divorce subsection (a), governing the total amount an injured patient may recover, from subsections (b) and (c), which divvies up how and by whom that recovery will be paid for—i.e., the first \$100,000 (now \$250,000) by the health care provider/insurer, and the remainder by the Fund. When a patient suffers a compensable injury due to malpractice, the patient and the Fund reasonably should expect the health care provider to pay his or her statutory share for each separate injury caused by separate acts of malpractice, regardless of the temporal proximity of those acts.³³

The court of appeals then gave what it considered as the definition of “occurrence”:

“[A]n occurrence of malpractice” under section 34-18-14-3(b) is the negligent act itself plus the resulting injury, with a health care provider’s liability limited to the lowest common denominator between act and injury. That is, if there is only one act but two injuries, there can only be one “occurrence” and health care provider payment; if there are two acts but only one injury, there can only be one “occurrence” and health care provider payment; if there are two distinct acts and two distinct injuries, there can be two “occurrences” and health care provider payments.³⁴

The court of appeals affirmed the trial court’s decision in this case and MAI was required to pay two \$100,000 payments on behalf of its insured Dr. Patel.

B. Sanford v. Castleton Health Care Center, LLC

A case of first impression in the State of Indiana dealt with the enforcement of an arbitration clause contained in an admission agreement to a nursing home. In this case the admission agreement was entered into by the nursing home and the patient’s daughter who had signed as legal representative on her mother’s behalf.³⁵ After several days at the nursing home the patient fell, sustained a fractured hip and subsequently died. The patient’s daughter, Stanford, became the personal representative for her mother’s estate, which filed an action for wrongful death and survival.³⁶ In response, the nursing home, Castleton Care Center, filed a motion to compel arbitration pursuant to the terms that were

31. *Id.*

32. *Id.*

33. *Id.* at 745.

34. *Id.* at 746.

35. *Sanford v. Castleton Health Care Ctr., LLC*, 813 N.E.2d 411, 414 (Ind. Ct. App. 2004).

36. *Id.*

contained in the nursing home admission agreement.³⁷ The trial court found on behalf of the nursing home and ordered that the wrongful death and survival issues would have to be arbitrated according to the terms of the nursing home admission agreement.³⁸

The estate appealed, arguing that the trial courts order was erroneous on four grounds. First, the admission contract was unenforceable as it was an unconscionable adhesion contract. Second, the Arbitration clause of the contract conflicts with the Federal Arbitration Act. Third, that the waiver of the decedent's constitutional right to a jury trial was unknowing and involuntary. In addition, the personal representative of the estate was not a party or in privity with a party to the contract.

In reviewing the Estate's four arguments the court of appeals reviewed the language contained in the admission contract which read as follows:

A. Preliminary Statements:

Patient [i.e., Bagley] individually or by and through Patient's Legal Representative (hereinafter referred to as Patient) has considered appropriate care settings and is desirous of receiving care at this Center; and Patient has reviewed this ADMISSION AND FINANCIAL CONTRACT, has had opportunity to ask questions of Center personnel about the contract and understands that admission to this Center constitutes agreement to be bound by said ADMISSION AND FINANCIAL CONTRACT . . .

* * * * *

H. Dispute Resolution Procedure:

1. INITIAL GRIEVANCE PROCEDURE: The parties agree to follow the Grievance procedure described in the patient Rights Booklet for any claims or disputes arising out of or in connection with the care rendered to patient by Center and/or its employees. Patient should know that Center is prepared to mediate any concerns at any time upon patient request . . .

2. MEDIATION: In the event there is a dispute and/or disputes arising out of or relating to (i) this contract or the breach thereof or any tort claim; or (ii) whether or not there has been a violation of any right or rights granted under state law, and the parties are unable to resolve such dispute through negotiation, then the parties agree in good faith to attempt to settle the dispute by mediation administered by Alternate Dispute Resolution Service of the American Health Lawyers Association before resorting to arbitration. . . .

3. ARBITRATION: Any disputes not settled by mediation within 60

37. *Id.* at 416.

38. *Id.*

days after a mediator is appointed shall be resolved by binding arbitration administered by the Alternate Dispute Resolution Service of the American Health Lawyers Association and judgment may be entered in any court having jurisdiction thereof. . . . A signature line, bearing Sanford's signature, appears immediately following the arbitration provision.³⁹

The court of appeals noted that Indiana has a strong policy favoring enforcement of arbitration clauses.⁴⁰ The court noted that before it could compel arbitration it must first resolve any claims relating to the validity of the contract which contained the arbitration clause. The court further noted that judicial inquiry is limited to the validity of the contract itself and not the construction of the arbitration clause.⁴¹

The court stressed that parties are only bound to arbitrate those issues that by clear language they have agreed to arbitrate, and that arbitration agreements will not be extended by construction or implication.⁴²

The court addressed each of the estate's arguments.

First, as to the issue of the contract being a contract of adhesion the court found that "[a] contract is not unenforceable merely because one party enjoys advantages over another."⁴³ The court found that there was a heading that clearly stated "ARBITRATION" and that even more compelling that directly below the arbitration section was a signature line, which bore the signature of, Sanford, the patient's legal representative.⁴⁴

The court applied Indiana contract law, noting that a person is "presumed to understand and assent to the terms of any contract that he or she signs."⁴⁵ Accordingly, the court found that because Sanford had executed the signature line that she is presumed to have read and understood its contents.

The second argument that the Estate put forth was that the admission contract conflicts with the Federal Arbitration Act⁴⁶ which discusses admission practices in the case of a nursing home. The Estate argued that the arbitration clause was "other consideration" and was therefore in violation of the Federal Arbitration Act.⁴⁷

The court, employing a doctrine of statutory construction, concluded that the general phrase "'other consideration,' when followed by a specific enumeration of the terms gift, money, or donation, does not encompass an arbitration

39. *Id.* at 415 (alterations in original).

40. *Id.* at 416.

41. *Id.*

42. *Id.*

43. *Id.* at 417 (citing *Dan Purvis Drugs, Inc. v. Aetna Life Ins. Co.*, 412 N.E.2d 129, 131 (Ind. Ct. App. 1980)).

44. *Id.* at 417-18.

45. *Id.* at 418 (citing *Buschman v. ADS Corp.*, 782 N.E.2d. 423, 428 (Ind. Ct. App. 2003)).

46. 42 U.S.C. § 1396r(c)(5)(A)(iii) (2000).

47. *Sanford*, 813 N.E.2d at 419.

agreement.”⁴⁸ The court noted that requiring a nursing home admittee to sign an arbitration agreement is not analogous to charging an additional fee or other consideration for admittance to the facility. The court concluded that an arbitration provision merely establishes the forum for future disputes; both parties are bound to it and both parties receive whatever benefits and detriments accompany that forum.⁴⁹

The Estate’s third argument focused on whether the arbitration clause unconstitutionally deprived the Estate of a jury trial.⁵⁰ Article I, section 20 of the Indiana Constitution provides that: “In all civil cases, the right of trial by jury shall remain inviolate.”⁵¹ However, the court of appeals went on to note that this constitutional right is not absolute and may be waived.⁵² In deciding upon this issue the court reviewed Trial Rule 38 (E) which governs a jury trial of right, and which states: “(E) Arbitration. Nothing in these rules shall deny the parties the right by contract or agreement to submit or to agree to submit controversies to arbitration made before or after commencement of an action thereon or deny the courts power to specifically enforce such agreements.”⁵³

The court noted that this trial rule recognizes a “very strong presumption of enforceability of contracts that represent the freely bargained agreement of the parties.”⁵⁴ The court concluded that the patient’s legal representative, by signing the admission contract which contained the arbitration clause, effectively waived the Estate’s right to a trial by jury and “agreed to submit any future controversies to arbitration.”⁵⁵

The Estate’s final argument is that it is not bound by the arbitration clause because it was not party to or privy to the contract.⁵⁶ In its analysis the court noted that an arbitration agreement like any other contract can only bind those who are in privity with a party. The court noted that “[p]rivity is found if a non-party holds ‘a mutual or successive relationship with [a party] with regard to property or [when] their interests are as identical as to represent the same legal right.’”⁵⁷

The court found this argument unpersuasive because regardless of whether or not there was privity to the admission contract regarding the arbitration clause, the Estate’s survival and wrongful death claims only arose out of Castleton Center’s alleged negligent treatment of the patient.⁵⁸ The court of appeals concluded that the trial court was correct in ordering that the nursing home

48. *Id.*

49. *Id.*

50. *Id.* at 420 (quoting *Scott v. Crussen*, 741 N.E.2d 743, 746 (Ind. Ct. App. 2000)).

51. IND. CONST. art. I, § 20.

52. *Sanford*, 813 N.E.2d at 420.

53. *Id.*

54. *Id.*

55. *Id.* (quoting *Ransburg v. Richards*, 770 N.E.2d 393, 395 (Ind. Ct. App. 2002)).

56. *Id.*

57. *Id.* (quoting *Isp.com LLC v. Theising*, 805 N.E.2d 767, 776 (Ind. 2004)) (alterations in original).

58. *Id.* at 421.

agreement must be arbitrated as opposed to being litigated in the courts.

C. *Golub v. Giles*

Another interesting decision made by the Indiana Court of Appeals concerned the involuntary commitment of a mentally ill patient to a mental health facility, pursuant to the definition of what constitutes a "grave disability" as defined by Indiana Code section 12-7-2-96. In deciding to hear this case, the court noted that while the issues were moot, that it would still decide the case on the merits because the issue of involuntary commitment is a matter of great public interest and one that is likely to recur.⁵⁹

Golub was a thirty-eight-year-old man who suffered from bipolar disorder.⁶⁰ Golub's mental illness caused him to be detained on an emergency basis at least three times between 1998 and August 2003.⁶¹ Due to Golub's behavior in April 2004, Indianapolis police officers detained Golub and transported him to Community Hospital North. Golub was examined by Dr. David Giles who had reaffirmed his prior diagnosis of bipolar disorder with psychotic symptoms, which had been made in August 2003.⁶²

There were a number of factors that Dr. Giles noted concerning Golub's behavior in the months and days leading up to April 2004, which caused Dr. Giles to reaffirm his diagnosis.⁶³ Specifically Golub had: "(1) lunged at a hotel manager, (2) threatened his brother, sister-in-law, and other family members, and (3) claimed that actor Leonardo DiCaprio assaulted him."⁶⁴ Further, Golub's brother, Marshall, "witnessed Golub attempting to direct traffic on Shadeland Avenue, and upon inquiry Golub stated: 'I'm talking to the birds. I'm talking to people up there. Just leave me alone.'"⁶⁵ Marshall Golub also noted that Golub had damaged the walls in the hotel where he was living, he had also destroyed the TV, taped up the electrical outlets, removed the fire alarm and taken all the pictures off the wall. Golub also left a voicemail for Marshall's wife, Lisa Golub, "accusing her of being part of the Federal Bureau of Investigation, accusing her of stalking and watching him, and informing her that he was sitting across the street from her house in a school watching her turn lights on and off."⁶⁶

As a result of Golub's behaviors Dr. Giles filed an Application for Emergency Detention of a Mentally Ill and Dangerous Person.⁶⁷ A commitment hearing was held on April 19, 2004, and the trial court issued an order of regular commitment, which committed Golub to Community Hospital North/Gallahue

59. *Golub v. Giles*, 814 N.E.2d 1034 (Ind. Ct. App. 2004), *trans. denied* (Ind. Feb. 17, 2005).

60. *Id.* at 1036.

61. *Id.* at 1037.

62. *Id.*

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

Mental Health Services as an inpatient.⁶⁸ The trial court's order of commitment provided that Golub would be committed as an inpatient. However, if it became the opinion of the staff that Golub no longer needed in-patient care, he "may be transferred to out-patient status for the balance of the commitment period, or from time to time as necessary."⁶⁹ The order also imposed five special conditions, requiring Golub to:

1. Take all medications as prescribed.
2. Attend all clinic sessions as scheduled.
3. Maintain his address and his telephone number on record if and when [Golub] is placed on out-patient commitment.
4. Not harass or assault family members or others.
5. Not use alcohol, or drugs, other than those prescribed by a certified medical doctor.⁷⁰

Golub appealed. On appeal, Golub argued that because he was "able to feed and clothe himself and otherwise function independently in society," that there was not clear and convincing evidence of a "grave disability" within the meaning of Indiana Code section 12-7-2-96.⁷¹

In reviewing this case, the court of appeals noted that the burden falls on the petitioner to prove by clear and convincing evidence that: "(1) the individual is mentally ill and either dangerous or gravely disabled; and (2) detention or commitment of that individual is appropriate."⁷² The court then looked at the definition of "gravely disabled," which is contained in Indiana Code section 12-7-2-96 and defines "gravely disabled" as:

[A] condition in which an individual, as a result of mental illness, is in danger of coming to harm because the individual:

(1) is unable to provide for that individual's food, clothing, shelter, or other essential human needs; or

(2) has a substantial impairment or an obvious deterioration of that individual's judgment, reasoning, or behavior that results in the individual's inability to function independently.⁷³

At the detention hearing, Dr. Giles asserted that Golub was "gravely disabled" because Golub had a "substantial impairment or an obvious deterioration of his judgment, reasoning, or behavior that results in his inability to function independently."⁷⁴ Dr. Giles based this conclusion on the fact that Golub fails to accept that he is mentally ill and refuses to cooperate with his treatment.⁷⁵

68. *Id.* at 1038.

69. *Id.*

70. *Id.*

71. *Id.*

72. *Id.* (quoting IND. CODE § 12-26-2-5(e) (2004)).

73. *Id.* at 1038-39.

74. *Id.* at 1039.

75. *Id.*

The court of appeals noted that the trial court was correct in concluding that Golub was “gravely disabled” because there was sufficient evidence presented at the hearing by Dr. Giles. Dr. Giles, who had conducted multiple interviews with Golub and Golub’s family members and who had an opportunity to review Golub’s medical records from past admissions, testified that it was his professional opinion that Golub suffered from a psychotic illness, namely bipolar disorder with psychotic symptoms.⁷⁶ Additionally, the court noted that it was established that Golub had a “five-year history of mental illness requiring hospitalizations and causing paranoia, delusional thoughts, and threatening and destructive behavior.”⁷⁷ Dr. Giles also testified that Golub “would benefit from taking anti-psychotic drugs,” however, Golub “refused to cooperate.”⁷⁸ The court of appeals noted that the trial court, as fact finder, could reasonably conclude that Golub was “gravely disabled” and should therefore be involuntarily committed.⁷⁹

II. HIPAA AND PRIVACY ISSUES

Individual rights were a paramount objective of the Administrative Simplification standards of the Health Insurance Portability and Accountability Act when passed in 1996. Of these rights, access to one’s medical records was a chief concern of Congress and has since been at the forefront of discussion in many states, including Indiana. Effective retroactively to July 1, 2003 and passed by the Indiana General Assembly seemingly unnoticed in the 2004 General Session, Section 24 of Public Law 78 changed the provision of an existing retrieval charge for providing copies of medical records in Indiana Code section 16-39-9-3 from a “retrieval” to a “labor” charge.⁸⁰ Although subtle, this purely semantic change has significant implications for both health care providers and individuals when dealing with granting or requesting access to medical records in the State of Indiana.

Unchanged by the substitution in verbiage, Indiana law allows a health care provider to collect a charge of twenty-five cents (\$0.25) per page for making and providing copies of medical records.⁸¹ Providers may also collect a fifteen dollar (\$15.00) *labor charge* in addition to the per page charge. If a provider collects the labor charge, the provider may not impose the per page charge on the first ten copies of the requested medical record.⁸² The purpose of the change was not to alter the allowable charge for copies, but rather to bring Indiana law into compliance with federal regulations.

The objective of many state medical record laws is to achieve a balance between the competing interests involved in ensuring access to, and releasing of, health information. On one hand, the individual patient has an undeniable

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

80. See Act of March 19, 2004, § 24, 2004 Ind. Acts 78.

81. IND. CODE § 16-39-9-3 (2004).

82. *Id.*

interest in their private health information, which includes reasonable access to his or her medical record. In recognizing this need for access by patients, health care providers, however, must consider several factors that affect the cost of releasing the information. These cost factors range from labor and technological costs involved in storage, recovery, re-filing of the information to capital costs associated with storage facilities, copying equipment, and supplies related to mailing and delivery.

The Health Insurance Portability and Accountability Act of 1996, commonly referred to as "HIPAA," was enacted to improve the portability and continuity of health insurance coverage, to combat waste, fraud, and abuse in health care, to promote the use of health savings accounts, to improve access to long term care, and to simplify the administration of health insurance.⁸³ Title II of HIPAA contains the Administrative Simplification rules, which includes certain Privacy and Confidentiality Standards to protect the confidentiality and security of protected health information ("PHI") as well as to bestow certain individual rights. The Privacy and Confidentiality Standards, referred to collectively as the Privacy Rule, regulate the use and disclosure of PHI by covered entities (defined as health care providers, health plans, and clearinghouses).⁸⁴ PHI, with certain exceptions, is all individually identifiable health information, including demographic information, transmitted or maintained in any format, including paper and electronic records.⁸⁵

As a general rule, any standard under HIPAA's Privacy regulations that is contrary to a provision of state law preempts the provision of state law, unless a stated exception or condition is found.⁸⁶ Among others, these conditions include that a provision of state law is more stringent than the privacy standard or that a provision of state law provides for mandatory reporting of various health care conditions or incidents. A state law will be deemed "more stringent" when it either provides individuals with greater access to information or restricts the use or disclosure of health information in circumstances under which it would otherwise be permissible under the federal Privacy standard.⁸⁷

In providing access to one's health information, HIPAA permits covered entities to impose reasonable, cost-based fees for the costs associated with copying and postage when granting an individual's request to review their medical record.⁸⁸ In other words, fees that are not cost-based, even if permitted by state statute, are most likely contrary to HIPAA regulations and therefore will be preempted by HIPAA. Such fees must be based on actual production costs incurred by the entity, which may include the cost of labor, supplies, and postage.⁸⁹ Excepted from this provision is a specific reference to costs associated with the search and retrieval of requested information. This limitation on the

83. 42 U.S.C. §§ 1320d to 1320d-8 (2000).

84. 45 C.F.R. § 160.103 (2002).

85. *Id.*

86. *Id.* § 160.203.

87. *Id.*

88. *Id.* § 164.524(c).

89. *Id.*

charges a health care provider can impose was ostensibly designed to minimize impediments in accessing one's medical records. Past clarification on this issue by the Department of Health and Human Services ("DHHS") that "the fee may not include costs associated with searching for and retrieving the requested information," strongly suggests that charges specifically associated with the retrieval of medical records are not permissible.⁹⁰ A covered entity may, however, charge a fee for preparation of a summary or explanation of protected health information in lieu of the actual medical records when requested to do so by the patient.

Widely-held interpretation of HIPAA's restrictions on fees associated with accessing health records coupled with the past DHHS guidance appears to have been the impetus to the recent changes by the General Assembly. In fact, the Indiana Legislative Services Agency stated in its legislation summary, "[t]he change of language should allow health care providers to continue to charge a minimal amount of labor costs associated with the cost of copying records."⁹¹

III. LABOR AND EMPLOYMENT UPDATE

Section XI of the 2003 Survey⁹² traced the progression of *Highhouse v. Midwest Orthopedic Institute*.⁹³ At the time of last year's publication, the Indiana Supreme Court had granted transfer but had not yet issued a ruling. The court's opinion, which was issued on May 5, 2004, merits further review.

Midwest Orthopedic Institute, P.C. ("MOI") employed Dr. Highhouse as an orthopedic surgeon. Pursuant to the terms of Dr. Highhouse's employment agreement, he received a base annual salary of \$250,000 and an annual bonus for each calendar year payable February 28 of the following year.⁹⁴ In practice, the bonus was paid at the end of each calendar quarter.⁹⁵ The bonus was calculated on the basis of Dr. Highhouse's production and the expenses of MOI's overall operations.⁹⁶

In March 1999, Dr. Highhouse gave notice of his resignation effective on June 30, 1999.⁹⁷ After he resigned, MOI continued to receive collections for services Dr. Highhouse rendered prior to his departure. MOI contended that Highhouse was entitled to no further compensation.⁹⁸ Dr. Highhouse sued,

90. U.S. Dep't of Health & Human Servs., Questions and Answers, at <http://answers.hhs.gov> (last modified July 18, 2003) ("If patients request copies of their medical records, are they required to pay for the copies?").

91. LEGISLATIVE SERVS. AGENCY, FISCAL IMPACT STATEMENT 2 (2004), available at <http://www.in.gov/legislative/bills/2004/PDF/FISCAL/HB1320.009.pdf>.

92. John C. Render & Neal A. Cooper, *Survey of Recent Developments in Health Care Law*, 37 IND. L. REV. 1161, 1209-10 (2004).

93. 807 N.E.2d 737 (Ind. 2004).

94. *Id.* at 738.

95. *Id.*

96. *Id.* at 740.

97. *Id.* at 738.

98. *Id.*

claiming he was entitled to bonus payments based on post-resignation receipts, and that the bonus constituted a “wage” entitling him, under the Indiana Wage Payment Statute,⁹⁹ to a payment of twice the unpaid amounts plus attorney’s fees.¹⁰⁰ The trial court held that Dr. Highhouse was not entitled to bonus payments for collections after the effective date of his resignation.¹⁰¹ The appellate court reversed, finding that Dr. Highhouse was entitled to the bonus payments and that the unpaid bonus constituted “wages” for purposes of the Indiana Wage Payment Statute.¹⁰² The Indiana Supreme Court granted transfer to determine whether Dr. Highhouse was entitled to the bonus payments and whether such payments constituted a “wage” under the Wage Payment Statute.

The first issue the court addressed was whether or not Dr. Highhouse was entitled to bonus payments based on the post-resignation collections MOI received for services that Dr. Highhouse rendered prior to his departure. The court of appeals took the view that Dr. Highhouse’s right to bonus payments vested at the time he performed the services that the bonus was based upon.¹⁰³ The Indiana Supreme Court agreed, finding that as a matter of contract law, Dr. Highhouse was entitled to a bonus based on post-resignation collections.¹⁰⁴

MOI argued that the plain language of the contract prohibited Dr. Highhouse from receiving bonuses after resigning. In support of its argument, MOI cited the termination without cause provision of the employment agreement, which provided that Dr. Highhouse would only receive his regular compensation if MOI terminated the agreement early and gave ninety-day notice. The court, however, was unconvinced, finding that this provision did not appear to apply to resignation and did not unambiguously terminate the right to payment after the effective date of a resignation.¹⁰⁵ Moreover, the court noted that absent some other arrangement or policy, when an employer makes an agreement to provide compensation for services, the employee’s right to compensation vests when the employee renders the services.¹⁰⁶ Because Dr. Highhouse’s employment agreement did not unambiguously call for termination of bonus payments as of his resignation, the court held that Dr. Highhouse was entitled to the bonus based on post-resignation collections for his services.¹⁰⁷

The second issue the court addressed was whether Dr. Highhouse had a right to statutory penalties for MOI’s alleged failure to pay “wages” every two weeks or semi-monthly under the Wage Payment Statute.¹⁰⁸ “Wage” is defined by

99. IND. CODE § 22-2-5-1 (2004).

100. *Highhouse*, 807 N.E.2d at 738.

101. *Id.*

102. *Id.*

103. *Id.* (citing *Highhouse v. Midwest Orthopedic Inst.*, 782 N.E.2d 1006, 1011 (Ind. Ct. App. 2003)).

104. *Id.*

105. *Id.* at 739.

106. *Id.* (citing *Baessler’s Super-Valu v. Ind. Comm’r of Labor*, 500 N.E.2d 243, 246 (Ind. Ct. App. 1986)).

107. *Id.*

108. *Id.*

statute as “all amounts at which the labor or service rendered is recompensed, whether the amount is fixed or ascertained on a time, task, piece, or commission basis, or in any other method of calculating such amount.”¹⁰⁹ The appellate court concluded that a bonus is a “wage” under the statute if the bonus “directly relates to the time than an employee works, is paid with regularity, and is not dictated by the employer’s financial success.”¹¹⁰ Although the court agreed with the appellate court’s formulation of the test of “wages,” the court concluded that Dr. Highhouse’s bonus, which depended partially upon the results of MOI’s operations, was not a wage.¹¹¹ Dr. Highhouse’s bonus turned on both his productivity and also on the expenses of MOI’s operations.¹¹² Although Dr. Highhouse’s efforts contributed to the calculation of his bonus, they were not the sole factor.¹¹³ The court concluded that Highhouse’s bonus presented the same problem as those discussed in *Pyle v. National Wine & Spirits Corp.*,¹¹⁴ *Herremans v. Carrera Designs, Inc.*,¹¹⁵ and *Manzon v. Stant Corp.*¹¹⁶

Finally, the court highlighted the practical reasons why Dr. Highhouse’s bonus was not a “wage.” Namely, his bonus was not consistent with the time constraints imposed by the Wage Payment Statute, which requires wages to be paid within ten days of the date they are “earned.”¹¹⁷ Because Dr. Highhouse’s bonus was tied to collections for his services, substantially more than ten days would be needed in order to calculate the bonus amounts. Moreover, the court found that the contract provision for annual bonus payments supported the view that the bonus was not a “wage.”¹¹⁸ Accordingly, the case was remanded to the trial court, Dr. Highhouse having prevailed on his claim for bonuses calculated on collections after June 30, 1999, while MOI prevailed on the claim for non-payment of wages under the Wage Payment Statute.¹¹⁹

109. *Id.* (quoting IND. CODE § 22-2-9-1).

110. *Id.* (citing *Highhouse v. Midwest Orthopedic Inst.*, 782 N.E.2d 1006, 1013-14 (Ind. Ct. App. 2003)).

111. *Id.* at 740.

112. *Id.*

113. *Id.*

114. 637 N.E.2d 1298 (Ind. Ct. App. 1999) (stating that discretionary bonuses based on financial success of employer were not “wages” for purposes of the Wage Claims Statute).

115. 157 F.3d 1118, 1121-22 (7th Cir. 1998) (stating that plaintiff’s pay based not on “his own time or effort or product . . . but on the profits of his plant” not a wage).

116. 138 F. Supp. 2d 1110, 1113 (S.D. Ind. 2001) (stating that bonus based on “the attainment of financial targets established by [the employer] and the achievement of individual personal objectives” was not a wage).

117. *Highhouse*, 807 N.E.2d at 740 (citing *Manzon*, 138 F. Supp. 2d at 1114).

118. *Id.*

119. *Id.* at 740-41.

IV. MEDICARE/MEDICAID UPDATE

A. Medical Error Reporting System

On January 10, 2005, newly inaugurated Indiana Governor Mitchell E. Daniels, Jr., issued Executive Order 05-10¹²⁰ directing the establishment of a medical error reporting system (“MERS”) for Indiana hospitals. The Executive Order (“EO”) cites a landmark report by the Institute of Medicine, along with other evidence, which demonstrated that medical errors are among the leading causes of death in the United States and impose an enormous economic cost on families and businesses. Hospitals across the country are implementing MERS to improve healthcare with successful implementation reducing the frequency of medical errors and potentially revealing the causes of errors. The EO states that Indiana hospitals are not currently required to implement a MERS and the successful implementation of a MERS would likely radically improve Hoosier healthcare and lessen healthcare costs.

Therefore, the Governor is directing the Department of Health “as soon as practicable” to promulgate regulations, and proposed legislation, if necessary, requiring each Indiana hospital to implement a MERS. The Department of Health is further directed to “confer with various representatives of the State’s hospitals, physicians, nurses, pharmacists, and quality improvement experts and [to] consult best practice guides, including the 10-measure ‘starter set’ of quality reporting indicators that are supported by the federal Hospital Quality Initiative, to develop minimum standards applicable to every MERS in the State.”¹²¹

To ensure that each MERS is effective, the EO calls for minimum MERS requirements, including assurance that patients’ and healthcare professionals’ identities are kept confidential and not discoverable in court or administrative proceedings, the system not be used as the basis for punishment of a healthcare professional, the system require healthcare professionals to report medical errors promptly, and the system require hospitals to report all MERS data to the Department of Health.¹²²

B. Change to Indiana Medicaid Hospital Appeal Deadline

Under Indiana Code section 12-15-13-3(e), hospitals had 180 days to either repay or appeal a determination by the Office of the Secretary of Family and Social Services that it had received an overpayment from the Medicaid program. All other providers under the statute had sixty days to appeal an overpayment determination. Agency practice was to inform providers, including hospitals, of the sixty-day time limit in which to appeal. Effective July 1, 2004, the statute was amended to change the deadline to repay and/or appeal an overpayment determination to sixty days from the date of the notice for all providers, including

120. Exec. Order No. 05-10, 28 Ind. Reg. 1900 (Mar. 1, 2005), available at http://www.in.gov/gov/eo/EO_05-10_Medical_Error_Reporting.pdf.

121. See CTRS. FOR MEDICARE AND MEDICAID SERVS., HOSPITAL QUALITY INITIATIVE OVERVIEW (Mar. 2005), available at <http://www.cms.hhs.gov/quality/hospital/overview.pdf>.

122. *Id.*

hospitals.¹²³ Subsequently, a Proposed Rule was published on October 1, 2004 in the Indiana Register to amend the corresponding regulations.¹²⁴ The Final Rule amending the regulations was published April 1, 2005.¹²⁵

While the statute under Title 12 (Human Services), Article 15 (Medicaid) has been amended to permit hospitals only sixty days to repay or appeal an overpayment determination, the statute under Title 4 (State Offices and Administration), Article 21.5 (Administrative Orders and Procedures) regarding hospital Medicaid reimbursement determinations has not been amended. Under Indiana Code section 4-21.5-3-6(a)(3) and (4), notice is required to be given for “[a] notice of program reimbursement or equivalent determination or other notice regarding a hospital’s reimbursement issued by the office of Medicaid policy and planning or by a contractor of the office of Medicaid policy and planning regarding a hospital’s year end cost settlement” and “[a] determination of audit findings or an equivalent determination by the office of Medicaid policy and planning or by a contractor of the office of Medicaid policy and planning arising from a Medicaid postpayment or concurrent audit of a hospital’s Medicaid claims.”¹²⁶

The following section, Indiana Code section 4-21.5-3-7, states that to qualify for review a person must petition for review in writing that is filed, “[for] a determination described in section 6(a)(3) or 6(a)(4) of this chapter [see above], with the office of Medicaid policy and planning not more than one hundred eighty (180) days after the hospital is provided notice of the determination.”¹²⁷ Therefore, the appeal time frame for hospitals to appeal a notice of program reimbursement or equivalent notice regarding Medicaid reimbursement remains 180 days as that statute has not been amended. While the Final Rule to amend 405 Indiana Administrative Code 1-1.5-2 eliminates the language, “[a] hospital’s request for an appeal of an action described in IC 4-21.5-3-6(a)(3) and IC 4-21.5-3-6(a)(4) must be filed within one hundred eighty (180) days,”¹²⁸ the applicable statute has not been amended and the statute is controlling over a regulation.

C. Medicaid Case Law Update

1. *Survey Damages*—*Golden Years Homestead v. Buckland*.—On March 30, 2004, the U.S. District Court for the Southern District of Indiana ruled on three motions to dismiss brought by defendants in *Golden Years Homestead v. Buckland*.¹²⁹ *Golden Years Homestead* (“GYH”), a Medicaid certified nursing facility, brought suit against various employees and officials of the Indiana State

123. Act of March 19, 2004, § 3, 2004 Ind. Acts 78. (codified as amended at IND. CODE § 12-15-13-3 (2004)).

124. 28 Ind. Reg. 257 (Oct. 1, 2004) (amending IND. ADMIN. CODE tit. 405, r. 1-1-5 and r. 1-1.5-2).

125. 28 Ind. Reg. 2129 (Apr. 1, 2005).

126. IND. CODE § 4-21.5-3-6(a)(3), -(4) (2004).

127. *Id.* § 4-21.5-3-7(a)(3)(B).

128. See 28 Ind. Reg. 2129 (Apr. 1, 2005).

129. No. IP02-0771-C-B/S, 2004 WL 950596 (S.D. Ind. Mar. 30, 2004).

Department of Health (“ISDH”) in their individual capacities as well as the Centers for Medicare and Medicaid Services (“CMS”), including individual employees of CMS who train the ISDH surveyors and supervisors on how to conduct surveys of nursing facilities, asserting that defendants conspired to and did violate its constitutional right to due process and its right to be free from unreasonable searches. GYH also complained of statutory violations for unfair reporting and included state common law and statutory claims for malicious prosecution, abuse of process, and frivolous litigation.¹³⁰

The court addressed three motions to dismiss filed by defendants which focused on the court’s exercise of jurisdiction and whether or not GYH asserted any claims upon which relief can be granted. The court determined that it did have jurisdiction because, even though the state administrative appeal and current lawsuit were both born of the surveys conducted by ISDH,¹³¹ GYH’s pursuit of the current claim did not interfere with the state proceedings despite defendants’ arguments to apply the *Younger* abstention doctrine.¹³² The court also discredited defendants’ argument of Eleventh Amendment immunity stating simply, “[i]n short, the Eleventh Amendment to our Constitution does not bar suits against state officials or employees in their individual capacities . . . [N]or does the Eleventh Amendment bar a suit for injunctive relief or declaratory relief against state officials in their official capacities.”¹³³

The court further noted that defendants’ argument for qualified immunity,¹³⁴ as a basis to dismiss, was premature as an answer to the complaint had not yet been filed so the court could not simply assume that the individual defendants followed the federal mandates for survey procedures. Defendants also moved for dismissal for failure to state a claim arguing that GYH’s assertion that it has a right to be free from unreasonable search and seizure under the Fourth Amendment is without merit, as courts have routinely upheld regulatory framework that grants the government the right to conduct unannounced and unexpected surveys of nursing homes. As GYH did not question the authority of defendants to conduct the surveys, but alleged the surveys were conducted in

130. *Id.* at *1.

131. ISDH sent a team of employees to GYH in April 2000 to investigate a complaint. The survey resulted in citation of certain deficiencies. The surveyors returned in July 2000 and September 2000 with deficiencies cited at both visits. As a result of the initial survey the ISDH discontinued GYH’s nurse aid training program for two years. The July survey resulted in requiring GYH to conduct certain in-service training sessions and a bar on Medicaid payments for new admissions. Following the September survey, further in-service programs were directed and the ISDH indicated it would revoke GYH’s Medicaid certification if it did not come into compliance with all federal regulations by mid-October. GYH was found in compliance by the end of September at which time the revocation threat and payment ban were lifted. *Id.* at *1.

132. *Id.* at *2 (citing *Younger v. Harris*, 401 U.S. 37 (1971)).

133. *Id.* at *3 (citations omitted).

134. Qualified immunity protects governmental officials performing discretionary functions “insofar as their conduct does not violate clearly established statutory or constitutional rights of which a reasonable person would have know.” *Id.* (quoting *Harlow v. Fitzgerald*, 457 U.S. 800, 818 (1982)).

a manner outside the statutory and regulatory guidelines, the court denied defendants' motion stating that, "[c]ertainly, a search can be unreasonable in manner or effect, though the authority to conduct it is unquestioned."¹³⁵

While the court did dismiss the conspiracy claims found in the complaints, the court denied the remainder of defendants' motions to dismiss permitting GYH to proceed with the remainder of its claims against the individual defendants.¹³⁶

2. *Indiana Family and Social Services Settlement Agreement*—*Kraus v. Hamilton*.—On September 23, 2004, the St. Joseph Superior Court approved a settlement agreement between a class of plaintiffs and the Indiana Family and Social Services Administration ("FSSA").¹³⁷ On December 18, 2000, plaintiffs Rodger Bennett and Tommy Jo Kraus, both with mental retardation and/or other developmental disabilities,¹³⁸ by guardians filed a complaint under 42 U.S.C. § 1983, among other statutes, against the Secretary of FSSA and the Assistant Secretary of the Office of Medicaid and Policy Planning ("OMPP"). Plaintiffs sought an injunction to prohibit the continued confinement of the plaintiffs and others similarly situated in nursing homes and to require the State of Indiana to develop a comprehensive plan for the placement of mentally retarded and developmentally disabled people "to live in integrated settings rather than in nursing homes and [to require] placement in a small group [Intermediate Care Facility for the Mentally Retarded ("ICF/MR")] or home and community based waiver program with reasonable promptness."¹³⁹

The Complaint alleged that the defendants failed to appropriately treat and accommodate the plaintiffs' disabilities resulting in the plaintiffs' segregation in nursing facilities where they were not provided with minimally adequate training, habilitation, or support services and where they remained "frozen on a 'home and community based waiver program list.'"¹⁴⁰ Plaintiffs claimed this treatment was in contravention of the Nursing Home Reform Act of 1987.

Pursuant to the settlement agreement, defendants agreed to take reasonable efforts to expand their capacity to provide waiver services and to seek to reduce, and, if possible, eliminate waiting time for class members so that the optimum number of persons seeking reimbursement for waiver services can benefit from waiver services.¹⁴¹ In addition, defendants agreed to seek to expand the number of persons who can be served under waivers for persons with developmental disabilities by increasing the number of waiver slots over the next four years.¹⁴² Defendants also agreed to disseminate information about the nature and availability of community services that are reimbursable under the waiver

135. *Id.* at *5.

136. *Id.* at *7.

137. *Kraus v. Hamilton*, No. 71D06-0012-CT-260 (St. Joseph Superior Ct. Sept. 23, 2004).

138. Complaint at 4, *Kraus* (No. 71D06-0012-CT-260) (citing section 12102(2)(A) of the Americans with Disability Act and section 794 of the Rehabilitation Act).

139. *Id.* at 3-4.

140. *Id.* at 3.

141. Settlement Agreement at 6, *Kraus* (No. 71D06-0012-CT-260).

142. *Id.* at 7.

program or under the state Medicaid plan through accessible, understandable, written, and visual materials as well as face to face meetings with class members.¹⁴³ Defendants did not admit to any failure to comply with applicable legal requirements and neither party made any concession as to the merits of the case or of the opposing parties' claims or defenses.¹⁴⁴

V. FRAUD AND ABUSE

A. Introduction

The federal Fraud and Abuse Anti-Kickback Statute is designed to prevent certain payments in connection with the furnishing of services reimbursable under the Medicare and Medicaid programs as well as other governmental health care initiatives.¹⁴⁵ This statute prohibits someone from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce the referral of any item or service for which payment may be made in whole or in part under Medicare, Medicaid, or other government health care program.¹⁴⁶

B. Safe Harbor Regulations

Section 431 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003¹⁴⁷ requires the addition of a Safe Harbor Regulation related to medically underserved populations to the numerous, existing Safe Harbor Regulations. It must provide that remuneration in the form of a contract, lease, grant, loan, or other agreement between a public or non-profit health center and an individual or entity providing goods and services to the health center will not violate the Anti-Kickback Statute if such an agreement contributes to the availability or quality of services applicable to a medically underserved population. Although the Safe Harbor Regulation was to be published by December 7, 2004, as of this writing, the Secretary of the DHHS has not published such a regulation.

C. Advisory Opinions

The Office of Inspector General ("OIG") of DHHS issued nineteen Advisory Opinions during 2004. Of particular interest is OIG Advisory Opinion Number 04-17,¹⁴⁸ in which the OIG applies some of its comments and theory that profit

143. *Id.* at 10.

144. *Id.* at 19.

145. 42 U.S.C.A. §§ 1320a to 1320a-8b (West 2003 & Supp. 2004).

146. *Id.*

147. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 431, 117 Stat. 2066, 2287.

148. Office of Inspector Gen., U.S. Dep't of Health and Human Servs., Advisory Op. 04-17 (Dec. 17, 2004), available at <http://oig.hhs.gov/Fraud/docs/advisoryopinions/2004/AO0417.pdf>. [hereinafter Advisory Op.].

in certain contractual arrangements can be remuneration to which no Safe Harbor protection applies, as first described in the Contractual Joint Ventures Special Advisory Bulletin, which was issued in April 2003.¹⁴⁹

The proposed arrangement that was the subject of Advisory Opinion 04-17 involved a pathology laboratory controlled group of companies (“Path Lab Companies”). One entity included in the Path Lab Companies was intended to be a non-provider operating company (“Turnkey Operator”) which was to be created to help physician groups establish “in house” pathology laboratories within their medical practices. Existing within the Path Lab Companies was also an entity (“Affiliated Lab”) that provided traditional pathology laboratory services to physician groups.¹⁵⁰

The proposed arrangement involved physician groups establishing their own in-house pathology laboratories and then engaging the Turnkey Operator in order to acquire all necessary management and administrative services, equipment leasing, premises subleasing, technical, professional, and supervisory pathology services, and, if requested, billing services for such in-house laboratories. The Turnkey Operator planned to contract with physician groups specializing in urology, gastroenterology, or dermatology. Most of the pathology services to be provided by the physician groups with the aid of the Turnkey Operator would be surgical pathology services that have separate reimbursement for technical and professional components.¹⁵¹

In consideration for services rendered, each physician group would compensate Turnkey Operator a (i) flat, monthly fee, (ii) per-specimen fee, and (iii) if applicable, a fee for billing and collection services equal to five percent of the total net revenue of the physician group’s in-house laboratory.¹⁵²

The OIG concluded that the proposed arrangement “could potentially generate prohibited remuneration under the anti-kickback statute.”¹⁵³ The OIG was not able to exclude the possibility that the parties’ contractual relationship was designed to permit the Path Lab Companies to “kickback” remuneration to the physician groups for referrals.¹⁵⁴ Factors that the OIG noted as particularly problematic included:

1. All referrals to the lab services provided by a particular physician group would come from that physician group.
2. The Path Lab Companies (through Affiliated Lab) would continue to be a competitor of the in-house laboratories established by the physician groups.
3. Each physician group would be expanding into a related line of business, pathology services, which would be dependent on referrals

149. Publication of OIG Special Advisory Bulletin on Contractual Joint Ventures, 68 Fed. Reg. 23,148 (Apr. 30, 2003).

150. Advisory Op. at 3.

151. *Id.*

152. *Id.*

153. *Id.* at 1.

154. *Id.* at 6.

from that physician group.

4. The physician groups would not actually participate in the operation of their in-house laboratories, but would contract out substantially all lab operations to the Turnkey Operator. The OIG felt the physician groups would commit almost nothing in the way of financial, capital, or human resources to the laboratory operations, and, therefore, would assume very little or no real business risk.
5. Each physician group would receive an economic benefit from the success of its in-house laboratory. In addition, by way of the consideration for services rendered, the Turnkey Operator would also receive an economic benefit from the success of such laboratory.¹⁵⁵

Finally, as in the Contractual Joint Ventures Special Advisory Bulletin, the OIG stated that its conclusion would not change even if each of the individual agreements making up the proposed arrangement could satisfy an Anti-Kickback Statute safe harbor because the OIG believes that the retention of profits from the pathology services by a physician group would not be protected by any safe harbor.¹⁵⁶

D. Discounts to the Uninsured by Tax-Exempt Hospitals

Historically, hospitals have charged uninsured patients full, undiscounted rates and, in many cases, aggressively pursued such patients for outstanding debt. The hospital industry took such an approach based on guidance received from CMS and the OIG that there could be negative legal and administrative consequences for not taking such positions, as well as the environment of aggressive fraud and abuse investigations and prosecutions.

The hospital industry sought clarification from CMS and the OIG about these issues. In response, CMS attempted to clarify its policies through a letter from Secretary of DHHS, Tommy Thompson, on February 19, 2004, addressed to Richard J. Davidson, President of the American Hospital Association, regarding the practice of the alleged overcharges.¹⁵⁷ Thompson claimed the concern raised by the hospital industry is “not correct and certainly does not reflect my policy.”¹⁵⁸ Released along with the letter was a CMS Question and Answer document.¹⁵⁹ On the same day, the OIG released a document similarly dismissing provider concerns.¹⁶⁰ Given the longstanding regulations and CMS policies that

155. *See id.* at 5-6.

156. *Id.* at 7.

157. Letter from Tommy G. Thompson, Sec’y, U.S. Dep’t of Health & Human Servs. of Health and Human Services, to Richard J. Davidson, President, Am. Hosp. Ass’n (Feb. 19, 2004), available at <http://www.hhs.gov/news/press/2004pres/20040219.html>.

158. *Id.*

159. *Id.*

160. OFFICE OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUMAN SERVS., HOSPITAL DISCOUNTS OFFERED TO PATIENTS WHO CANNOT AFFORD TO PAY THEIR HOSPITAL BILLS (Feb. 2, 2004), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA021904hospital>

prohibited discounts to uninsured patients and failing to pursue debt from such patients, the industry sought clarification of various issues. CMS held a Town Hall meeting in an attempt to clarify its policies, which, at times even appeared to contradict the approach taken by the OIG.

Also during 2004, numerous class action lawsuits were brought on behalf of uninsured patients against tax-exempt hospitals, related to alleged over-charging of such patients.¹⁶¹ This heightened scrutiny, along with the apparent relaxation of regulatory and policy interpretations by CMS and the OIG caused many hospitals to re-examine their charge structure, how and when they give discounts, and their charity care policies, often leading to modifications of such policies and procedures to be somewhat broader.

VI. LEGISLATIVE CHANGES

A. Indiana Comprehensive Health Insurance Association House Enrolled Act 1273

Indiana Comprehensive Health Insurance Association House Enrolled Act 1273 (“Act”), effective on January 1, 2005, made several important changes to the Indiana Comprehensive Health Insurance Association (“ICHIA”).¹⁶² ICHIA is a nonprofit legal entity which assures that health insurance is available to each eligible Indiana resident applying to it for coverage.¹⁶³ ICHIA provides health insurance coverage for individuals who are not eligible for Medicaid or commercial health insurance because of their pre-existing condition or chronic disease or illness. ICHIA is funded in part by assessments or carrier, health maintenance organizations, limited service health maintenance organizations, and self-insurers providing health insurance or health care services in Indiana. All such organizations must be members of ICHIA. The remaining funding comes from premiums charged to enrolled insureds and subsidiaries from the state of Indiana. Included in the changes to ICHIA is a provision permitting it to negotiate rates and enter into contracts with individual health care providers and health care provider groups for the care of its insureds.¹⁶⁴

To deal with net losses incurred, if any, by ICHIA, the Act requires at the close of ICHIA’s fiscal year that ICHIA shall determine its incurred losses for the year. Twenty-five percent of any net loss shall be apportioned among all members of ICHIA in proportion to their respective shares of total health insurance premiums received in Indiana during the same fiscal year. The remaining seventy-five percent of any net loss shall be paid by the state of Indiana.¹⁶⁵

discounts.pdf.

161. See generally *Lawsuits Challenge Charity Hospitals on Care for Uninsured*, WALL ST. J., June 17, 2004, at B1.

162. Act of Mar. 18, 2004, 2004 Ind. Acts 97.

163. IND. CODE § 27-8-10-2.1 (effective Jan. 1, 2005).

164. *Id.*

165. *Id.*

In setting annual premiums, ICHIA may, on October 1 of each year, adjust premiums equal to the percentage changes in medical cost experienced by it during the preceding fiscal year minus the percentage change in Indiana medical care component of the Consumer Price Index of the United States Bureau of Labor Statistics. In no event may an annual premium adjustment exceed ten percent.¹⁶⁶

The Act modifies the manner in which members of ICHIA may take tax credits in relation to assessments paid. Beginning on January 1, 2005, a member who has paid an assessment prior to that date and has not taken a tax credit is not entitled to carry forward unused credits. However, such a member may, beginning January 1, 2007, take a credit of not more than ten percent of the amount of assessments paid before January 1, 2005, against which a tax credit has not been taken before January 1, 2005. If this allowable maximum tax credit exceeds a member's liability for taxes, the member may carry the unused part of the tax credit forward to subsequent taxable years. The total tax credits taken under this provision may not exceed the total assessments paid by a member before January 1, 2005.¹⁶⁷

In making payments for medically necessary eligible expenses to health care providers for its insureds, the Act specifies that ICHIA payments must be based on its usual and customary fee schedule or a health care provider network arrangement previously negotiated.¹⁶⁸

The Act clarifies that health care providers shall not bill an ICHIA insured for any amount exceeding the payment made by ICHIA and any permissible co-payment, deductible, or coinsurance amounts.

All of the modifications to the Act are intended to improve the financial stability of ICHIA, reduce the burden upon its members, and insure that eligible individuals will continue to be able to obtain insurance.¹⁶⁹

B. Creation of Psychiatric Advance Directives

Effective July 1, 2004, a new type of advance directive was established by Senate Enrolled Act 133 ("Act").¹⁷⁰ The Act creates a new chapter of the Indiana Code authorizing certain individuals to execute an advance directive by written instrument expressing that individual's preference and consent to various treatments during subsequent periods of incapacity.¹⁷¹ In this respect, it parallels the existing statute regarding living wills.

A person creating a psychiatric advance directive must not then be incapacitated and the advance directive must be in writing, must name the individual creating it, and must name the treatment program and sponsoring entity in which the individual is enrolled, if applicable. Additionally, the

166. *Id.*

167. *Id.*

168. *Id.*

169. *Id.*

170. Act of July 1, 2004, § 2, 2004 Ind. Acts 16.

171. *Id.*

advance directive must provide the name, address, and telephone number of the individual's treating physician or other treating mental health personnel. The advance directive must be signed by the individual creating it, and must be dated. It must also include the name, address, and telephone number of the designated health care representative under Indiana Code section 16-36-1.5-5(b)(4).¹⁷² Lastly, the advance directive shall contain the signature of the psychiatrist treating the individual entering into the psychiatric advance directive attesting to the appropriateness of the treatment preferences and to the individual's capacity.

An individual creating a psychiatric advance directive may specify directive treatment measures relating to admission for treatment, type, and method of administration of medications, restraint, seclusion, electroconvulsive therapy, or counseling.

A person who treats an individual who has executed a psychiatric advance directive is not subject to civil or criminal liability based on non-compliance with the directive, if the person is unaware that the individual has executed a valid psychiatric advance directive. The chapter does not prevent an attending physician from treating the patient in a manner that is in the patient's best interest.¹⁷³

VII. STARK LAW UPDATE

The federal Stark Law restricts physician referrals to an entity for the provision of certain "designated health services"¹⁷⁴ that may be payable under Medicare or Medicaid when the physician has a financial relationship with such entity.¹⁷⁵ On March 26, 2004, the Centers for Medicare and Medicaid Services ("CMS") issued "Phase II" of the final regulations ("Phase II")¹⁷⁶ for Section 1877 of the Social Security Act, better known as the Stark II legislation.¹⁷⁷ CMS first issued the proposed Stark II regulations in January 1998 ("Proposed Rule")¹⁷⁸ and, due to the broad scope of the regulations, bifurcated the final rule finalizing the process in two phases. Phase I of the final regulations was issued in January 2001.¹⁷⁹ After six years of operating under proposed regulations, the long awaited Phase II regulations have been issued to provide the health care industry further guidance on matters related to physicians' referrals to entities with which they have financial relationships. Overall, in Phase II, CMS sought

172. IND. CODE § 16-36-1.5-5(b)(4).

173. Act of July 1, 2004, § 5, 2004 Ind. Acts 16.

174. The term "designated health services" includes such items as radiology, clinical laboratory services, physical and occupational therapy services, and durable medical equipment ("DME") and supplies. 42 U.S.C.A. § 1395nn(h)(6) (2003).

175. *Id.* § 1395nn.

176. Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16,054 (Mar. 26, 2004) (to be codified at 42 C.F.R. pts. 411, 424) [hereinafter Physicians' Referrals].

177. 42 U.S.C.A. § 1395nn.

178. Physicians' Referrals, 69 Fed. Reg. at 16055.

179. *Id.*

to (i) address the comments to, and revise portions of, the Phase I final rule, and (ii) provide final regulations on the remaining provisions of the Stark II legislation not previously addressed in Phase I.

A. Overview

There are several key provisions in the Phase II regulations, which became effective July 26, 2004. First, with regard to physician compensation, Phase II provided clarification regarding how physicians may be compensated as members of a group practice, employees, or independent contractors, including the provision of productivity bonuses.¹⁸⁰ Second, Phase II provided an exception for existing relationships that inadvertently fall into noncompliance by granting the parties a ninety-day grace period to return to compliance, provided this exception can only be used once every three years for a specific physician.¹⁸¹

Third, Phase II clarified certain issues related to group practices and the In-Office Ancillary Exception which allows medical groups to provide designated health services ("DHS") within their practice.¹⁸² One important change was the clarification of the definition of "same building" to provide group practices with greater latitude to provide DHS at buildings in which they do not maintain a full time presence.¹⁸³ In addition, Phase II incorporated the current moratorium on physician ownership in specialty hospitals.¹⁸⁴ Fifth, in Phase II, CMS clarified certain existing exceptions, and created several new exceptions. Although no new DHS categories were added, CMS stated that it will continue to *consider* the application of the Stark II prohibitions to nuclear medicine.¹⁸⁵ Last, Phase II provided clarification regarding indirect compensation arrangements.¹⁸⁶

B. Detailed Summary

1. *Physician Compensation.*—Phase II provided clarification regarding the type of compensation arrangements an entity can have with physicians under (1) a Group Practice Arrangement; (2) the Employment Exception; (3) the Personal Services Exception; (4) the Fair Market Value Exception; and (5) Academic Medical Centers Exception. The greatest latitude for compensation exists for physicians within a group practice. Such physicians may receive (1) a productivity bonus based upon both personally performed services and services provided "incident to";¹⁸⁷ and (2) distributions from profits derived from DHS,

180. Note that percentage compensation arrangements were allowed. *Id.* at 16,066. In addition, Phase II created a safe harbor for establishing the fair market value of hourly payments to physicians. 42 C.F.R. § 411.351 (2005).

181. *Id.* § 411.325.

182. *Id.* § 411.355(b).

183. *Id.* § 411.355 (b)(2)(i).

184. *Id.* § 411.356 (c)(3).

185. Physicians' Referrals, 69 Fed. Reg. at 16,100. CMS also stated its intent to revisit the definition of outpatient prescription drugs in a future rulemaking. *Id.* at 16,106.

186. See 42 C.F.R. § 411.354 (2005).

187. See *id.* §§ 411.351; 410.26(a).

provided such distributions are not directly related to the physician's referrals of DHS to the group practice.¹⁸⁸ In addition, the compensation for these physicians does not have to be "set in advance."¹⁸⁹

For arrangements under the Employment Exception, a physician may be paid a productivity bonus based upon personally performed services,¹⁹⁰ but may not receive payment based upon referrals of DHS, either directly or indirectly as allowed for group practice physicians.¹⁹¹ In addition, the compensation for these physicians does not have to be "set in advance."¹⁹²

For those arrangements within the Personal Services Exception, the Fair Market Value Exception, and the Academic Medical Centers Exception, a physician's compensation must be "set in advance."¹⁹³ Under Phase II, the term "set in advance" requires that either (i) the aggregate compensation; (ii) time-based unit or per unit of service amount; or (iii) a specific formula (e.g., percentage compensation arrangement) is established prior to the commencement of the agreement.¹⁹⁴ While changes to the compensation model may occur during the term of the agreement, such changes should be carefully structured to assure continued compliance. Any productivity bonus¹⁹⁵ may take into account only those services personally provided by the physician-contractor.¹⁹⁶

The Phase II regulations also created a safe harbor for hourly payments made for a physician's personal services. Permissible payment arrangements include: (1) an hourly rate which is less than or equal to the average hourly rate for emergency room physician services;¹⁹⁷ and (2) an hourly rate which is determined by dividing by 2000 hours the fiftieth percentile compensation level for that physician's specialty, averaged between at least four nationally recognized physician compensation surveys.¹⁹⁸

2. *Exception for Certain Arrangements Involving Temporary Noncompliance.*—Phase II created a new exception to protect against inadvertent noncompliance with the Stark II rules. In order for the noncompliant period to qualify for the exception, the following conditions must be met: (1) the financial relationship between the entity and the physician has fully complied with Stark II for at least 180 days prior to the date the relationship became noncompliant; (2) the relationship became noncompliant for reasons beyond the control of the entity and the entity promptly took steps to rectify the noncompliance; (3) the financial relationship is in compliance with the Anti-Kickback Statute and other

188. *Id.* § 411.352 (2005).

189. *Id.*

190. However, this does not include "incident to" services.

191. 42 C.F.R. § 411.357(c) (2005).

192. *Id.*

193. *Id.* §§ 411.357(d); 411.357 (l); 411.355 (e).

194. *Id.* § 411.354(d)(1).

195. For example, a bonus based on the percentage of revenue generated.

196. 42 C.F.R. § 411.357(d).

197. However, there must be at least three emergency rooms in the relevant marketplace. *Id.* § 411.351.

198. *Id.*

applicable laws; and (4) the noncompliance was rectified within ninety days.¹⁹⁹ It is important to note that this exception may only be used once every three years for each physician, and does not apply to relationships under the Non-Monetary Compensation and Medical Staff Incidental Benefit Exceptions.²⁰⁰

3. *Changes to In-Office Ancillary Services Exception and Group Practice Definition.*—The final regulations amended certain provisions of the In-Office Ancillary Services Exception. This important exception protects the in-office provision of certain DHS that are truly ancillary to the medical services being provided by the physician practice.²⁰¹ Under this exception, DHS must be furnished to patients in the same building where the referring physicians provide their regular medical services, or, in the case of a group practice, in a central building, provided that certain conditions are met.²⁰²

Phase II retained the “centralized building” definition, which includes all or part of a building, including mobile vehicles, that is owned or leased on a full-time basis by a group practice and is used exclusively by the group.²⁰³ In addition, the regulations simplified the “same building” determination by developing three new alternative tests, which have varying numbers of hours per week that the referring physician, or in some instances, other members of the referring physician’s group practice, must practice at the office that is located in the “same building” that the DHS are furnished.²⁰⁴ The amount of physician services unrelated to the furnishing of DHS, required to be performed in the “same building,” was reduced from “substantial” to “some,” interpreted pursuant to its plain meaning.²⁰⁵ Finally the regulations clarified that physicians and group practices may purchase the technical component of mobile services²⁰⁶ and bill for such services pursuant to applicable Medicare rules.²⁰⁷

Under Stark II, a “group practice” can take advantage of certain exceptions under the law, although it is incorrect to state that there is a group practice exception. Rather, “group practice” is a definition, whereby once the definitional elements are met, the group is in position to meet a relevant exception, such as the in-office ancillary services exception. The Phase II regulations modified the “primary purpose” of the definition to make clear that the relevant inquiry is the current operation of the group practice.²⁰⁸ The regulations also eliminated the requirement for centralized utilization review under the “unified business test.”²⁰⁹

199. *Id.* § 411.353.

200. *Id.* § 411.353(f)(3)-(4). The Non-Monetary Compensation and Medical Staff Incidental Benefit Exceptions are discussed *infra* Part VII.B.6.a.iii.

201. *Id.* § 411.355(b).

202. *Id.*

203. *Id.* § 411.351.

204. *Id.* § 411.355(b)(2).

205. *Id.* § 411.355(b)(2)(A)(1).

206. Mobile services are not considered buildings for purposes of the in-office ancillary services exception. Physicians’ Referrals, 69 Fed. Reg. at 16,073.

207. *Id.*

208. *Id.* at 16,076.

209. *Id.*

Further, they reiterated that hospitals employing two or more physicians do not qualify as “group practices.”²¹⁰ Phase II also provided that a single legal entity may meet the definition if it is owned by another medical practice, provided such medical practice is no longer operating as a physician practice.²¹¹

The regulations declined to expand the group practice definition to permit independent contractors to fulfill the “two or more physicians” requirement.²¹² However, such requirement may be met by part-time employed physicians.²¹³ The regulations created a new twelve-month grace period for compliance with the “substantially all” test when the addition of a new member, who has relocated his practice to an existing group, would otherwise cause the group to fall out of compliance.²¹⁴ Finally, with regard to compensation, CMS allowed profit sharing or productivity bonuses to be based directly on services that are “incident to” the physician’s personally performed services.²¹⁵

4. *Specialty Hospitals*.—In accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), CMS revised the Hospital Ownership Exception to include the new eighteen-month moratorium on physician ownership of specialty hospitals.²¹⁶

5. *Clarifications and Modifications to Current Statutory Exceptions*.—

a. *The rental of office space and equipment*.—Phase II adopted the regulatory language of the Proposed Rule with regard to the rental of space and equipment with several modifications. The regulations allowed leases or rental agreements to be terminated with or without cause, as long as the parties do not enter into a new agreement within the initial one-year period of the lease.²¹⁷ In addition, CMS permitted month-to-month holdover leases for up to six months on the same terms as the original lease.²¹⁸ The “exclusive use” provision was modified to allow subleases in many cases, so long as the lessee or sublessee does not share the rented space or equipment with the lessor during the time it is leased.²¹⁹ The clarifications affirmed that per-click²²⁰ rental payments are permitted as long as the payments are fair market value and do not take into account the volume or value of referrals or other business generated between the parties.²²¹ Finally, under appropriate circumstances, lease payments may decrease as volume increases, provided such payment structure is commercially

210. *Id.* at 16,077.

211. 42 C.F.R. § 411.352(a) (2005).

212. Physicians’ Referrals, 69 Fed. Reg. at 16,077.

213. *Id.*

214. 42 C.F.R. § 411.352(c)(5).

215. *Id.* § 411.352(i)(1). See *id.* §§ 411.351, 410.26(a) for definition of “incident to” services.

216. *Id.* § 411.356 (c)(3).

217. *Id.* § 411.357(a)(2).

218. *Id.* § 411.357(a)(7).

219. *Id.* § 411.357(a)(3). Note, however, that the sublease arrangement may create an indirect compensation arrangement. Physicians’ Referrals, 69 Fed. Reg. at 16,085.

220. For example, per use or per service payments.

221. *Id.* § 411.357(a)(3).

reasonable and at fair market value.²²²

b. Bona fide employment relationships.—The Phase II regulations adopted the regulatory language of the Proposed Rule regarding bona fide employment relationships with the following modifications: (1) CMS eliminated the limitation on productivity bonuses and the addition of the “other business generated between the parties” language; and (2) narrowed the instances in which an employer may require an employee to refer to the employer.²²³ Such instances include: (1) the referring physician is compensated at fair market value; and (2) the referral restriction relates solely to the physician’s services covered by the scope of the employment and is reasonably necessary to effectuate the legitimate purpose of the relationship.²²⁴ The referrals requirement does not apply when the patient requests a different provider, the patient’s insurer mandates a different provider, or the referral is not in the patient’s best medical interest as determined by the physician.²²⁵

c. Personal services arrangements.—In addition to the compensation changes discussed above, Phase II made several modifications to the Personal Services Arrangement exception. First, CMS clarified the treatment of termination provisions to allow for the agreement to be terminated within the initial one-year period, with or without cause, so long as the parties do not enter the same or substantially the same arrangement during the initial one-year period.²²⁶ Further, payments from downstream subcontractors are included in the physician incentive plan exception.²²⁷ The regulations relaxed the requirements for separate contracts related to items or equipment used under the personal services exception.²²⁸ Lastly, the integration requirements²²⁹ were modified to allow for either the incorporation of other agreements, or the cross-referencing to a master list of contracts that is maintained centrally.²³⁰

d. Remuneration unrelated to the provision of DHS.—CMS stated that the Remuneration Unrelated to the Provision of DHS exception will be interpreted narrowly, and will protect only remuneration that is wholly unrelated to the provision of DHS.²³¹

e. Physician recruitment.—The Phase II regulations substantially modified the Proposed Rule regarding physician recruitment. First, a recruited physician must relocate his practice²³² either: (1) a minimum of twenty-five miles; or (2)

222. *Id.*

223. Physicians’ Referrals, 69 Fed. Reg. at 16,087-88.

224. *Id.* at 16,087. For example, the employer cannot require a part-time employee to refer patients seen outside of the scope of the part-time employment to the employer. *Id.*

225. *Id.*

226. 42 C.F.R. § 411.357(d)(1)(iv).

227. *Id.* § 411.357(d)(2); Physicians’ Referrals, 69 Fed. Reg. at 16,092.

228. 42 C.F.R. § 411.357(d)(1)(ii).

229. For instance, arrangement must be integrated into a single contract.

230. 42 C.F.R. § 411.357(d)(1)(ii).

231. Physicians’ Referrals, 69 Fed. Reg. at 16,093 (including, for example, the rental of residential property).

232. Relocation of a physician practice does not necessarily require the physician to change

such that the new medical practice derives at least seventy-five percent of its revenues from patients not historically treated by the physician.²³³ However, residents and physicians in practice one year or less are not subject to the relocation requirement described above.²³⁴ The final regulations also extended the exception to cover federally qualified health clinics (“FQHCs”).²³⁵

Recruitment payments may be made to existing groups in connection with the recruitment of a new physician if the following conditions are met:

- (1) Except for costs incurred by the group, all other recruitment support is passed directly through or remains with the recruited physician;
- (2) For income guarantees, the allocation of overhead to the recruited physician may not exceed the actual additional incremental overhead attributable to the recruited physician;
- (3) The group must maintain records of actual cost and passed through recruitment support for at least five years;²³⁶
- (4) The recruitment payment may not take into account the value or volume of referrals the existing group makes to the hospital;
- (5) The group may not impose additional practice restrictions on the recruited physician²³⁷ other than those related to quality of care; and
- (6) The recruitment arrangement must not violate the Anti-Kickback statute or other applicable laws governing billing or claims submission.²³⁸

f. Isolated transactions.—This exception protects remuneration paid in an isolated financial transaction, for example a one-time sale of property or physician practice. Phase II modified the definition of “isolated transactions” to allow for appropriate post-closing adjustments and installment payments, if the following conditions are met: (1) the total aggregate payment is fixed before the first payment is made; and (2) payments are either immediately negotiable or are guaranteed by a third party, secured by a negotiable promissory note; or subject to a similar mechanism to assure payment in the event of default.²³⁹

g. Payments made by a physician for items or services.—This exception applies to certain fair market value payments from a physician to an entity in exchange for items provided or services rendered by the entity. The Phase II Rule removed the proposed exception for discounts.²⁴⁰ Previously, discounts were permitted provided the discount was passed on in full to the patients or their insurers and did not benefit the physician in any manner.²⁴¹

his residence.

233. 42 C.F.R. § 411.357(e)(2).

234. *Id.* § 411.357(e)(3).

235. *Id.* § 411.357(e)(5).

236. Such records must be made available CMS upon request. *Id.* § 411.357(e)(4)(iv).

237. Including, for example, covenants-not-to-compete.

238. *See* 42 C.F.R. § 411.357(e)(4).

239. Physicians’ Referrals, 69 Fed. Reg. at 16,098.

240. *Id.* at 16,099.

241. *Id.*

6. *Regulatory Exceptions.*—Regulatory exceptions are those exceptions added by CMS under the limited authority granted by the Social Security Act to create exceptions that protect arrangements that have no risk of fraud and abuse.

a. *Modifications to existing regulatory exceptions.*—

i. *Academic medical centers.*—The Academic Medical Center exception applies to services provided by an academic medical center if certain conditions are met. The definition of an academic medical center was modified to permit hospitals or health systems that sponsor four or more approved medical education programs to qualify if they meet other specified criteria.²⁴² In addition, a safe harbor provision was added to clarify the meaning of “substantial academic services or clinical teaching services.”²⁴³ Lastly, the regulations were amended to cover research money used for teaching.²⁴⁴

ii. *Services furnished under certain payment rates.*—In Phase I, CMS defined DHS to exclude services that are reimbursed by Medicare as a part of a composite rate.²⁴⁵ Phase II deletes the ASC / ESRD / Hospice exception to prevent undue confusion with the new composite rate exception.²⁴⁶

iii. *Non-monetary compensation and medical staff incidental benefits.*—Compensation from an entity in the form of items or services, not including cash or cash equivalents, are protected by this exception if certain criteria are met.²⁴⁷ The \$300 and \$25 thresholds included in the exception will be increased annually for inflation.²⁴⁸ The listing of affiliated physicians in hospital advertising is a permissible incidental benefit, however the advertising or promoting of a physician’s private practice on the hospital’s website is not covered by this exception.²⁴⁹

iv. *Compliance training.*—Phase I created a new exception to protect compliance training provided by a hospital to a physician or immediate family member that practices in the hospital’s local community or service area, provided the training is held in the local community or service area. The final rule expanded this exception to include all DHS entities, and training addressing the requirements of a compliance program, state or Federal health care program or any Federal, state, or local law.²⁵⁰

b. *New regulatory exceptions.*—

i. *Anti-kickback law safe harbors.*—Phase II created two new regulatory

242. 42 C.F.R. § 411.355(e).

243. *Id.* § 411.355(e)(1)(i)(D).

244. *Id.* § 411.355(e)(1)(iii)(C).

245. Defined services include Ambulatory Surgery Center (“ASC”) services, Skilled Nursing Facility (“SNF”) Part A services, and End-Stage Renal Disease (“ESRD”) composite rate services. Physicians’ Referrals, 69 Fed. Reg. at 16,111.

246. *Id.*

247. *See* 42 C.F.R. §§ 411.357(k)(1); and (m).

248. *Id.* § 411.357(k)(2).

249. *Id.* § 411.357(m)(2).

250. *Id.* § 411.357(o). However, continuing medical education (“CME”) does not qualify under the exception. *Id.*

exceptions that incorporate Anti-Kickback Statute²⁵¹ safe harbors related to the following: (1) Obstetrical Malpractice Insurance Subsidies; and (2) Referral Services.²⁵²

ii. Professional courtesy.—The professional courtesy exception protects the provision of free or discounted health care items or services to a physician, the physician's immediate family member, or office staff, by an entity, under certain conditions. "Professional courtesy" is defined as the provision of free or discounted health care items or services to a physician or his or her immediate family member or office staff.²⁵³ The professional courtesy exception protects arrangements that meet the following criteria:

- (1) The professional courtesy is offered to all physicians on the entities' bona fide medical staff or in the entity's local community without regard to the volume or value of referrals or other business generated between the parties;
- (2) The health care items or services provided are of the type routinely provided by the entity;
- (3) The entity's professional courtesy policy is set out in writing and approved in advance by the entity's governing board;
- (4) The professional courtesy is not provided to any physician (or immediate family member) who is a Federal health program beneficiary, unless there is a good faith showing of financial need;
- (5) If the professional courtesy involves any whole or partial reduction of any coinsurance obligation, the insurer is informed in writing of the reduction; and
- (6) The arrangement does not violate the anti-kickback statute . . . or any Federal or State law or regulation governing billing or claims submission.²⁵⁴

iii. Charitable donations by a physician.—Phase II created this exception to protect bona fide charitable donations made by a physician (or immediate family member) to a DHS entity.²⁵⁵ Such donations generally must be made to charitable health care entity's general fund-raising campaign, or risk violation of the Anti-Kickback statute.

iv. Intra-family referrals.—A referring physician may make a referral to an immediate family member or an entity with which the immediate family member has a financial relationship if certain requisite conditions are met. First, the patient is in a rural area, as defined in the regulations.²⁵⁶ Except for services furnished in the home, no other person or entity must be available to furnish services in a timely manner within twenty-five miles of the patient's residence.²⁵⁷

251. See 42 U.S.C.A. §§ 1320a to 1320-8b (2003).

252. See 42 C.F.R. § 357(r) and (g), respectively.

253. *Id.* § 411.351.

254. *Id.* § 411.357(s).

255. *Id.* § 411.357(j).

256. See *id.* § 411.355(c)(1).

257. *Id.* § 411.355(j)(1)(ii).

For services furnished in the home, no other person or entity is available to furnish the services in a timely manner.²⁵⁸ The arrangement must not violate the Anti-Kickback Statute, and the referring physician must take reasonable steps to determine if other providers are available, provided such search does not have to exceed twenty-five miles from the patient's residence.²⁵⁹

v. *Retention payments in underserved areas.*—A Hospital or a FQHC may provide financial support to retain a physician in the Hospital or FQHC's service area under specified conditions. To be deemed permissible, the arrangement must be in writing, neither conditioned upon referrals by the retained physician, nor based upon the volume or value of referrals or other business generated by the parties, and the physician must not be prohibited from joining other hospitals' medical staff.²⁶⁰ Furthermore, the Hospital or FQHC must be situated in a Health Professional Shortage Area, or in an area with demonstrated need for the physician as determined by the Secretary in a formal advisory opinion.²⁶¹ The physician must also have a bona fide, firm, written recruitment offer from a hospital or FQHC to move at least twenty-five miles, and outside of the hospital or FQHC's service area.²⁶²

The retention payment is limited to the lower of: (1) the difference between the physician's current income and the income being offered to recruit the physician; or (2) the reasonable costs the hospital/FQHC would incur in replacing the recruited physician.²⁶³ The retention payment is subject to the same obligations and restrictions on repayment or forgiveness as in the bona fide offer.²⁶⁴ Further, the hospital or FQHC may not enter a retention arrangement with a particular physician more than once every five years.²⁶⁵ The arrangement must not violate the Anti-Kickback Statute.²⁶⁶

vi. *Community-wide health information system.*—Items or services may in some instances be provided to a physician to allow access to, and sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts and related information in order to enhance the community's overall health.²⁶⁷ The items or services must be principally used by the physician as part of the community-wide health information system, and not provided to a physician based upon volume or value of referrals or other business generated by the physician.²⁶⁸ Further, the community-wide health information systems must be made available to all providers, practitioners, and residents of the community who desire to

258. *Id.* § 411.355(j)(1)(iii).

259. *Id.* §§ 411.355(j)(1)(iv) and (j)(2).

260. *Id.* § 411.357(t)(1)(i).

261. *Id.* § 411.357(t)(1)(ii).

262. *Id.* § 411.357(t)(1)(iii).

263. *Id.* § 411.357(t)(1)(iv).

264. *Id.* § 411.357(t)(1)(v).

265. *Id.* § 411.357(t)(1)(vi).

266. *Id.* § 411.357(t)(1)(viii).

267. *Id.* § 411.357(u).

268. *Id.* § 411.357(u)(1).

participate.²⁶⁹ Again, the arrangement must not violate the Anti-Kickback Statute or other applicable laws.²⁷⁰

7. *Designated Health Services*.—Phase II made certain minor changes to the definition of designated health service. With regard to nuclear medicine, CMS declined at this time to include nuclear medicine in the definition of DHS; however, the inclusion of such will continue to be evaluated.²⁷¹ Several bone density tests were added as DHS under “radiology and certain other imaging services.”²⁷² Further, CMS clarified that radiology services performed immediately after a procedure to confirm the placement of an item placed during the procedure is not DHS.²⁷³ An updated CPT list of DHS services was included in the final regulations.²⁷⁴ Finally, in light of the expanded coverage of outpatient prescription drugs as a result of the MMA, CMS intends to revisit the definition of outpatient prescription drugs in a future rulemaking.²⁷⁵

8. *Indirect Compensation Arrangements*.—Phase II provided clarification regarding what will constitute an indirect compensation arrangement between an entity and a physician subjecting the relationship to the Stark II rules. Both excepted and non-excepted relationships are included in the “unbroken chain of financial relationships” that is required for an indirect compensation arrangement to exist.²⁷⁶ A referring physician may be treated as “standing in the shoes” of his or her wholly-owned professional corporation, thereby creating direct compensation arrangements.²⁷⁷ The meaning of direct and indirect ownership was explained, and the regulations affirmed that common ownership does not create an ownership interest by one common investor in another, but the investment interest in the common entity may be a link in the chain necessary to create an indirect compensation arrangement.²⁷⁸ The relationship between the “indirect compensation arrangement” definition and the “volume or value” and “other business generated” standards was also clarified.²⁷⁹

C. Conclusion

This section of the article is intended to provide highlights of the substantive provisions of Stark II, Phase II. Although Phase II provided some degree of clarity to prohibited financial relationships with physicians and, in some cases, expanded the scope of authorized arrangements, the far-reaching impact of its underlying substance continues to require all transactions between entities and

269. *Id.* § 411.357(u)(2).

270. *Id.* § 411.357(u)(3).

271. Physicians’ Referrals, 69 Fed. Reg. at 16,100.

272. *Id.* at 16,117.

273. *Id.* at 16,103.

274. *See id.* at 16,143.

275. *Id.* at 16,106.

276. 42 C.F.R. § 411.354(c)(2) (2005); Physicians’ Referrals, 69 Fed. Reg. at 16,058.

277. Physicians’ Referrals, 69 Fed. Reg. at 16,058.

278. *Id.* For example, in equipment leasing company joint venture entities. *Id.*

279. *See* 42 C.F.R. § 411.354(c)(3).

physicians to be carefully scrutinized for compliance with the statute and implementing regulations.

Although CMS created new exceptions that incorporate two of the federal Fraud and Abuse Anti-Kickback safe harbors, providers are cautioned to continue to carefully distinguish between the prohibitions of Stark II and the proscriptions contained in the Anti-Kickback Law. Stark II is a bright-line civil statute in which compliance is mandatory or a physician's referrals and ensuing billings are illegal. The Anti-Kickback Law is a criminal law, which encompasses more than physician referrals but is violated only when criminal intent exists to offer, pay, solicit, or receive remuneration in exchange for or to induce any services payable under government health care programs.

