

SURVEY OF RECENT DEVELOPMENTS IN HEALTH CARE LAW

JOHN C. RENDER*
NEAL A. COOPER**

Health care in Indiana, as in the rest of the United States, is governed by a dynamic body of law, both state and federal, covering a vast number of topics. Indeed, this 2003 survey discusses disciplines ranging from legislation and litigation to antitrust and immigration, demonstrating the complexities of the practice of health law today.

I. LEGISLATIVE CHANGES

A. Amendments to the Hospital Care for the Indigent Program

Effective July 1, 2003, many important legislative changes were adopted affecting the Hospital Care for the Indigent Program.¹ Most notably, hospitals licensed under section 16-21 of the Indiana Code began on the effective date to file claims with the State Division of Family and Children² (the Division) for payment for emergency care³ rendered to indigent persons.⁴ Physicians⁵ and transportation providers⁶ will continue to file claims as under the former program, but total aggregate payment to these providers shall not exceed \$3 million in any state fiscal year.⁷ Payments made to physicians and transportation providers for services rendered under this program is at the same rate as payment for the same type of services provided for the fee-for-service Medicaid program.⁸ Payment to a hospital under this program is in the form of a Medicaid add-on and is subject to the availability of sufficient Hospital Care for the Indigent property tax levies transferred to the Medicaid Indigent Care Trust Fund to pay the non-federal share of Medicaid payments under the Act.⁹ To be eligible for assistance under this program, a person must be a citizen of the United States or a lawfully admitted alien,¹⁰ whose medical condition necessitates immediate intervention

* Partner, Hall, Render, Killian, Heath & Lyman, P.S.C. B.S., 1966, Butler University; J.D., 1971, Indiana University School of Law—Indianapolis. The authors wish to thank James M. Shafer, Associate, Hall, Render, Killian, Heath & Lyman, P.S.C., and Kevin A. Stella, Associate, Hall, Render, Killian, Heath & Lyman, P.S.C., for their contributions to this Article.

** Associate, Hall, Render, Killian, Heath & Lyman, P.S.C. B.S., Milliken University; J.D., 1998, John Marshall School of Law.

1. *See generally* 2003 Ind. Acts 255 (effective July 1, 2003).

2. IND. CODE § 12-15-15-9(b) (Supp. 2003).

3. *Id.* § 12-16-3.5-1.

4. *Id.* § 12-16-3.5-3.

5. *Id.* § 12-16-6.5-5.

6. *Id.*

7. *Id.* § 12-16-7.5-5.

8. *Id.* § 12-16-9.5-1.

9. *Id.* § 12-15-15-9.5(d).

10. *See id.* § 12-16-7.5-7.

and treatment,¹¹ and who is an indigent person.¹² In determining eligibility, the Division shall examine whether the person is a resident of the state.¹³ If the person is not a resident of the state or if residency cannot be determined, the Division shall determine the county where the onset of the medical condition that necessitated the care occurred.¹⁴

To receive payments under the Hospital Care for the Indigent Program, hospitals, physicians, and transportation providers must file applications with the Division within thirty days after treating the affected person.¹⁵ If assistance is denied, the Division shall notify in writing the person affected by the denial and the hospital, physician or transportation provider, any of whom may appeal the determination within ninety days after the mailing of the notice of an adverse determination.¹⁶ If an appeal is filed, a hearing shall be scheduled and notice shall be served upon all persons interested in the matter at least twenty days prior to the hearing.¹⁷

Among the more important changes to the program is a modification of the methodology used to compute liability for taxes for the Hospital Indigent Care for the counties. For taxes due and payable in 2003, each county shall impose a Hospital Care for the Indigent property tax levy equal to its levy in 2002 multiplied by the county's assessed value growth quotient for taxes due and payable in 2003.¹⁸ For 2004, 2005, and 2006, each county shall impose a Hospital Care for the Indigent property tax levy equal to its levy in the preceding year multiplied by the then current year assessed value growth quotient.¹⁹ For taxes first due and payable in 2007, each county shall impose a Hospital Care for the Indigent tax levy equal to the average annual amount of payable claims attributed to the county during State fiscal years 2004, 2005, and 2006.²⁰

The effect of all these changes in the Hospital Care for the Indigent Program was to establish accountability for providers in rendering care and making claims and to ensure stability of taxation and direct per county accountability for the care of indigent persons.

B. Health Care Provider Billing Practices

Several sections of House Enrolled Act 1407 (1407 Act),²¹ effective January 1, 2004, made important changes to the manner in which hospitals, hospices,

11. *Id.* § 12-16-3.5-1.

12. *Id.* § 12-16-3.5-3.

13. *Id.* § 12-16-5.5-1.

14. *Id.* § 12-16-7.5-4.5(a).

15. *Id.* § 12-16-4.5-2 (pertaining to hospitals); *id.* § 12-16-4.5-8 (pertaining to physicians and transportation providers).

16. *Id.* § 12-16-6.5-1.

17. *Id.* § 12-16-6.5-4.

18. *Id.* § 12-16-14-3(b).

19. *Id.* § 12-16-14-3(c).

20. *Id.* § 12-16-14-3(d).

21. 2003 Ind. Acts 178.

home health agencies, health facilities or ambulatory surgical centers bill patients. The 1407 Act requires that if a patient receives notice concerning a third-party billing for a service provided to the patient, the notice must conspicuously state that it is not a bill.²² Further, the notice may not contain a tear-off portion or a return mail envelope.²³ These provisions are intended to clarify that billing notices should be distinguished from actual billings to prevent confusion for affected patients.

C. Testing for Exposure to Communicable Diseases

Effective July 1, 2003, any patient exposing his or her blood or body fluids to an emergency medical services provider²⁴ is considered to have consented to testing for the presence of a dangerous communicable disease and to releasing the testing results to a medical director²⁵ or physician designated by a medical facility.²⁶ The medical director or physician must notify the emergency medical services provider of the test results.²⁷

If a patient subject to this 1407 Act refuses to provide a blood or body-fluid specimen for testing, the exposed provider, his or her employer, or the State Department of Health may petition the circuit or superior court having jurisdiction in the county of the patient's residence or where the exposed provider's employer has its principal office for an order requiring the patient provide a blood or body fluid specimen.²⁸ The 1407 Act also permits the exposed medical service provider, the provider's employer, or the State Department of Health to petition the circuit or superior court for an order requiring that the patient provide a blood or body fluid specimen in instances when the patient is not in a medical facility.²⁹

If a patient is in a medical facility at the time of exposure or is admitted afterward, a physician designated by the medical facility must order a collection of blood or body fluids and complete testing within seventy-two hours after receiving notice of the exposure.³⁰ The medical director or designated physician must notify the exposed medical services provider of the test results within forty-

22. IND. CODE § 16-21-2-16 (pertaining to hospitals and ambulatory surgical centers); *id.* § 16-25-3-11 (pertaining to hospices); *id.* § 16-27-1-17 (pertaining to home health agencies); *id.* § 16-28-2-10 (pertaining to health facilities).

23. *See* statutes cited *supra* note 22.

24. IND. CODE § 16-41-10-1 (defining medical services provider as a licensed physician or nurse, firefighter, law-enforcement officer, emergency medical technician, or anyone providing emergency medical services in the course of employment).

25. *Id.* § 16-41-10-2.5(a).

26. *Id.*

27. *Id.*

28. *Id.* § 16-41-10-3(a)(2)(B).

29. *See id.* § 16-41-10-3(a)(2)(B); *id.* § 16-41-10-3.5.

30. *Id.* § 16-41-10-3(a)(1).

eight hours of receipt.³¹

A medical facility is not permitted to physically restrain a patient subject to the 1407 Act in order to test the patient for the presence of a dangerous communicable disease.³² In lieu of physical restraints, a medical facility must petition the appropriate circuit or superior court for an order requiring the patient to give a specimen.³³ A provider or facility that tests a patient over the patient's objection or without the patient's consent but pursuant to the 1407 Act is immune from liability for the performance of the test.³⁴ This 1407 Act continues recent policy of the Indiana General Assembly in affording protection to potential victims of dangerous communicable diseases even if a patient's privacy or consent rights are lessened.

D. Indiana Comprehensive Health Insurance Association

Several sections of House Enrolled Act 1749 (1749 Act),³⁵ effective on July 1, 2003, made minimal changes to the Indiana Comprehensive Health Insurance Association,³⁶ usually referred to as ICHIA. ICHIA provides health care insurance coverage to persons who are not eligible for Medicaid and cannot obtain commercial health insurance because of a pre-existing condition or chronic disease or illness. Persons of any age or financial condition may be eligible if they have been rejected for insurance coverage.³⁷ Funding for ICHIA comes from assessments on health insurers and from premiums from enrolled insureds.³⁸

Included in the changes to ICHIA is a new definition of "eligible resident" which is an individual legally domiciled in Indiana for at least twelve months before applying for ICHIA coverage or a federally eligible individual legally domiciled in Indiana.³⁹ New premium rates have been authorized whereby persons whose family income is less than 351% of the federal income poverty level will be charged not more than 150% of the average premium rate charged by the five carriers with the largest premium volume in the state for an insured in the same class.⁴⁰ For those persons whose family income exceeds 351% of the federal income poverty level, they will be charged a premium between 151% and 200% of that charged by the five carriers with the largest premium volume in the

31. *Id.* § 16-41-10-3(c).

32. *Id.* § 16-41-10-3(a).

33. *Id.* § 16-41-10-2.5(b).

34. *Id.* § 16-41-10-3.5(c) (noting, however, that immunity does not apply to acts or omissions that constitute gross negligence or willful or wanton misconduct).

35. 2003 Ind. Acts 193.

36. IND. CODE § 27-8-10-2.1(a).

37. *Id.* § 27-8-10-1(j) (defining a federally eligible individual).

38. *See id.* § 27-8-10-2.1(f) (requiring an actuarial recommendation in developing member assessments); *id.* § 27-8-10-2.1(g) (describing the methodology for premium determination).

39. *Id.* § 27-8-10-1(z).

40. *Id.* § 27-8-10-2.1(g).

state for an insured in the same class.⁴¹

Until March 15, 2004, assessments on health insurers to fund ICHIA will require that fifty percent of the program's net annual loss be assessed against health insurers based on an insurer's premiums in proportion to the total health insurance premiums paid in the state during the same period.⁴² The remaining fifty percent of the program's net annual loss will be assessed based on the insurer's number of insured individuals in proportion to the total number of insured individuals in the state during the same period.⁴³ The 1749 Act also permits the ICHIA Board and the Office of Medicaid Policy and Planning⁴⁴ to attempt to obtain additional federal Medicaid payments for health care providers that provide services to ICHIA enrollees.⁴⁵ The current assessments of the ICHIA program would provide the state share of revenue required for additional Medicaid funding.⁴⁶ Payment to providers of services to ICHIA enrollees is limited under the 1749 Act to that amount paid by Medicare for the same services, plus ten percent.⁴⁷

II. FRAUD AND ABUSE

A. Office of Inspector General Semiannual Report

On December 3, 2003, the Office of Inspector General (OIG), the enforcement arm of the Department of Health and Human Services (DHHS), issued its semiannual report to Congress for the period of April through September 2003.⁴⁸ In its report, OIG indicated that its operations resulted in savings of over \$23 billion, including \$1.393 billion in audit receivables, additional recoveries, and investigative receivables.⁴⁹ OIG also reported that it had excluded 3275 individuals or entities for Medicare and Medicaid fraud or abuse, convicted 576 individuals or entities of crimes against federal health care programs, and initiated 243 civil actions under the False Claims Act (FCA),⁵⁰ civil monetary penalty law, claims alleging unjust enrichment, and administrative recoveries related to providers' self-disclosures.⁵¹ The report highlights several

41. *Id.*

42. *Id.* § 27-8-10-14.

43. *Id.*

44. *See* IND. CODE § 12-8-6-1 (2002) (establishing the Office of Medicaid Policy and Planning).

45. IND. CODE § 27-8-10-12 (Supp. 2003).

46. *Id.* § 12-15-15-9.6(8).

47. *Id.* § 27-8-10-12.

48. U.S. DEP'T OF HEALTH AND HUMAN SERVS., 2003 OFFICE OF INSPECTOR GEN. SEMIANN. REP. TO THE CONGRESS [hereinafter HHS SEMIANN. REP.].

49. *Id.* at 46, 51, 55.

50. 31 U.S.C. §§ 3729-3733 (1994).

51. HHS SEMIANN. REP., *supra* note 48, at 14, 51.

areas of intense OIG activity, including prescription drugs,⁵² nursing home complaints and staff credentialing,⁵³ issues regarding organ donation,⁵⁴ Medicaid access for foster children,⁵⁵ bioterrorism preparedness,⁵⁶ and hospital short stay patients transferred to post acute care settings.⁵⁷ Deputy Inspector General Dara Corrigan indicated that current fiscal year savings represented a record high for the OIG.⁵⁸

The semiannual report was preceded by the OIG's work plan for fiscal year 2004.⁵⁹ According to its work plan, the OIG plans to focus its efforts primarily on Medicare issues. As in most years, the fiscal year 2004 work plan indicates that the OIG will review Medicare contractor performance.⁶⁰ Medicare fiscal intermediaries and carriers, those responsible for processing Medicare claims and Medicare cost reports, will be subject to recommendations and corrective actions where appropriate.⁶¹

OIG will also focus on nursing home issues in fiscal year 2004, including quality of care, state compliance with nursing home complaint investigation guidelines, and effectiveness of CMS and state enforcement actions against noncompliant nursing homes.⁶² For hospitals, OIG will continue an investigation into hospital inpatient outlier claims to determine whether such claims were submitted according to Medicare rules and to identify program vulnerabilities with regard to outlier payments, and will also extend the outlier investigation to the Medicaid program.⁶³ OIG will also look at the inpatient prospective payment system rates to determine whether the market basket updates used in computing those rates are sufficient and equitable.⁶⁴

Durable medical equipment will continue to be a focus of the OIG in 2004, including the continuing investigation into power wheelchairs and other high cost items.⁶⁵ OIG will also investigate whether DME suppliers are appropriately using and maintaining certificates of need in accordance with local law (which are not presently required in the State of Indiana), and whether documentation in support of claims for DME support medical necessity and demonstrate the

52. *Id.* at 19, 20.

53. *Id.* at 34.

54. *Id.* at 29.

55. *Id.* at 36.

56. *Id.* at 28.

57. *Id.* at 4.

58. *Id.* at introduction.

59. U.S. DEP'T OF HEALTH & HUMAN SERVS., WORK PLAN: FISCAL YEAR 2004, OFFICE OF INSPECTOR GENERAL.

60. *Id.* at 21.

61. *Id.*

62. *Id.* at 8.

63. *Id.* at 2.

64. *Id.* at 1.

65. *Id.* at 14.

items to be reasonable and necessary.⁶⁶

A significant component of the fiscal 2004 work plan focuses on Medicaid drug pricing. OIG will audit and evaluate physician acquisition costs for Medicaid prescription drugs, particularly looking into the amount below average wholesale price that doctors pay for drugs.⁶⁷ OIG will also compare average manufacturer prices with average wholesale prices, and evaluate trends in drug rebate programs in compliance with drug rebate pricing laws.⁶⁸ Finally, OIG will investigate the effects that new versions of existing drugs have on the Medicaid drug rebate program, assessing the adequacy of drug manufacturers' calculations of average manufacturers' prices and best prices, and uncollected drug rebates billed to drug makers.⁶⁹

B. Developments in the FCA

The FCA has become an extremely important weapon in the fight against Medicare and Medicaid fraud and abuse. In particular, the statutory requirement that a portion of any recoveries in an FCA case brought as a private right of action should be paid to a whistle blower or *qui tam* relator⁷⁰ has catalyzed an enormous volume of private suits brought on behalf of the government. This section will highlight some of the more notable developments in FCA litigation.

1. *Implied Certification*.—During the survey period, courts have evaluated a theory of liability dubbed “implied false certification,” which expands upon the “false certification” theory of FCA liability.⁷¹ The false certification theory is based on the fact that Medicare and Medicaid claims include certifications from the claimant that it will comply with applicable law.⁷² For example, the standard form for submitting Medicare and Medicaid claims for physicians' services expressly states:

I certify that the services shown on this form were medically indicated and necessary for the health of the patient and [sic] were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision. . . . No Part B Medicare benefits may be paid unless this form is received as required by existing law and regulations.⁷³

The false certification theory suggests that a health care provider may be liable under the FCA if the claim includes a knowingly false certification that the

66. *Id.*

67. *Id.* at 28.

68. *Id.*

69. *Id.* at 29.

70. 31 U.S.C. § 3730(d) (1994).

71. *United States ex rel. Mikes v. Straus*, 274 F.3d 687, 696 (2d Cir. 2001).

72. 42 C.F.R. § 424.32 (2003); *see Mikes*, 274 F.3d at 698 (“An expressly false claim . . . falsely certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment.”).

73. Form CMS-1500, available at <http://www.cms.hhs.gov/providers/edi/cms1500.pdf>.

claimant complied with applicable statutes and regulations, even if the allegedly false claim accurately reflects the applicable services and fees and does not otherwise contain untrue statements.⁷⁴ Liability under the false certification theory only attaches, however, if the government would not have paid the claim had it known of the underlying violation of law.⁷⁵ The theory assumes that the health care provider is aware of all applicable law with respect to the right to payment under a claim, and that based on that assumed body of knowledge is guilty of fraud if it submits a claim in violation of any applicable law.⁷⁶

“*Implied* false certification” takes the false certification theory further, suggesting that a claimant can be liable under the FCA for submitting a facially accurate and true claim for which it failed to comply with all applicable laws and

74. *Id.*; *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266-67 (9th Cir. 1996). Violations of laws, rules, or regulations alone do not create a cause of action under the FCA. It is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit. . . . “The heart of fraud is an intentional misrepresentation. A violation of a regulatory provision, in the absence of a knowingly false or misleading representation, does not amount to fraud.”

Id. (citations omitted).

75. *Mikes*, 274 F.3d at 697.

[A] claim under the Act is legally false only where a party certifies compliance with a statute or regulation as a condition to governmental payment. *See United States ex rel. Siewick v. Jamieson Sci. & Eng’g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000) (“[A] false certification of compliance with a statute or regulation cannot serve as the basis for a *qui tam* action under the [FCA] unless payment is conditioned on that certification.”); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d [776], 786-87, 793 [(4th Cir. 1999)]; *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997); *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266-67 (9th Cir. 1996).

Id.

76. *But see United States ex rel. Perales v. St. Margaret’s Hosp.*, 243 F. Supp. 2d 843 (C.D.

Ill. 2003):

Mere non-compliance with a statute or regulation, in the absence of a false certification, is insufficient to constitute a false statement within the meaning of the FCA. . . . “The Supreme Court has cautioned, however, that the FCA is not designed to punish every type of fraud committed upon the Government.” . . . The FCA is not intended “to operated [sic] as a stalking horse for enforcement of every statute, rule, or regulation.” . . . To hold that the mere submission of a claim for payment, without more, always constitutes an “implied certification” of compliance with the conditions of the Government program seriously undermines this principle by permitting FCA liability potentially to attach every time a document or request for payment is submitted to the Government, regardless of whether the submitting party is aware of its non-compliance. While ignorance of the law is usually no excuse to justify one’s actions, the FCA requires that a false statement be made with actual knowledge, deliberate ignorance, or reckless disregard of the statement’s falsity.

Id. at 865-66 (citations omitted).

regulations affecting the right to receive payment under the claim, even where no express certification is made.⁷⁷ Importantly, the theory has been limited to instances in which the claimant allegedly violated a law upon which payment was conditioned.⁷⁸ Several decisions in 2003 support such a limitation.⁷⁹ Whether

77. *Mikes*, 274 F.3d at 700 (“[I]mplicitly certified compliance with a particular rule as a condition of reimbursement [should apply only] in limited circumstances.”); *see also* *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, *7 (D. Mass. 2003) (“The Court agrees with the government that recent caselaw supports implied-certification FCA claims in the healthcare context, including kickback-based claims.”).

78. *Mikes*, 274 F.3d at 700 (“Specifically, implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies expressly states the provider must comply in order to be paid.”); *see also* *United States ex rel. Willard v. Humana Health Plan Inc.*, 336 F.3d 375, 382 (5th Cir. 2003) (stating “the critical point is that an action on which payment was conditioned had not been performed.”). The *Willard* court noted that:

Other circuits that have recognized the “implied certification” theory have also set forth this requirement. *See* *United States ex rel. Augustine v. Century Health Svs., Inc.*, 289 F.3d 409, 415 (6th Cir. 2002); *Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001); *United States ex rel. Siewick v. Jamieson Sci. & Eng’g, Inc.*, 214 F.3d 1372, 1376 (D.C. Cir. 2000).

Id. at 382. The *Willard* court, however, decided that it “need not determine here whether it will recognize the ‘implied certification’ theory, because even if assuming for the sake of argument we were to apply such a theory here, Willard would still lack a cognizable claim” *Id.* at 382. The court further noted that the plaintiff “failed to allege facts that would show that [the government] conditioned its payment to Humana on any implied certification of compliance with the anti-discriminatory regulations . . . [, and that the plaintiff failed to allege] facts sufficient to reflect that there was any regulatory violation.” *Id.* at 382-83.

79. *United States ex rel. Coppock v. Northrup Grumman Corp.*, 2003 WL 21730668, at *11 (N.D. Tex. 2003) (“As the court recognized [previously], certification, whether implied or express, must be a prerequisite to a received benefit before it can be considered legally false.”); *see also* *United States ex rel. Gross v. AIDS Research Alliance-Chicago*, 2003 WL 22508153, at *3 (N.D. Ill. 2003) (“Where plaintiffs rely on technical violations to support a false certification FCA claim, the Seventh Circuit has required them to demonstrate some motive for the alleged deception.”); *United States ex rel. Cooper v. Gentiva Health Servs., Inc.*, 2003 WL 22495607, at *8 (W.D. Pa. 2003) (“[T]he implied certification theory applies ‘only when the underlying . . . regulation . . . expressly states [that] the provider must comply in order to be paid.’” (citation omitted)); *United States ex rel. Graves v. ITT Educ. Servs., Inc.*, 284 F. Supp. 2d 487, 497 (S.D. Tex. 2003) (“The Fifth Circuit, with the Second, Fourth, Ninth, and District of Columbia Circuits, has held that a claim under the [FCA] is ‘legally false’ only where a party affirmatively certifies compliance with a statute or regulation as a condition to receiving governmental payment or property.”); *United States ex rel. McCabe v. Lincoln Tech. Inst., Inc.*, 2003 WL 22474586, at *3 (N.D. Tex. 2003) (“The Fifth Circuit has not addressed whether it will recognize the ‘implied certification theory.’ However, as this Court previously recognized, under either implied or express certification theories, the certification must be a prerequisite to receive the government benefit in order to be legally false.” (citations omitted)). “The critical question is whether the certification of compliance with a particular regulation or statute was a condition for payment by the government.” *Id.* at *4.

payment is conditioned on compliance with any given law suggests that a materiality standard applies to false certification and implied false certification allegations.

2. *Materiality*.—The plain language of the FCA does not state that materiality of the alleged falsehood should play a role in applying the FCA.⁸⁰ The FCA does require, however, that a defendant must have knowingly submitted a false claim, and further must have *knowingly* intended to commit fraud against the government.⁸¹ Recent cases have indicated that the law allegedly violated must be material to the provider's right to receive payment—that the government would not have paid the claim were it aware of the violation.⁸² Thus, courts are increasingly using a materiality requirement to evaluate the falsehood underlying the alleged violation. The consensus among courts examining the issue is that the fact that a claimant makes a claim false must be material to the claimant's right to receive payment from the government, and that the government would not have paid the claim were it aware of the false fact.

80. 31 U.S.C. §§ 3729 (1994).

81. *Id.* § 3729(a).

82. *United States ex rel. Barrett v. Columbia/HCA Healthcare Corp.*, 251 F. Supp. 2d 28, 33 (D.D.C. 2003) ("The implied certification theory essentially requires a materiality analysis. Certification of compliance with the statute or regulation alleged to be violated must be so important to the contract that the government would not have honored the claim presented to it if it were aware of the violation."); *United States ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 614 (N.D. Ill. 2003).

To succeed, Bidani must show that the alleged AKS violation was material to the government's treatment of defendants' Medicare claims. . . . Courts have split over whether the FCA materiality element requires a showing of outcome materiality . . . or claim materiality. . . . In addressing this issue the Seventh Circuit leans toward an outcome materiality definition, stating that an omission must be "material to the government's buying decision."

Id.; *Coppock*, 2003 WL 21730668, at *11 ("[C]ertification, whether implied or express, must be a prerequisite to a received benefit before it can be considered legally false. . . . 'Mere regulatory violations do not give rise to a viable FCA action . . . where regulatory compliance was not a *sine qua non* of receipt of [benefit].'" (citation omitted)); *United States ex rel. Costner v. United States*, 317 F.3d 883, 887 (8th Cir. 2003).

Although we have not heretofore directly considered whether a materiality element is implicit in the Act, we have stated that the Act provides recovery from one "who makes a material misrepresentation to avoid paying some obligation owed to the government."

Moreover, our decision in *Rabushka ex rel. United States v. Crane Co.* suggests that outcome materiality is the proper standard.

Id.; *Gross*, 2003 WL 22508153, at *2 ("Only statements that are materially false when made can be fraudulent. . . . There can be no 'fraud in hindsight,' and innocent mistakes and negligence are not actionable." (citations omitted)). The Fifth Circuit has decided a FCA case, not in the health care context, determining that a false statement must be material, and the falsity must have been such that it would negate the claimant's right to be paid, before the false statement is actionable under the FCA. *United States v. Southland Mgmt. Corp.*, 326 F.3d 669 (5th Cir. 2003).

Inextricably linked to the materiality of the alleged falsehood is the defendant's knowledge and intent: if the defendant did not know of the falsity of the claim, and did not intend to defraud the government, there can be no false claim.⁸³ The thrust of the cases following this logic is that the FCA is a fraud statute, and if the defendant did not knowingly intend to commit fraud then there can be no violation.⁸⁴

3. *Pleading by Example.*—Another interesting development in the FCA deals with the extent of the plaintiff's knowledge. A whistleblower, a person who brings suit on behalf of the government, may allege that a health care provider submitted a volume of false claims based on a limited number of examples, which is permissible under the Federal Rules of Civil Procedure.⁸⁵ A plaintiff's right to plead by example must be balanced with the pleading requirements of Rule 9(b).⁸⁶ Rule 8⁸⁷ allows a plaintiff to allege multiple false claims based on one or more examples *if the plaintiff has personal knowledge of the multiple claims*, while Rule 9(b) requires that in "all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity."⁸⁸ Claims about which the plaintiff has no personal knowledge cannot be stated with particularity, and thus the plaintiff can only satisfy the pleading requirements of Rule 9(b) with respect to the example or examples. Some relators have sought to plead vast numbers of claims by example without the requisite knowledge, often to gain access through the discovery process to the goldmine that is a provider's patient records and banking on the fact that discovery into the provider's records will reveal other false claims upon which to build a stronger case.⁸⁹ "[A]lthough Yuhasz argues that he cannot obtain the information demanded by the trial court absent discovery, 'there is no general right to discovery upon filing of the complaint. The very purpose of Fed.R.Civ.P.

83. 31 U.S.C. § 3729(a) (1994); *see, e.g., Gross*, 2003 WL 22508153, at *2-3; *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 769 (N.D. Tex. 2003).

[M]ost Courts, including those in the Fifth Circuit, require a fourth element: materiality.

"Liability for both a 'false claim' and a 'fraudulent claim' implicitly requires a showing that what makes the claim either false or fraudulent is material to the asserted claim of entitlement to receive money or property from the government."

Id. (citing *United States ex rel. Wilkins v. North Am. Constr. Corp.*, 173 F. Supp. 2d 601, 619 n.10 (S.D. Tex. 2001)). "After reviewing the case precedent, the [c]ourt concludes that materiality is a necessary element of a cause of action under the FCA." *Medica-Rents*, 285 F. Supp. 2d at 769 n.62.

84. *Medica-Rents*, 285 F. Supp. 2d at 769 n.2; *see Costner*, 317 F.3d at 887-88; *United States ex rel. Watson v. Conn. Gen. Life Ins. Co.*, 2003 WL 303142 (E.D. Penn. 2003).

85. FED. R. CIV. P. 8; *see also United States ex rel. Harris v. Bernad*, 275 F. Supp. 2d 1, 8-9 (D.D.C. 2003); *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46-47 (D. Mass. 2001).

86. FED. R. CIV. P. 9(b).

87. FED. R. CIV. P. 8.

88. FED. R. CIV. P. 9(b); *see Harris*, 275 F. Supp. 2d at 8-9; *Franklin*, 147 F. Supp. 2d at 46-47.

89. *See, e.g., Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559 (6th Cir. 2003).

12(b)(6)' is to enable defendants to challenge the legal sufficiency of complaints without subjecting themselves to discovery."⁹⁰ Such a "fishing expedition" is not supported by the Federal Rules of Civil Procedure, and has been rejected by various courts during the survey period.⁹¹

90. *Id.* at 566 (citation omitted).

91. *United States ex rel. Barmak v. Sutter Corp.*, 2003 WL 21436213, at *6 (S.D.N.Y. 2003). To hold otherwise would open the court's [sic] to a raft of baseless fraud suits brought by outsiders solely on the hope and expectations of finding something to justify a recovery. The smear of fraud on the good name of those innocent defendants could neither be erased nor compensated. Relator's outsider status is not a recognized exception to requirements of Rule 9(b).

Id.; see *United States ex rel. Doe v. Dow Chem. Co.*, 343 F.3d 325, 328 (5th Cir. 2003) ("Claims brought under the FCA must comply with Federal Rule of Civil Procedure 9(b), which requires pleading with particularity in cases alleging fraud."); *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 342 F.3d 634, 641 (6th Cir. 2003) ("We recently held in a published case that a complaint alleging FCA violations must allege the underlying facts with particularity as required by Rule 9(b)."); *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 376 (7th Cir. 2003) ("These rules [9(b) and 8(a)] are not in conflict; it is possible to write a short statement narrating the *claim*—which is to say, the basic grievance—even if Rule 9(b) requires supplemental particulars."); *United States v. Cancer Treatment Ctrs.*, 2003 WL 21504998, at *2 (N.D. Ill. 2003).

And fraud must be pleaded with particularity. But the breadth of the claims may be such that alleging all the "who, what, when and where" of the claims would lead, ultimately, to an extremely long, complex and incomprehensible complaint. Still, a *qui tam* action is not a roving commission to investigate all the financial dealings of the defendants. . . . Here, the relator has alleged some specific examples. That saves the complaint from total dismissal. In other allegations there are no specific examples, or examples alleged are somewhat general or lack the who or the when. Relator contends she can add details as necessary and talks about filing another amended complaint. We think the better way to proceed is by tailoring discovery to the specificity of the claims

Id.; *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 2003 WL 21228801, at *4, *9 (D. Mass. 2003).

Even where allegations are based on information and belief, however, "claims . . . of fraud may not be based upon speculation or conclusory allegations," but fact. [A] "complaint demonstrates the proposition that a 'complaint can be long-winded, even prolix, without pleading with particularity. Indeed, such a garrulous style is not an uncommon mask for an absence of detail.'"

Id. (citation omitted); *United States ex rel. Stewart v. La. Clinic*, 2003 WL 21283944, at *9 (E.D. La. 2003) ("The district judge specifically held that relators had been given ample opportunity to identify fraud, noted that the balance of the equities in this case weigh against further leave to amend, and proscribed further proceedings bent on 'finding fraud during the discovery process.'"); see also *Yuhasz*, 341 F.3d at 563 ("The requirement that fraud be plead with particularity need not be relaxed in FCA cases in order to protect the public because the government's ability to intervene on the basis of information brought to its attention vindicates the public interest."); *Watson*, 2003 WL 303142, at *9.

4. *Erosion of Sovereign Immunity*.—Governmental defendants have argued that governments are not “persons” within the meaning of the FCA, and because the FCA provides for treble damages,⁹² such damages further punitive objectives and thus are not applicable to governmental defendants.⁹³ The U.S. Supreme Court decided, in 2000, that the Vermont Agency of Natural Resources, as a state body, was a not “person” within the meaning of the FCA.⁹⁴ The decision was based, in part, on the punitive character of the treble damages provision.⁹⁵ Based on the Supreme Court’s 2000 decision, Cook County, Illinois, sought dismissal of a whistleblower’s FCA suit in 2003.⁹⁶

The Supreme Court held that local governments are “persons” subject to the FCA on the rationale that corporations are “persons” within the meaning of the FCA; at the time the FCA was enacted, municipal corporations existed; and the legislative history behind the FCA contains no mention of an exclusion of municipalities from the class of “persons” covered by the Act.⁹⁷ Thus, the Court ruled, a county municipal corporation is a person under the FCA.⁹⁸ A state, however, is not a municipal corporation, the Court noted in distinguishing *Chandler* from *Stevens*.⁹⁹

Contrasting the potentially punitive nature of remedies under the FCA with the exclusively punitive nature of traditional punitive damages, the Supreme Court disagreed with the County that FCA damages do not apply to a county. The Court noted that a judge, not a jury, will determine the ultimate amount to be awarded in a FCA case, and thus the judge can ensure that the municipality will not be subject to unlimited punitive damages.¹⁰⁰ Furthermore, the Court dismissed the argument that local taxpayers will ultimately pay the punitive damages by finding that “[t]his very case shows how FCA liability may expose only local taxpayers who have already enjoyed the indirect benefit of the fraud, to the extent that the federal money has already been passed along in lower taxes or expanded services.”¹⁰¹ The Supreme Court thus affirmed the Seventh Circuit’s decision that municipal corporations constitute persons for purposes of the FCA.¹⁰²

92. 31 U.S.C. § 3729(a)(7) (1994).

93. See *Cook County v. United States ex rel. Chandler*, 538 U.S. 119 (2003).

94. *Vt. Agency of Natural Res. v. United States ex. rel. Stevens*, 529 U.S. 765 (2000).

95. *Id.* at 784.

96. *Chandler*, 538 U.S. at 119.

97. *Id.* at 128-29.

98. *Id.* at 134.

99. *Id.* at 130.

100. *Id.* at 132; 31 U.S.C. § 3729(a) (1994).

101. *Chandler*, 538 U.S. at 132.

102. *Id.* at 122 (“[T]he question is whether local government are amenable to such suits, and we hold that they are.”). The Supreme Court in *Chandler* stated as follows:

While § 3729 does not define the term “person,” we have held that its meaning has remained unchanged since the original FCA was passed in 1863. There is no doubt that the term then extended to corporations, the Court in 1826 having expressly recognized

5. *Qui Tam Relator's Statutory Share*.—The Sixth Circuit Court of Appeals recently ruled in support of a *qui tam* relator seeking payment from the federal government's recovery against Community Health Systems, Inc.¹⁰³ Sean Bledsoe had filed a *qui tam* action against Community Health Systems, Inc. (CHS) related to Medicare and Medicaid billing.¹⁰⁴ The government declined intervention in Bledsoe's case, but thereafter filed a separate suit against CHS based on the same facts that Bledsoe raised in his original complaint.¹⁰⁵ CHS ultimately settled the government's suit for nearly \$31 million.¹⁰⁶ The government declined to provide Bledsoe with a statutory share of 15 to 30% of the proceeds obtained by the government.¹⁰⁷ The government contended that the relator's complaint was materially defective, did not plead with particularity the facts supporting relators' claims and did not constitute an original source of information upon which the government based its own FCA complaint.¹⁰⁸

The court ruled that the statutory language of the FCA speaks directly to the question at bar: "If any such remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section."¹⁰⁹ Notwithstanding the government's right to intervene in a *qui tam* relator's suit, the government may elect to pursue its claim through any alternate remedy

the presumption that the statutory term "person" extends as well to persons politic and incorporate, as to natural persons whatsoever. . . . Essentially conceding that private corporations were taken to be persons when the FCA was passed in 1863, the County argues that municipal corporations were not so understood until six years later, when *Cowles v. Mercer County*, 7 Wall. 118, 19 L.Ed.86 (1868), applied the *Letson* rule to them. *Cowles*, however, was not an extension of principle but a natural recognition of an understanding going back at least to Coke, *supra*, that municipal corporations and private ones were simply two species of "body politic and corporate," treated alike in terms of their legal status as persons capable of suing and being sued. . . . Indeed, "[t]he archetypal American corporation of the eighteenth century [was] the municipality"; only in the early nineteenth century did private corporations become widespread.

Id. at 125-27 (citations omitted); *see also* *Donald v. Univ. Bd. of Regents*, 329 F.3d 1040, 1044 (9th Cir. 2003) ("[W]e are persuaded that the Court's holding in *Stevens*--that a private party may not bring a *qui tam* action against a state entity under § 3729(a) of the FCA—forecloses the relator's § 3730(d)(1) claim to a share of the proceeds from the government's settlement with the Regents."); *United States v. Hickman County, Tenn.*, 60 Fed. Appx. 569, 570, 2003 WL 1465335 (6th Cir. 2003) ("[L]ocal governments are considered persons under the FCA and the potential remedy of treble damages does not preclude recovery against a county government."); *United States ex rel. Sarasola v. Aetna Life Ins. Co.*, 319 F.3d 1292 (11th Cir. 2003).

103. *United States ex rel. Bledsoe v. Cmty. Health Sys., Inc.*, 342 F.3d 634 (6th Cir. 2003).

104. *Id.* at 637.

105. *Id.*

106. *Id.* at 639.

107. *Id.* at 639-40; 31 U.S.C. § 3730(d) (1994).

108. *Bledsoe*, 342 F.3d at 643, 646.

109. 31 U.S.C. § 3730(c)(5).

available to the government, including any administrative proceeding to determine a civil monetary penalty.¹¹⁰ The court deemed the government's independent settlement negotiations with the defendant CHS to be such an alternate remedy, entitling the relator to his statutory share.¹¹¹ "We hold that 'alternate remedy' refers to the government's pursuit of any alternative to intervening in a relator's *qui tam* action."¹¹² The circuit court remanded the case to the district court to determine the appropriate amount of the \$31 million recovery to be paid to Bledsoe.¹¹³

III. PRIVACY

A. Privacy Legislation

The Centers for Medicare and Medicaid Services (CMS) issued answers to frequently asked questions about the Health Insurance Portability and Accountability Act of 1996 (HIPAA)¹¹⁴ Privacy Rule¹¹⁵ that offered some insight as to how the Privacy Rule would be interpreted.¹¹⁶ The Department of Health and Human Services (HHS) issued the first installment of its so-called Enforcement Rule on April 17, 2003, effective until September 2004,¹¹⁷ which established rules of procedure under which the Secretary of HHS may impose civil money penalties on entities that violate HIPAA privacy regulations.¹¹⁸ Compliance with the Transactions Rule¹¹⁹ was originally required by October 16, 2003, but on July 24, 2003, CMS issued guidance effectively giving covered entities more time to comply.¹²⁰ The guidance indicated that covered entities could continue to send and accept non-HIPAA standard transactions without the fear of fines or penalties as long as they could show a good faith effort to become

110. *Bledsoe*, 342 F.3d at 647.

111. *Id.* at 651.

112. *Id.* at 647.

113. *Id.* at 651.

114. Health Insurance Portability and Accountability Act, Pub L. No. 104-191, 110 Stat. 1936 (1996) (codified in scattered sections of 26 U.S.C., 29 U.S.C., and 42 U.S.C.).

115. Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,461 (Dec. 12, 2000) (codified at 45 C.F.R. pts. 160, 164).

116. See <http://answers.hhs.gov> for the FAQ's.

117. Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings, 68 Fed. Reg. 18,895 (Apr. 17, 2003) (to be codified at 45 C.F.R. pt. 160).

118. 45 C.F.R. § 160.500 (2003).

119. Health Insurance Reform: Standards for Electronic Transactions, 65 Fed. Reg. 50,312 (Aug. 17, 2000) (to be codified at 45 C.F.R. pts. 160, 162).

120. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE ON COMPLIANCE WITH HIPAA TRANSACTIONS AND CODE SETS; AFTER THE OCTOBER 16, 2003, IMPLEMENTATION DEADLINE, (2003), available at <http://www.cms.hhs.gov/hipaa/hipaa2/education/guidance-final.pdf>.

compliant.¹²¹ The Indiana Health Records Act¹²² was amended to control disclosures of patient information consistent with the analogous provisions of HIPAA.¹²³

B. Mental Health

The Indiana Court of Appeals recently decided *In re Commitment of Berryman*,¹²⁴ which determined the extent to which a defendant in a murder case has a right to maintain confidentiality of mental health records. Alan Lee Berryman was found not responsible for the murder of Keith Krieger by reason of insanity.¹²⁵ Berryman was subsequently involuntarily committed to Logansport State Hospital pursuant to the Voluntary and Involuntary Treatment of Mentally Ill Individuals Act.¹²⁶ Within the commitment order was a requirement that, pursuant to the Act, the Logansport State Hospital's superintendent or Berryman's attending physician would provide the State with 20 days notice of Berryman's discharge, and with any reviews of Berryman's care and treatment pursuant to the Act.¹²⁷ The superintendent or attending physician was also required to file quarterly reviews of Berryman's treatment with the trial court, and to provide notice to the State of those reviews.¹²⁸ An amendment to the commitment order also required the superintendent or attending physician to provide notice of Berryman's discharge to Teresa Krieger, Keith's surviving spouse.¹²⁹

Berryman brought this case after the trial court granted the State's motion to disseminate the quarterly reviews of his treatment at Logansport State Hospital, which contained confidential mental health records, to Teresa Krieger, a third party.¹³⁰ The appellate court examined the relevant statutory provisions of the Voluntary and Involuntary Treatment of Mentally Ill Individuals Act and the Indiana Health Records Act,¹³¹ as well as the legislative intent behind both Acts.¹³² The court ultimately determined that the trial court's order that Berryman's quarterly reviews be disseminated to Teresa Krieger was deficient for three reasons.¹³³ First, Teresa Krieger herself did not file a petition requesting the release of the mental health records pursuant to the Indiana Health

121. *Id.* at 1.

122. IND. CODE § 16-39-5-3 (2002).

123. 2002 Ind. Acts 44.

124. 797 N.E.2d 820 (2003).

125. *Id.* at 822.

126. IND. CODE § 12-26-7-1 to -5 (2003).

127. *Berryman*, 747 N.E.2d at 822.

128. *Id.*

129. *Id.*

130. *Id.*

131. IND. CODE § 16-39-2-1 to -9.

132. *Berryman*, 797 N.E.2d at 823-24.

133. *Id.* at 825.

Records Act.¹³⁴ Second, the trial court failed to find that other reasonable methods of obtaining these records were unavailable or ineffective, and that Teresa Krieger's need for the information outweighed the potential harm that disclosing his mental health records might cause Berryman.¹³⁵ Third, the trial court's dissemination order did not appropriately limit the disclosure of protected information in Berryman's medical records.

Indiana law requires that the superintendent of the hospital or the attending physician of an individual involuntarily committed for treatment of a mental disorder "shall file with the court a review of the individual's care and treatment."¹³⁶ In addition, the superintendent or attending physician must give notice of the review to the petitioner in the commitment proceeding and to "other persons that were designated by the court . . ."¹³⁷ Nothing in the Voluntary and Involuntary Treatment of Mentally Ill Individuals Act requires the dissemination of the review to the petitioner or other persons designated by the court, but only notice of the review.¹³⁸

The appellate court further noted that, without the consent of a patient, a court order is required for disclosure of the patient's medical record pursuant to the Indiana Health Records Act.¹³⁹ In so doing, the court established a clear legal standard for Indiana courts to use in evaluating whether to disclose a patient's medical records. An individual may petition the court for access to a patient's mental health record and shall be granted a hearing on that petition.¹⁴⁰ The court may find in favor the petitioner only if a preponderance of the evidence supports the conclusion that other reasonable methods of obtaining the information are neither available nor effective, and that the petitioner's need for disclosure outweighs the patient's potential harm.¹⁴¹ In weighing the patient's potential harm, the court considers the impact of disclosure on the physician-patient privilege and the patient's rehabilitative process.¹⁴² In ordering such disclosure, the trial court must protect the confidentiality of the patient's medical records by taking appropriate measures to limit the scope of the disclosure to those parts of the medical record that are essential to satisfy the order's purpose, and to limit dissemination to only those persons whose need for information forms the basis of the order.¹⁴³ Furthermore, the court must provide for any measures necessary to limit disclosure for the protection of the patient, the physician-patient privilege and the patient's rehabilitative process.¹⁴⁴

134. *Id.*

135. *Id.*

136. IND. CODE § 12-26-15-1(a) (1994).

137. *Id.* § 12-26-15-1(b).

138. *Id.*

139. *Berryman*, 797 N.E.2d at 824 (citing IND. CODE § 16-39-2-6 (1993)).

140. *Id.* (citing IND. CODE § 16-39-3-4).

141. *Id.* at 825.

142. *Id.* (citing IND. CODE § 16-39-3-7).

143. IND. CODE § 16-39-3-9.

144. *Id.*

IV. ANTITRUST

A. Price-Fixing

The Federal Trade Commission (FTC) entered into several consent orders during the period under survey, mostly dealing with physician-controlled networks allegedly fixing prices without being financially or clinically integrated. The orders demonstrate the FTC's increasing aggression against messenger-model¹⁴⁵ physician-hospital organizations (PHOs) and independent physician associations (IPAs), and the increasing scope of parties involved in the FTC's inquiries.¹⁴⁶

Recently, the FTC alleged that Carlsbad Physician Association, Inc., a PHO, violated the antitrust laws. The PHO represented approximately 75% of all physicians, and 80% of all primary care physicians, in the Carlsbad, New Mexico market.¹⁴⁷ The PHO was intended to operate a messenger model for its members, but according to a consent decree the entity's only purpose was to allow the member physicians to collectively bargain with health plans in order to obtain "favorable reimbursement" for members' services.¹⁴⁸ This consent order is notable because, in addition to the PHO itself, the organization's executive director and certain members of the Board's contract committee were named and agreed to specific personal obligations and requirements.¹⁴⁹ In addition, the FTC included the unusual requirement that the PHO be dissolved to prevent its misuse in the future.

Two additional consent orders reflect the expanding scope of the FTC's perception of PHO's anticompetitive conduct. The FTC alleged that the Maine Health Alliance and its executive director William R. Diggins operated a PHO network that engaged in anticompetitive collusion and fixed prices in Northeast Maine.¹⁵⁰ The Alliance represented 325 physicians and eleven hospitals, and was involved in contracts for both hospital services and physician services. This is

145. A messenger model network employs a third party to act as a courier of payor offers and physician acceptance or rejection. The courier should be neutral with respect to adequacy of price and related terms. Where the messenger is controlled by its physician members, however, the FTC believes that the messenger's neutrality is compromised and the potential for collusion is heightened. *See generally infra* note 174.

146. As noted by one commenter, "non-integrated, provider-controlled contracting networks purporting to operate as messenger arrangements but which in actuality are fixing prices [must be corrected] so they comply with section 1 of the Sherman Act." John Miles, *Ticking Antitrust Time Bombs: A Message to Messed up Messenger Models*, HEALTH LAWS. NEWS 5 (2002) (discussing the perils messenger models currently face).

147. Carlsbad Physician Ass'n, Inc., 68 Fed. Reg. 25,374 (F.T.C. May 12, 2003) (consent order entered June 13, 2003).

148. *Id.*

149. *Id.*

150. Me. Health Alliance, 68 Fed. Reg. 43,515 (F.T.C. July 23, 2003) (consent order entered Aug. 27, 2003).

a particularly notable consent order because it represents the first FTC action alleging charges that a PHO engaged in price fixing or anticompetitive collusive conduct in the provision of *hospital* services in addition to physician services. Less than two months later, the FTC entered into a similar consent order with South Georgia Health Partners, L.L.C.,¹⁵¹ a PHO, along with its five owner PHO's and three associated IPA's. South Georgia Health Partners represented fifteen member hospitals and approximately 500 physicians (approximately 90% of all physicians) in a large portion of Southern Georgia, and allegedly collectively negotiated contracts for both hospital and physician services.¹⁵² Following the logic in the Maine Health Alliance consent order,¹⁵³ the FTC alleged that the PHO conducted collective negotiations with payors, and that the members refused to deal with payors individually, constituting price-fixing and anticompetitive collusive conduct with respect to both physician and hospital services.¹⁵⁴

In several other actions undertaken during the survey period, the FTC determined that other networks that purported to operate physician-controlled messenger model networks instead served as vehicles for naked price-fixing, including the following:

- (1) SPA Health Organization, a purported messenger model PHO representing approximately 1000 physicians in the Dallas/Fort Worth, Texas area, executed a consent order for alleged anticompetitive collective bargaining as to third-party payor contracts.¹⁵⁵
- (2) The FTC formally charged California Pacific Medical Group, Inc., d/b/a Brown and Toland Medical Group, with anticompetitive conduct and price fixing.¹⁵⁶ Brown and Toland is a multi-specialty IPA with more than 1500 members practicing in the San Francisco, California area.¹⁵⁷ Brown and Toland settled the matter in February, 2004.
- (3) Grossmont Anesthesia Services Medical Group, Inc.,¹⁵⁸ and

151. S. Ga. Health Partners, L.L.C., 68 Fed. Reg. 54,456 (F.T.C. Sept. 17, 2003) (consent order entered Oct. 31, 2003).

152. *Id.*

153. Me. Health Alliance, 68 Fed. Reg. 43,515 (F.T.C. July 23, 2003) (consent order entered Aug. 27, 2003).

154. S. Ga. Health Partners, L.L.C., 68 Fed. Reg. 54,456.

155. SPA Health Org., 68 Fed. Reg. 36,795 (F.T.C. June 19, 2003) (consent order entered July 17, 2003).

156. Cal. Pac. Med. Group, Inc., 69 Fed. Reg. 7,485 (F.T.C. Feb. 17, 2004) (complaint entered July 9, 2003).

157. *Id.*

158. Grossmont Anesthesia Servs. Med. Group, Inc., 68 Fed. Reg. 36,558 (F.T.C. June 18,

Anesthesia Service Medical Group, Inc.,¹⁵⁹ with approximately 180 physicians in San Diego County, California, entered into a consent order with the FTC for purportedly colluding to fix prices against Grossmont Hospital and to extract an on-call stipend for the groups' members.

- (4) The FTC executed a consent order with Washington University Physician Network, a purported messenger-model PHO representing approximately 1500 physicians in greater metropolitan St. Louis, Missouri, for the PHO's alleged price-fixing.¹⁶⁰
- (5) Physician Network Consulting, L.L.C., a negotiating agent for Professional Orthopedic Services, Inc., an IPA, the agent's managing director, the IPA itself (a purported messenger-model network representing 28 orthopedic specialists in the Baton Rouge, Louisiana area), and the IPA's three member physician practices, allegedly engaged in naked price-fixing in negotiations with health insurance payors and other third-party payors.¹⁶¹
- (6) North Texas Specialty Physicians, a group of approximately 600 physicians in the Fort Worth, Texas area, allegedly fixed prices by polling members to determine the minimum acceptable fees each would accept, establishing minimum fees the group would collectively accept based on averages computed from the polling data, and negotiating price and price-related terms on behalf of the member physicians.¹⁶²
- (7) Finally, according to the FTC's consent order, Surgical Specialists of Yakima consisting of two physician groups and 24 physicians practicing in five surgical specialties, representing 90% of all general surgery physicians in the Yakima, Washington area, allegedly engaged in anticompetitive collective bargaining. This consent order is particularly notable in that the FTC required as part of the consent order that the group revoke the membership of its two group practice members.¹⁶³

2003) (consent order entered July 11, 2003).

159. Anesthesia Serv. Med. Group, Inc., 68 Fed. Reg. 36,557 (F.T.C. June 18, 2003) (consent order entered July 11, 2003).

160. Wash. Univ. Physician Network, 68 Fed. Reg. 43,517 (F.T.C. July 23, 2003) (consent order entered Aug. 22, 2003).

161. Physician Network Consulting, L.L.C., 68 Fed. Reg. 44,337 (F.T.C. July 28, 2003) (consent order entered Aug. 27, 2003).

162. N. Tex. Speciality Physicians, No. 9312, 2003 WL 22168992 (F.T.C. Sept. 16, 2003) (complaint issued).

163. Surgical Specialists of Yakima, P.L.L.C., File No. 021 0242, 2003 WL 22225615 (F.T.C.

In each of these cases, the FTC determined that the physicians' practices were not sufficiently financially or clinically integrated to justify the network's collective bargaining on behalf of its physician members. The clinical integration concept was discussed in an FTC advisory opinion issued in response to a request from MedSouth, Inc., a Denver, Colorado IPA.¹⁶⁴ The MedSouth advisory opinion was the first such opinion to approve collective bargaining on the basis of clinical integration. The FTC has not since issued any additional opinions approving a clinically integrated physician practice.

In contrast to the allegations in the FTC consent order with the North Texas Specialty Physicians,¹⁶⁵ the FTC issued an advisory opinion to Bay Area Preferred Physicians regarding the development of a "standing offer" messenger model—the first time the FTC has approved of such an arrangement.¹⁶⁶ In fact, just one week earlier the FTC filed its complaint against North Texas Specialty Physicians for operating an allegedly effective standing offer messenger model network.¹⁶⁷ Six county medical societies in the San Francisco Bay area of Northern California obtained FTC approval to form a nonprofit mutual benefit corporation called Bay Area Preferred Physicians ("BAPP"), representing approximately 1,300 physicians (or roughly 13% of all physicians) practicing in a seven-county region.¹⁶⁸ BAPP will have non-exclusive representation of the participating physicians, allowing them to negotiate individually with payors.¹⁶⁹ Under a traditional messenger model, a messenger is expected to communicate payors' offers to providers and providers' acceptance or rejection back to payors,¹⁷⁰ but BAPP's messenger function will differ from the norm.

The FTC approved a so-called "standing offer" messenger model, in which a BAPP non-physician employee will collect minimum payment information from each physician member individually "in a way that does not suggest the price level that the doctor should select," and will maintain the confidentiality of that information.¹⁷¹ The messenger will have a power of attorney to accept contracts on behalf of any physician where the payor's offer is greater than or equal to the physician's stated minimum, and will provide the remaining network members an opportunity to "opt in" to that contract by delivering the payor's offer to those physicians whose minimum price is greater than that offered by the

Sept. 24, 2003) (consent order).

164. MedSouth, Inc., 2002 WL 463290 (F.T.C. Feb. 19, 2002) (advisory opinion).

165. *N. Tex. Specialty Physicians*, 2003 WL 22168992; *see also* Tenet Healthcare Corp., File No. 0210119, 2003 WL 23025349 (F.T.C. Dec. 22, 2003) (complaint and consent order) (alleging PHO's use of collusive fee schedule constituted price fixing).

166. Bay Area Preferred Physicians, 2003 WL 22207195 (F.T.C. Sept. 23, 2003) (advisory opinion).

167. *N. Tex. Specialty Physicians*, 2003 WL 22168992.

168. *Bay Area Preferred Physicians*, 2003 WL 22207195, at *1, *7.

169. *Id.* at *2.

170. Miles, *supra* note 146, at 6.

171. *Bay Area Preferred Physicians*, 2003 WL 22207195, at *2.

payor.¹⁷² In the event that the offer is equal to or greater than the minimum prices of fewer than 50% of the group's physicians, BAPP's messenger will so notify the payor, and the payor may seek to contract directly with the providers or may increase and resubmit its offer.¹⁷³ Presumably the messenger would also have the authority to inform the payor how many physicians would accept its offer at different price levels (as each price level could be viewed as a separate offer) to facilitate the payor's ability to develop a network panel of sufficient scope to serve its beneficiaries. However, the BAPP advisory opinion is silent on this point.¹⁷⁴

B. Antitrust and Physician Credentialing

In *Poliner v. Texas Health Systems*,¹⁷⁵ a physician's antitrust and unfair practices claims were disposed of on summary judgment.¹⁷⁶ A peer review committee, acting on quality of care concerns, temporarily suspended Dr. Poliner's cardiac catheter lab and echocardiography privileges at Texas Health Systems, d/b/a Presbyterian Hospital of Dallas.¹⁷⁷ Dr. Poliner, alleging anticompetitive conduct, sued the hospital and several physicians who were involved in the peer review process that led to the suspension.¹⁷⁸ The court took notice that the suspension was applicable to Dr. Poliner's privileges at only one of eight hospitals, and found no evidence of conspiracy and, more importantly, no showing of harm to competition in any market.¹⁷⁹ Because Dr. Poliner made no showing that the relevant market should be limited to Presbyterian Hospital of Dallas, or that the named defendants had market power or the ability or opportunity to dominate or monopolize a market broader than the hospital itself, the court ruled that the undisputed facts in the case did not state a case under the antitrust laws.¹⁸⁰

C. "Own-Use" Limitations

In two advisory opinions issued in 2003, *Arkansas Children's Hospital*,¹⁸¹ and *Valley Baptist Medical Center*,¹⁸² the FTC ruled on the applicability of the

172. *Id.*

173. *Id.*

174. *Cf.* U.S. DEP'T OF JUSTICE & FED. TRADE COMM., STMTS. OF ANTITRUST ENFORCEMENT POLICY ON HEALTH CARE 106 (1996), STMT. 9: Enforcement Policy on Multiprovider Networks, available at <http://www.ftc.gov/reports/hlth3s.pdf> (last visited Mar. 16, 2004).

175. No. Civ.A.3:00CV-1007-P, 2003 WL 22255677 (N.D. Tex. Sept. 30, 2003).

176. *Id.* at *2.

177. *Id.*

178. *Id.*

179. *Id.* at *6-7.

180. *Id.* at *7.

181. 2003 WL 1257421 (F.T.C. Mar. 13, 2003) (advisory opinion).

182. 2003 WL 1257423 (F.T.C. Mar. 13, 2003) (advisory opinion).

Non-Profit Institutions Act¹⁸³ (“NPIA”) to hospitals’ sales of pharmaceuticals. The NPIA exempts hospitals and certain other non-profit institutions from the Robinson-Patman Antidiscrimination Act with respect to supplies the institutions purchase for their “own use.”¹⁸⁴ The advisory opinions revisit the seminal Supreme Court decision in *Abbott Laboratories v. Portland Retail Druggists Ass’n*,¹⁸⁵ brought by retail pharmacies alleging unfair competition from a hospital’s discounted resale of pharmaceuticals it purchased at a discount.

As the Court held in *Abbott Labs*, the exception provided under the NPIA is a narrow one and does not apply universally to all of a hospital’s pharmaceutical purchases.¹⁸⁶ The statutory phrase “for its own use” was intended to apply only where pharmaceuticals were purchased for “use *by the hospital* in the sense that such use is a part of and promotes the hospital’s intended institutional operation in the care of persons who are its patients.”¹⁸⁷ Ultimately, the Court held that the exception generally did not apply to drugs the hospital dispensed to walk-in patients, non-hospital patients, and former patients.¹⁸⁸ Thus, a hospital’s purchase of pharmaceuticals for resale to individuals in these categories is not protected under the NPIA.

These FTC advisory opinions addressed new issues relating to hospitals’ sales of pharmaceuticals.

1. *Arkansas Children’s Hospital*.—In the *Arkansas Children’s Hospital* opinion, the FTC addressed a question of first impression as to whether the requesting hospital (Arkansas Children’s Hospital, or “ACH”), a not-for-profit organization, may acquire pharmaceuticals for resale directly to the patients of the University of Arkansas for Medical Services (“UAMS”), which is also not-for-profit.¹⁸⁹ ACH and UAMS are academically affiliated and clinically coordinated, and a significant number of UAMS medical personnel work at ACH.¹⁹⁰ Both ACH and UAMS operate outpatient clinics on the ACH campus, and ownership of these clinics is indistinguishable.¹⁹¹ In addition, a significant number of patients are treated at both ACH and UAMS clinics.¹⁹² Prior to the advisory opinion, ACH only filled prescriptions from ACH physicians; patients seeking to fill prescriptions from UAMS physicians would have to go to the UAMS’ outpatient pharmacy.¹⁹³

The FTC concluded that the ACH pharmacy could acquire pharmaceuticals for resale directly to UAMS physicians’ patients without violating the “own use”

183. 15 U.S.C. § 13(c) (2003).

184. *Id.*

185. 425 U.S. 1 (1976).

186. *Id.* 13-14.

187. *Id.* at 14 (emphasis added).

188. *Id.* at 14-18.

189. 2003 WL 1257421, at *1 (F.T.C. Mar. 13, 2003) (advisory opinion).

190. *Id.*

191. *Id.*

192. *Id.*

193. *Id.*

requirement of the NPIA.¹⁹⁴ Because of the transparent ownership distinctions between ACH and UAMS clinics and common purpose to care for the same patient population, and recognizing the inconvenience and confusion to the patients caused by ACH's pharmacy's prohibition against prescriptions written by UAMS physicians, the FTC concluded that the parties had formed "a joint venture to care for pediatric patients at the full range of outpatient clinics operated on the ACH campus."¹⁹⁵ Although the facts are very specific in the *Arkansas Children's Hospital* opinion, the analysis helps illuminate the FTC's posture regarding the analysis of joint enterprises under the NPIA.

2. *Valley Baptist Medical Center*.—The inquiry in Valley Baptist Medical Center's ("VBMC's") request focused on the status of contract employees.¹⁹⁶ VBMC has some 200 independent contractors (food and laundry service workers) who are not covered by the hospital's health or retirement benefits.¹⁹⁷ VBMC's management wanted to dispense discounted pharmaceuticals to its contract workers, but in *Abbott Labs*, although the Court determined that a hospital's purchase of pharmaceuticals for resale to its employees was exempt under the NPIA, it was silent as to independent contractors.¹⁹⁸ The FTC noted that the Court concluded "that employees are necessary for the hospital to function and that providing them with pharmaceuticals enhances the hospital's operation."¹⁹⁹

Compelled by the Supreme Court's rationale in the *Abbott Labs* opinion that the existence of an "obvious and institutionally intimate" relationship between [certain non-employees] and the hospital's purposes and activities" caused the two groups to be equal for NPIA analysis, the FTC determined that VBMC's contract workers played a role equivalent to its employees.²⁰⁰ The contract workers were exclusively assigned to VBMC, worked on VBMC's premises, and in many instances worked for VBMC for very long periods of time.²⁰¹ Because the contract workers' functions were integral to VBMC's operations, and because VBMC had asserted "plausible reasons" why the dispensation of pharmaceuticals to the contractors would directly benefit the hospital through increased productivity, the FTC concluded that VBMC's contract workers were equivalent to employees under the *Abbott Labs* analysis, and that VBMC's purchase of pharmaceuticals for resale directly to its independent contractors would be for the hospital's "own use" under the NPIA.²⁰²

194. *Id.* at *3.

195. *Id.*

196. 2003 WL 1257423, at *1 (F.T.C. Mar. 13, 2003) (advisory opinion).

197. *Id.*

198. 425 U.S. 1, 16 (1976).

199. *Valley Baptist Med. Ctr.*, 2003 WL 1257423, at *2.

200. *Id.* at *3.

201. *Id.*

202. *Id.*

D. Evolution of Physician/Hospital Competition

A hospital's governing body may prefer that the members of its medical staff be loyal and refer their patients only to the hospital at which they have clinical privileges. Some physicians have philosophical differences with such expectations, and believe that they can furnish better quality patient care or better access to care by creating a specialty facility focused on one or more discrete areas of medical expertise, or even creating an entire full-service hospital. These physicians may themselves invest in the hospital or specialty facility, and as a consequence divert their patients to their own entity rather than the hospital at which they have clinical privileges. Some detractors believe that, due to their investment in the entity, such physicians have an economic incentive to refer patients to their entity,²⁰³ although lawmakers are not unanimous in that belief and recognize that many physicians are offended by the suggestion that economics affect their medical judgment.²⁰⁴ Regardless, when members of a hospital's medical staff introduce a competitor to the hospital, the result will be increased competition, and the hospital may look for ways to protect against patient loss.

203. See, e.g., Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 507 (amending 42 U.S.C. §§ 1395nn(d)(3), (h)(7) (2003)) (imposing an eighteen-month moratorium on specialty hospitals' use of the Stark law's "whole hospital" or "rural hospital" exceptions); Introduction of the Hospital Investment Act, 149 CONG. REC. E634-35 (daily ed. Apr. 1, 2003) (statement of Rep. Stark). Rep. Stark explained his:

concern that these specialty hospitals are skirting the spirit of the physician self-referral laws [and have] great potential for conflicts-of-interest for physicians who may be induced to base their treatment decisions on profits generated by the facility rather than on the clinical needs of their patients. . . . The investors in these joint ventures and specialty hospitals skim the profits off full-scale hospitals of their most profitable business, leaving those existing hospitals much worse off financially.

Id.

204. See, e.g., *Hearing Before the Subcomm. on Health of the Comm. on Ways and Means, House*, 106th Cong. 34 (1999) (statement of Rep. McCrery) (stating that "courts should hold . . . the Government to a high standard in proving its [Antikickback Statute] case. Maybe we should . . . not assum[e] that all physicians [self-refer] to make the maximum amount of money. Not all physicians are crooks."); *id.* at 54 (statement of K. Buto, Dep. Dir., Center for Health Plans and Providers, Health Care Fin. Admin.) ("We are assuming that the providers are complying with the [Stark] statute."); *id.* (statement of Rep. Thomas) ("I honestly think the genesis of this legislation was exactly the opposite of the statement that [K. Buto] just made. That, in fact, [Rep. Stark believes] health care professionals, by and large, are crooks."); *id.* at 79-80 (statement of Rep. Thomas). Rep. Thomas stated:

[Lawmakers] simply compared volume [of procedures by self-referring physicians] and drew a conclusion that they were crooks. . . . I don't think that is fair. But that is exactly the methodology that was used as outlined to justify this law. . . . We will catch the crooks. What we ought not to do is put up a net that prohibits responsible, reasonable, and appropriate delivery of care.

Id.

The health care marketplace is seeing growing competition between hospitals and their medical staff members' private ventures.²⁰⁵ In Indianapolis, this phenomenon is evidenced by the development of specialty cardiac hospitals such as the Heart Center of Indiana (a joint venture of St. Vincent Health and cardiologist-owned The Care Group) and The Indiana Heart Hospital (a joint venture of Community Hospital Network and physician-owned Indiana Heart Associates).²⁰⁶ The specialty hospitals will compete for patients in the greater metropolitan Indianapolis area, and in the case of the Heart Center of Indiana will compete against the hospital partner in the joint venture.²⁰⁷ Indianapolis is also home to the Krannert Institute of Cardiology, a hospital-in-a-hospital housed within Riley Children's Hospital and owned by Riley, Methodist and Indiana University hospitals, and soon St. Francis Hospital & Health Centers will complete its cardiac facility in southern Indianapolis.²⁰⁸ Physicians in Indiana also have invested in whole hospitals, such as the recently announced Arnett Clinic's 150-bed, \$100 million full-service hospital to be opened in Lafayette, Indiana, by the fall of 2005.²⁰⁹

1. *Use of Exclusive Contracts.*—A hospital might respond to physician competition by entering into an exclusive contract with one or more dominant payors with respect to the specialty served by the physician venture. For example, in 2001, two cases were filed in response to hospitals' retaliatory actions against medical staff members with investments in facilities competing with the hospitals: *Surgical Care Center, L.L.C. v. Hospital Service District No. 1*,²¹⁰ and *Rome Ambulatory Surgery Center, L.L.C. v. Rome Memorial Hospital*.²¹¹ Where a hospital retaliates against its medical staff for undertaking competitive ventures, the antitrust laws are implicated.

a. *Surgical Care Center.*—In *Surgical Care Center*,²¹² a hospital's surgeons built an ambulatory surgery center, in response to which the hospital allegedly negotiated exclusive contracts with payors to freeze the competition out and generally refused to cooperate with the center.²¹³ The court held that the hospital's conduct was neither predatory nor unlawful, as it found no monopolization or attempted monopolization over the surgery marketplace because the hospital lacked market power.²¹⁴ The court justified the hospital's

205. M. Norbut, *Battle of the Beds*, AM. MED. NEWS, May 5, 2003 (discussing Indianapolis as a "perfect example of the rise of specialty hospitals . . .").

206. *Id.*

207. *Id.*

208. *Id.*

209. K. Cullen, *Hospitals Chief: Rivals Won't Steer Our Strategy*, J. & COURIER (Lafayette, Ind.), Dec. 16, 2003; K. Cullen, *Physician Group Gives Hospital Venture a Shot*, J. & COURIER (Lafayette, Ind.), Dec. 28, 2003.

210. 2001-1 Trade Cas. (CCH) 73,215 (E.D. La. 2001).

211. No. 01-CV-002 (N.D.N.Y. Jan. 3, 2001).

212. 2001-1 Trade Cas. (CCH) 73,215 (E.D. La. 2001).

213. *Id.*

214. *Id.*

use of exclusive contracts by taking note of the physicians' economic incentive to steer patients to their ambulatory surgery center.²¹⁵

b. *Rome Ambulatory Surgery Center*.—The *Rome Ambulatory Surgery Center* case, unlike *Surgical Care Center*, is still an active case.²¹⁶ The facts are similar to those in *Surgical Care Center*, but the physician investors in the Rome Ambulatory Surgery Center also alleged that the hospital threatened to take adverse action against the physicians' clinical privileges, and took other steps to dissuade physicians from referring patients to the surgery center and away from the hospital.²¹⁷ It will be interesting to follow *Rome Ambulatory Surgery Center* to learn how the court will apply the antitrust laws to Rome Hospital's credentialing activities.

2. *Economic Credentialing*.—Hospitals have also responded to physician competition by taking, or threatening, adverse action against the clinical privileges the competing physicians enjoy at the hospital, known colloquially as "economic credentialing."²¹⁸ Recently, an Ohio trial court heard *Walborn v. UHHS/CSAHS-Cuyahoga, Inc.*,²¹⁹ in which Dr. Walborn and other doctors alleged that St. John West Shore Hospital ("St. John") had implemented an unlawful credentialing policy.²²⁰ Approximately ten months before the plaintiffs filed suit, St. John had announced a new "Medical Staff Development Plan" under which "staff members who 'have entered into employment agreements with competing health systems . . . or whose medical practice is managed by a competing health system which results in a material conflict of interest will not be eligible for appointment or reappointment to [St. John's] Medical Staff.'"²²¹ Physicians applying for clinical privileges at St. John would be required to notify the hospital of their employment relationships.²²²

St. John's separate credentialing policy identifies two classes of physicians ineligible for application or reapplication to the Hospital's medical staff: individuals with a "material financial relationship" and individuals with a "material conflict of interest."²²³ Evidence adduced at trial indicated that St. John's credentialing policy was intended to ensure the long-term viability of St. John and its affiliate St. Vincent Hospital, and to improve the quality of care

215. *Id.*

216. No. 01-CV-002 (N.D.N.Y. Jan. 3, 2001).

217. *Id.*

218. See, e.g., J. Blum, *Evaluation of Medical Staff Using Fiscal Factors: Economic Credentialing*, 26 J. HEALTH & HOSP. LAW 3, 65 (Apr. 1993); J. Blum, *Exclusive Contracting: The Original Economic Credentialing*, 26 J. HEALTH & HOSP. LAW 4, 65 (May 1993); T. Hudson, *Factoring in the Financials: Court Gives Nod to Economic Credentialing*, HOSPITALS 36 (Apr. 5, 1993).

219. No. CV-02-479572, slip op. (Ct. Com. Pl. June 16, 2003).

220. *Id.*

221. *Id.* at *3.

222. *Id.*

223. *Id.*

at both hospitals.²²⁴ Further, the credentialing policy was intended to apply certain quality initiatives established by the hospitals' owners to St. John and St. Vincent.²²⁵ The court held that such goals are reasonably related to the operation of a hospital.²²⁶

The plaintiff physicians were notified by St. John that requests for application for reappointment to the medical staff that they had submitted were being denied because of a material financial interest with a competing health system, which is in conflict with the hospital's conflict of interest credentialing policy.²²⁷ Although the notice informed the plaintiffs that they had a right to an administrative hearing, and although the plaintiffs requested such a hearing on at least two occasions, no such hearing ever took place.²²⁸

St. John was criticized because the hospital did not track or enforce the material conflict of interest provision of its credentialing policy, a fact that St. Johns admitted.²²⁹ In fact, St. John admitted it has physicians on its staff that would fall within the material conflict of interest criteria, and who are responsible for large numbers of admissions at the hospital.²³⁰ The court found that St. John's medical staff was never asked to adopt the credentialing policy, and that the credentialing policy was materially in conflict with the medical staff bylaws concerning physician credentialing.²³¹ The court also found that the plaintiffs were actively diverting patients away from St. John and to a facility with which the plaintiffs had a financial relationship, and that in many cases patients were referred to facilities farther from their communities than St. John Hospital.²³²

The court found that whether a hospital board may enact policies that restrict medical staff membership on the basis of a physician's conflict of interest was a question of first impression under Ohio law.²³³ Despite the fact that the hospital enforced its credentialing policy haphazardly, the court declined to enjoin enforcement of the policy.²³⁴ Although Ohio law prohibits a hospital from discriminating against an applicant on the basis of the individual's certification or licensure, the court determined that the St. John credentialing policy used other factors to exclude individuals: the applicants' financial interest or employment relationships.²³⁵ Because St. John's credentialing policy made no

224. *Id.*

225. *Id.*

226. *Id.* at 8.

227. *Id.*

228. *Id.*

229. *Id.* at 9.

230. *Id.* at 10.

231. *Id.* at 11.

232. *Id.* at 21.

233. *Id.* at 24.

234. *Id.* at 25.

235. *Id.* at 27.

distinction based on the plaintiff's certification or licensure; the policy did not violate Ohio law.²³⁶ Ultimately, the court found that

given the competitive market for healthcare, as well as the facts adduced regarding the business practices [of plaintiffs], the [c]ourt finds that St. John's adoption and implementation [sic] the credentialing policy was not arbitrary or capricious therefore, the [c]ourt will not substitute its judgment for that of St. John. The [c]ourt concludes the credentialing policy is a valid corporate policy that could be applied to every physician requesting privileges at the Hospital.²³⁷

3. *Bundling*.—The concept of “bundling” is commonplace in many industries such as telecommunication, but is a recent addition to the competitive practices between hospitals and physician ventures.²³⁸ Bundling refers to multi-product discount arrangements in which buyers receive a price discount on a package of services that, if purchased separately, would not be discounted.²³⁹ A health care provider may bundle its full scope of services a health care provider offers to offer a payor a discount.²⁴⁰ Bundling may be used as a competitive or anticompetitive tool by offering a payor an attractive discount over a broad range of services, provided the payor will refuse to contract with the provider's competitors.²⁴¹ If or when bundling is anticompetitive and in violation of the Sherman Act is yet to be decided.

a. *McKenzie-Willamette v. PeaceHealth*.²⁴²—An independently owned hospital in Eugene, Oregon, McKenzie-Willamette Hospital, won a \$16.2 million jury verdict October 31 in an antitrust lawsuit against PeaceHealth, which owns Sacred Heart Hospital—the only other major hospital in the area.²⁴³ PeaceHealth also owns two smaller hospitals in Lane County, in which Eugene is located.²⁴⁴

At trial, the jury found that PeaceHealth had attempted to monopolize the Lane County hospital services market in violation of the antitrust laws. It also found for McKenzie-Willamette Hospital on two state claims, one alleging

236. *Id.*

237. *Id.* at 31.

238. See, e.g., C. Stern, *Comcast Bundles TV, Internet to Keep Customers*, WASH. POST, Mar. 26, 2003, at G1 (describing internet access fee increase for subscriber who do not also purchase cable television services from same vendor).

239. See, e.g., *Group Purchasing Organizations; Use of Contracting Processes and Strategies to Award Contracts for Medical-Surgical Products: Hearing Before Sen. Subcomm. on Antitrust, Competition Policy, and Consumer Rights, Comm. on the Judiciary*, 108th Cong. 6 (2003) (statement of Marjorie Kanef, Director, Health Care-Clinical and Military Health Care Issues, U.S. Gen. Acctg. Office).

240. *Id.*

241. *Id.*

242. No. 02-6032-HA (D. Or. Oct. 31, 2003).

243. *Id.* at 1-2, 4-5.

244. *Id.* at 4-5.

discriminatory pricing and one alleging wrongful interference.²⁴⁵ The jury determined that McKenzie-Willamette Hospital had suffered \$5.4 million in damages, but under the applicable antitrust remedy of treble compensatory damages will receive \$16.2 million.²⁴⁶ The hospital may also be awarded attorneys' fees and expenses of \$2 million to \$4 million.²⁴⁷

McKenzie-Willamette alleged that PeaceHealth used its monopoly in cardiovascular and neonatal care to negotiate an exclusive agreement with Regence Blue Cross and Blue Shield of Oregon, the major insurer in the Lane County market (insuring approximately one-third of the County population).²⁴⁸ Because McKenzie-Willamette did not furnish cardiovascular and neonatal services, PeaceHealth was able to offer the payor a total package discount with which McKenzie-Willamette could not compete. McKenzie-Willamette alleged that PeaceHealth offered Regence two pricing schemes, one that permitted the payor to contract with McKenzie-Willamette, and one that did not.²⁴⁹ Under the scheme that allowed Regence patients to go to McKenzie-Willamette, PeaceHealth charged more for cardiovascular and neonatal services.²⁵⁰ If Regence patients were not eligible for coverage at McKenzie-Willamette, PeaceHealth offered a greater discount on its cardiovascular and neonatal services.²⁵¹

A hearing is to be scheduled to hear PeaceHealth's motion to set the verdict aside and to hear arguments on motions by McKenzie-Willamette for injunctive relief.

*b. LePage's Inc. v. 3M.*²⁵²—While not a health care case, *LePage's* is an important development in antitrust enforcement relating to bundling. "LePage's brought this antitrust action asserting that 3M used its monopoly over its Scotch tape brand to gain a competitive advantage" over private label tape wholesalers.²⁵³ LePage's asserted that 3M used a "bundled rebate" to offer retailers greater financial incentives if the retailers purchased products in several of 3M's product lines, and that offering such financial incentives constituted an improper use of its monopoly power.²⁵⁴ LePage's is a private label tape wholesaler that competes with 3M, and in its complaint alleged that 3M offered cash payments, promotional allowances, and other cash incentives in exchange for exclusive dealing arrangements with 3M.²⁵⁵

245. *Id.* at 12.

246. *See* 11 HEALTH L. REV. 247 (2002).

247. *Id.*

248. *McKenzie-Willamette*, No. 02-6032-HA, at 8-11.

249. *Id.* at 6.

250. *Id.*

251. *Id.*

252. 324 F.3d 141 (3d Cir. 2003) (en banc), *petition for cert. filed*, 124 S. Ct. 365 (2003) (mem.).

253. *LePage's*, 324 F.3d at 145.

254. *Id.*

255. *Id.*

LePage's alleged causes of action "for unlawful agreements in restraint of trade under § 1 of the Sherman Act,²⁵⁶ monopolization and attempted maintenance of monopolization under § 2 of the Sherman Act,²⁵⁷ and exclusive dealing under § 3 of the Clayton Act."²⁵⁸ In the lower court, the jury awarded LePage's damages of \$22,828,899 on its claims based on monopolization and attempted monopolization.²⁵⁹ The jury decided against LePage's on its claims under § 1 of the Sherman Act and § 3 of the Clayton Act.²⁶⁰

The district court ruled as a matter of law against LePage's on its "attempted maintenance of monopoly power" claim but denied the remainder of 3M's motion and denied its motion for new trial.²⁶¹ The district court awarded LePage's damages of \$68,486,697 plus interest.²⁶² Both 3M and LePage's appealed.²⁶³

On appeal, 3M conceded that it used exclusive contracts, but argued that such conduct was legal, as a matter of law, because 3M never priced its tape below cost.²⁶⁴ 3M adopted the posture that "if the big guy is selling above cost, it has done nothing which offends the Sherman Act. . . ."²⁶⁵ The Third Circuit Court examined more than eighty years of Supreme Court decisions under § 2 of the Sherman Act, ultimately determining that "nothing that the Supreme Court has written since *Brooke Group* dilutes the Court's consistent holdings that a monopolist will be found to violate §2 of the Sherman Act if it engages in exclusionary or predatory conduct without a valid business justification."²⁶⁶

With one judge dissenting, the *en banc* circuit court held that "[t]here was ample evidence that 3M used its market power over transparent tape, backed by its considerable catalog of products, to entrench its monopoly to the detriment of LePage's, its only serious competitor, in violation of § 2 of the Sherman Act."²⁶⁷ As the panel found no reversible error, the circuit court affirmed the district court.²⁶⁸

Arguably, the rationale of the decision in *LePage's* could apply to bundling in the health care context. For example, where a full-service hospital offers a discount to a payor across its entire product line, a specialty competitor may be disadvantaged by the market power of the hospital. The specialty provider would find it impracticable, if not impossible, to discount its prices sufficiently to

256. 15 U.S.C. § 1 (2002).

257. *Id.* § 2.

258. *Id.* § 12.

259. *LePage's*, 334 F.3d at 145.

260. *Id.*

261. *Id.* (citing *Le Page's Inc. v. 3M*, 2000 WL 280350 (E.D. Pa. 2000)).

262. *Id.*

263. *Id.*

264. *Id.* at 147.

265. *Id.* (quoting transcript of oral argument, Oct. 30, 2002, at 11).

266. *Id.* at 152.

267. *Id.* at 169.

268. *Id.*

motivate a payor to reject the hospital's full-service scope discount. Query whether *LePage's* will be adopted in the context of health care antitrust analysis of bundling arrangements in cases such as *McKenzie-Willamette*.²⁶⁹

V. TAX

A. *Sarbanes-Oxley*²⁷⁰

The American Competitiveness and Corporate Accountability Act of 2002, commonly known as the Sarbanes-Oxley Act ("Sar-Ox") has imposed new duties on executives and directors of publicly traded companies concerning corporate governance and accountability since July 30, 2002. To recap, Sar-Ox regulates what boards must do to ensure that their company's "independent" auditors are truly independent.²⁷¹ It also creates and defines the role of a new federal entity—the Public Company Accounting Oversight Board, which is empowered to enforce standards for audits of public companies.²⁷² Sar-Ox also explains how to elect competent audit committee members and regulates adequate reporting procedures.²⁷³ Finally, Sar-Ox calls for the creation of additional regulations and creates stringent enforcement measures for businesses, whether non-profit or for-profit concerning document destruction and protections for whistle-blowers.²⁷⁴

Immediately following its enactment, the Securities and Exchange Commission ("SEC") rapidly began implementation and enforcement of Sar-Ox. In the first half of 2003 alone, the SEC filed 72 enforcement actions involving financial fraud and reporting against public companies and sought to bar ninety-five dishonest corporate executives and directors from holding such positions with publicly traded companies.²⁷⁵ A closer look at the enforcement activity of the SEC reveals that the first-ever enforcement action filed under Sar-Ox was against a publicly traded health care company, HealthSouth Corporation and its CEO, for irregularities in its financial statements.²⁷⁶ Shortly thereafter, the Department of Justice brought criminal charges against HealthSouth's CFO, who pled guilty to several charges, including fraud and false certification of financial records.²⁷⁷

In response to the growing public scrutiny of all corporate actors and their dealings, in April 2003, the OIG, in conjunction with the American Health Lawyers Association ("AHLA"), published guidance under Sar-Ox for health

269. *McKenzie-Williamette v. PeaceHealth*, No. 02-6032-HA (D. Or. Oct. 31, 2003).

270. Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745 (2002).

271. *Id.* at tit. 2.

272. *Id.* at tit. 1.

273. *Id.* §§ 406-407.

274. *Id.* at tits. 8, 9, 11.

275. SEC Chairman William H. Donaldson, Speech to the National Press Club, Washington, D.C. (July 30, 2003).

276. *SEC v. HealthSouth Corp.*, No. CV-03-J-0615-S (N.D. Ala. Mar. 20, 1985).

277. Press Release, U.S. Dep't of Justice, HealthSouth Office Charged with Conspiracy to Commit Wire and Securities Fraud (Mar. 31, 2003) (on file with author).

care entities, regardless of their public, private or non-profit status.²⁷⁸ The joint OIG/AHLA educational guidance poses several questions all health care entities should ask in light of Sar-Ox, concerning best governance practices. For example, some of the questions covered such topics as: structure of the health care entity's corporate compliance program, codes of conduct for the organization, policies and procedures governing compliance risk areas, and measures to prevent and respond to violations of the company's policies and procedures.²⁷⁹

These recent enforcement efforts under Sar-Ox and the OIG guidance are evidence of an increasing trend toward extending Sar-Ox's duties to all health care entities, regardless of their private or public status. For example, the New York State Attorney General, Elliott Spitzer, has publicly declared his desire for a state law that applies to non-profit corporations that mirrors Sar-Ox's federal compliance requirements for public corporations.²⁸⁰ Moody's Investors Service may reflect not-for-profit hospitals' board governance in their bond ratings, through the use of a corporate compliance section in their bond rating methodology, similar to the new corporate governance ratings that apply to public companies.²⁸¹

While Sar-Ox has had a direct and immediate impact on public corporations, its influence on non-profit and health care organizations has begun to be felt and will continue to increase over the years. Through legislative and judicial recognition of the universal principles governing honesty and fair play contained in Sar-Ox, all corporate actors—public, private and non-profit, especially health care—will need to pay significant attention further developments in this arena.

*B. St. David's Healthcare System, Inc. v. United States*²⁸²

St. David's Healthcare System, Inc. ("St. David's") has become the latest battleground for the Internal Revenue Service ("IRS") to attack certain transactions between tax-exempt organizations and for-profit entities.²⁸³ In 1996, St. David's entered into a so-called whole hospital joint venture transaction with Columbia/HCA Healthcare Corporation ("HCA"), in which St. David's contributed all of its assets to a partnership in exchange for a minority ownership interest in the partnership.²⁸⁴ In 1998, the IRS audited St. David's and the

278. OIG, AHLA, CORPORATE RESPONSIBILITY AND CORPORATE COMPLIANCE: A RESOURCE FOR HEALTH CARE BOARDS OF DIRECTORS (2003).

279. *Id.*

280. New York Attorney General's Legislative Program, Program Bill # 02-03 (January 21, 2003).

281. Mary Chris Jaklevic, *Modern Healthcare: Rating Adjustment* (Dec. 1, 2003).

282. 349 F.3d 232 (5th Cir. 2003) ("*St. David's II*").

283. See, e.g., *Redlands Surgical Servs. v. Comm'r*, 242 F.3d 904 (9th Cir. 2001) (per curiam); Rev. Rul. 98-15, 1998-1 C.B. 718; Rev. Rul. 69-545, 1969-2 C.B. 117; Gen. Couns. Mem. 39862 (Nov. 21, 1991).

284. *St. David's Health Care System, Inc. v. United States*, 2002 WL 1335230, at *2 (W.D.

partnership, and ultimately revoked St. David's tax-exempt status in 2002 because, the IRS stated, once it entered into the partnership St. David's was no longer engaged in activities that primarily furthered a charitable purpose and thus it no longer qualified to be recognized as exempt under Section 501(c)(3) of the Internal Revenue Code.²⁸⁵ St. David's paid the taxes the IRS alleged to be due under protest, then brought suit in district court for a refund.²⁸⁶

In district court, the IRS explained that St. David's should forfeit its exemption for two primary reasons. First, the partnership was not run by a community board.²⁸⁷ Second, HCA received an impermissible private benefit from the partnership.²⁸⁸ The district court granted St. David's motion for summary judgment, stating that "it is difficult to imagine a corporate structure more protective of an organization's charitable purpose than the one at issue in this case."²⁸⁹ The district court also ordered the United States to pay St. David's reasonable litigation costs in the amount of \$951,569.83 and to refund \$103,000 "in taxes paid by St. David's for the 1996 tax year."²⁹⁰

The IRS appealed to the Fifth Circuit Court, arguing that the determinative issue is not whether the partnership was organized to protect St. David's charitable purposes, but whether St. David's ceased to engage primarily in activities to further St. David's charitable purposes when it ceded control of its operations to HCA.²⁹¹ St. David's countered that the issue is whether the partnership functioned in a manner that furthered St. David's exempt purpose.²⁹²

The court of appeals explained that the ultimate question is whether St. David's continued to operate exclusively in furtherance of an exempt purpose.²⁹³ "Exclusively" in this context has been determined to mean "primarily," such that the partnership "cannot be deemed to operate exclusively *or primarily* for charitable purposes when a substantial portion of the organization's activities further non-charitable purposes."²⁹⁴ The court explained that "[i]n order to

Tex. 2002) ("St. David's I").

285. *Id.*; *St. David's II*, 349 F.3d at 234.

286. *St. David's II*, 349 F.3d at 234.

287. *St. David's I*, 2002 WL 1335230, at *1.

288. *Id.*

289. *Id.* at *8.

290. *St. David's II*, 349 F.3d at 234 (granting plaintiff's application for litigation costs).

291. *Id.* at 235.

292. *Id.*

293. *Id.* at 237.

[I]n determining whether an organization satisfies the operational test, we do not simply consider whether the organization's activities further its charitable purposes. We must also ensure that those activities do *not* substantially further other (non-charitable) purposes. If more than an "insubstantial" amount of the partnership's activities further the non-charitable interests, then St. David's can no longer be deemed to operate *exclusively* for charitable purposes.

Id. (emphasis added).

294. *Id.* at 237 n.6 (emphasis in original).

ascertain whether an organization furthers non-charitable interests, we can examine the structure and management of the organization. . . . In other words we look to which individuals or entities *control* the organization.”²⁹⁵ To determine the issue of control, the circuit court looked to the partnership’s governing documents, which required it to be operated in accordance with the IRS community benefit standard.²⁹⁶ The partnership agreement also provided that St. David’s and HCA each appointed one-half of the governing board.²⁹⁷ St. David’s pointed out that the partnership agreement and management services agreement gave St. David’s various powers to ensure that the partnership was operated for charitable purposes, such as the power to terminate the CEO, to terminate the company hired to manage day-to-day operations, and to dissolve and liquidate the partnership under certain circumstances.²⁹⁸ The Fifth Circuit concluded that these powers were not sufficient, as a matter of law, to ensure that St. David’s retained effective control over the partnership.²⁹⁹

First, the Fifth Circuit found that the form of the governing documents did not give St. David’s the power to control a majority of the partnership’s board, but merely a veto power.³⁰⁰ “Thus, at best, St. David’s can prevent the partnership from taking action that might undermine its charitable goals; St. David’s cannot necessarily ensure that the partnership will take new action that furthers its charitable purposes.”³⁰¹

Second, the court found that although Galen Health Care, Inc. (“Galen”), the for-profit subsidiary of HCA responsible for the partnership’s day-to-day management, was required under a management services agreement to abide by the IRS community benefit standard, it was a subsidiary of HCA and would naturally be inclined to prioritize HCA’s for-profit motives rather than St. David’s charitable purposes.³⁰² The court also indicated that St. David’s sole means of enforcement of this provision would be by taking legal action, a remedy so burdensome as to pull the teeth from St. David’s authority.³⁰³

Third, the court found that while St. David’s had the unilateral power to terminate the CEO of the partnership, St. David’s had already demonstrated the ineffectiveness of this power.³⁰⁴ Although the partnership agreement required the CEO to file annual reports to the board with the amount of charity care provided by the partnership, the CEO had not prepared any such report, and St. David’s had not taken any punitive action against the CEO.³⁰⁵

295. *Id.* at 237 (emphasis in original) (internal citations omitted).

296. *Id.* at 240.

297. *Id.* at 241.

298. *Id.*

299. *Id.* at 241-44.

300. *Id.* at 241-42.

301. *Id.* at 242.

302. *Id.*

303. *Id.* at 243.

304. *Id.*

305. *Id.*

Finally, the court found that St. David's unilateral right to dissolve the partnership was illusory, as it only applied in the event of a change of law, and to dissolve the partnership would likely destroy St. David's business; the parties had executed a non-competition covenant triggered by dissolution.³⁰⁶

The circuit court thus vacated the lower court's ruling and remanded the case back to the district court for further proceedings.³⁰⁷ Although the circuit court ruled in favor of the government, the case is still pending before a trial judge in the district court. In vacating the district court's summary judgment ruling, the circuit court determined only that the case can move forward through trial. St. David's will thus have the opportunity to demonstrate, if it can, that it did not cede control to HCA, and that no more than an "insubstantial" amount of the partnership's activities further non-charitable interests.³⁰⁸ Exempt organizations and their counsel will be closely following the outcome of *St. David's II*.

VI. EMTALA: INTERIM GUIDANCE

On September 9, 2003, CMS published its final rule regarding the Emergency Medical Treatment and Active Labor Act ("EMTALA"),³⁰⁹ which became effective November 10, 2003, clarifying the responsibilities of Medicare participating hospitals and Critical Access Hospitals ("CAH") in treating individuals who present to the hospital requesting examination or treatment.³¹⁰ The final rule provided needed clarification of many provisions of EMTALA. CMS expanded the definition of "hospital emergency department" and the meaning of the phrase "come to the emergency department."³¹¹ The EMTALA requirements apply if an individual presents (1) at the hospital's dedicated emergency department and requests examination or treatment for a medical condition, or (2) elsewhere on the hospital's property that is not part of the

306. *Id.* at 244. The court noted that if St. David's dissolved to the partnership, it would be forbidden from competing in the Austin, Texas community and would effectively cause St. David's to cease to exist. *Id.* Moreover, without HCA as its partner, St. David's would not likely survive financially. *Id.* at 239.

The present case illustrates why, when a non-profit organization forms a partnership with a for-profit entity, courts should be concerned about the relinquishment of control. St. David's by its own account, entered into the partnership with HCA out of financial *necessity* (to obtain the revenues needed for it to stay afloat). HCA, by contrast, entered the partnership for reasons of financial *convenience* (to enter a new market). The starkly different financial positions of these two parties at the beginning of their partnership negotiations undoubtedly affected their relative bargaining strength.

Id.

307. *Id.* at 244.

308. *Id.* at 237.

309. 42 U.S.C. § 1395 (2003).

310. Medicare Program; Clarifying Policies Related to the Responsibilities of Medicare-Participating Hospitals in Treating Individuals with Emergency Medical Conditions, 68 Fed. Reg. 53,222 ("EMTALA Final Rule").

311. *Id.* at 53,227 - 53,234 (to be codified at 42 U.S.C. § 489.24(b)).

dedicated emergency department and requests examination or treatment for what may be a medical condition.³¹² In either case, a hospital is required to provide an appropriate medical screening examination.³¹³ If the individual has an emergency medical condition, the hospital must provide the necessary stabilizing treatment within the hospital's capacity or capabilities and if necessary, arrange for an appropriate transfer to another hospital.³¹⁴

EMTALA applies not only to dedicated emergency departments but also to other areas of the hospital's main campus or property when an individual presents requesting medical treatment.³¹⁵ If an individual is in a location of the hospital other than the dedicated emergency department and, based on a "prudent layperson's" belief, that individual clearly needs medical attention or services (e.g., visitor collapses in the hospital's cafeteria or appears to be suffering chest pains in the waiting room), the hospital should have policies and procedures to assure that the individual receives an appropriate medical screening examination and EMTALA requirements are followed.³¹⁶

A "dedicated emergency department" is defined in the final rule as any hospital department or facility, regardless whether it is located on or off the main hospital campus, meeting at least one of the following requirements:

- a facility licensed by the State as an emergency department (applicable only in a few states);

- a hospital department or clinic that is held out to the public as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or

- a hospital department or facility that provides at least one-third of its entire outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.³¹⁷

A hospital's dedicated emergency department would not only encompass what is generally thought of as a hospital's "emergency room," but also include other departments of a hospital (e.g., labor and delivery departments and psychiatric units of hospitals), that provide emergency or labor and delivery services, or both, to individuals who may present as unscheduled ambulatory patients but are routinely admitted to be evaluated and treated.³¹⁸

The third criteria, a facility that accepts patients without requiring appointments, may encompass urgent care centers owned by a hospital and

312. *Id.*

313. *Id.*

314. *Id.*

315. *Id.* at 53,238 - 53,243 (to be codified at 42 U.S.C. § 489.24(b)).

316. *Id.* at 53,240 - 53,242 (to be codified at 42 U.S.C. § 489.24(b)).

317. *Id.* at 53,227 - 53,234 (to be codified at 42 U.S.C. § 489.24(b)).

318. *Id.*

reimbursed under the hospital's Medicare provider number.³¹⁹

Hospital property includes "the entire main hospital campus including the parking lot, sidewalk, and driveway," but for purposes of EMTALA does not include "other areas or structures of the hospital's main building that are not part of the hospital, such as physician offices, or other entities that participate separately in Medicare, or restaurants, shops, or other non-medical facilities."³²⁰

Urgent Care Centers, owned and billed under a hospital's provider number, are not categorically exempt from EMTALA regulations.³²¹ It would be difficult for any individual in need of emergency care to distinguish between a hospital department that provides care for an "urgent need" and one that provides care for an "emergency medical condition."³²² Thus, if the department or facility is held out to the public as a place that provides care for emergency medical conditions, it would meet the definition of a dedicated emergency department.³²³ If an urgent care center participates in Medicare through a hospital and operates as a satellite facility off the main hospital campus, the urgent care center may transfer a patient in an unstable condition to an affiliated hospital, if the urgent care center first screens the individual and determines treatment of the individual's condition is not within the capability or capacity of the center.³²⁴ That is, if a patient presents to an urgent care center owned by Hospital "X," the center must first screen the patient. If the center's screen indicates that the patient has an emergency medical condition for which the center is not equipped, the center may transfer the patient to Hospital "X." In addition, an urgent care center may transfer a patient in an unstable condition to a non-affiliated hospital if, in addition to screening the patient, the benefits of transfer exceed the risks.³²⁵

VII. QUALITY ASSESSMENT, ASSURANCE AND IMPROVEMENT

Several changes have developed in the role of quality assessment and improvement in health care in 2003. The Department of Health and Human Services promulgated a regulation mandating quality and performance initiatives from all Medicare-participating hospitals and skilled nursing facilities;³²⁶ the Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") modified its survey process to include a hospital self-assessment with quality-specific goals;³²⁷ and managed care payors continued to increase their use of quality measurements as a component of total fees paid for health care

319. *Id.*

320. *Id.*

321. *Id.* at 53,231.

322. *Id.*

323. *Id.*

324. *Id.*

325. *Id.*

326. Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435 (Jan. 24, 2003) (codified at 42 C.F.R. Part 482.21 (2004)).

327. *Shared Visions—New Pathways*, 22 PERSPECTIVES 1, Oct. 2002 (JCAHO newsletter).

services.³²⁸ In addition, CMS partnered with Premier, an alliance of 1500 hospitals, to undertake a three-year demonstration project in which the Medicare program will pay a premium for quality by rewarding top performing hospitals with additional funds.³²⁹

In addition, quality assurance is receiving a great deal of attention from our nation's lawmakers. Congress took up the issue with the House of Representatives, introducing bills such as the Patient Safety and Quality Improvement Act³³⁰ and the Patient Safety Improvement Act of 2003,³³¹ and the Senate introducing its own Patient Safety and Quality Improvement Act of 2003,³³² all designed to address voluntary reporting of medical errors, the development of patient safety organizations, and the creation of a privilege applicable to information reported under such a system.³³³

A. Medicare Condition of Participation

Since 1986, Medicare regulations have required hospitals, as a condition of participation in the Medicare program, to maintain a system to evaluate the provision of patient care, to assess deficiencies in the delivery of medical care,

328. See, e.g., *Profiles of Organizations Using Quality Incentive*, NATIONAL HEALTH CARE PURCHASING INSTITUTE, at <http://www.nhcpi.net/pdf/profiles.pdf> (finding that 14 of 14 profiled health insurers, purchasers, and employer coalitions use quality-based incentive programs in managed care contracting). In addition, Anthem Inc., one of Indiana's larger private health care insurers, uses a Hospital Quality Improvement Program to develop a Hospital Quality Scorecard for each hospital, which data is used in the computations establishing hospital reimbursement rates. Anthem regularly makes information regarding such programs available on its Internet website, www.anthem80.com.

329. See *HHS to Launch Medicare Demonstration to Promote High Quality Care in Hospitals*, HHS News Release, July 10, 2003; C. Becker, *Time to Pay for Quality*, MODERN HEALTHCARE 6 (June 30, 2003).

330. H.R. 663, 108th Cong. (2003). The Patient Safety and Quality Improvement Act was proposed to amend Title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely affect patient safety. H.R. 663 would also impose specific clinical improvement initiatives based on data collected under the initiatives the bill would create. As a safeguard, the bill would also provide for limited privilege and confidentiality provisions regarding reported data. See *id.* § 3(a) (recommended additions to "Part C" of Title IX).

331. H.R. 877, 108th Cong. (2003). The Patient Safety Improvement Act of 2003 would implement a medical information technology reporting mechanism for medical errors, along with a technology advisory board and voluntary standards intended to induce information technology interoperability in the healthcare marketplace.

332. S. 720, 108th Cong. (2003). The Patient Safety and Quality Improvement Act of 2003 (bearing the same short name as H.R. 663) would implement medical error reporting similar to that of H.R. 663, but would provide more comprehensive privilege and confidentiality provisions. See *id.* § 3.

333. H.R. 663, H.R. 877, and S. 720 all resurrect legislation that did not survive the 107th Congress. See H.R. 5478, 107th Cong. (2002); H.R. 4889, 107th Cong. (2002).

and to take remedial action where necessary.³³⁴ In 1999, a report published by the Institute of Medicine (“IOM”) announced that “at least 44,000 Americans die each year as a result of [preventable] medical errors [and] the number may be as high as 98,000.”³³⁵ The IOM report ultimately encouraged the Department of Health and Human Services and its Centers for Medicare and Medicaid Services (“CMS”) to promulgate a regulation intended to modify its Medicare conditions of participation to more closely reflect the current state of quality improvement practices.³³⁶ The updated rule expands the existing regulations and requires each Medicare-certified hospital to adopt a Quality Assessment and Performance Improvement (“QAPI”) program as a condition of participation in the Medicare program.³³⁷

Many privately accredited hospitals already have a quality assurance policy in place, though no such approach has previously been mandated for state-certified Medicare-participating hospitals. Hospitals that obtain JCAHO accreditation will be deemed to be in compliance with the conditions of participation including the QAPI,³³⁸ and organizations reviewed by Quality Improvement Organizations (“QIOs”) are deemed to have satisfied the utilization review and evaluation conditions of participation.³³⁹ Hospitals that are not accredited by QIOs rely instead on state agencies to assess compliance with the certification requirements of the Medicare program.³⁴⁰ A state agency or QIO will determine whether the hospital is in compliance with the QAPI condition of participation, which is directed at ensuring uniformity in quality standards for all Medicare-participating hospitals.³⁴¹ This rule requires, at a minimum, that each hospital must systematically examine its quality performance and implement specific improvement projects on an ongoing basis.³⁴² More importantly, QAPI is intended to identify preventable errors, and to enable hospitals to develop means to prevent them.

The condition of participation requires every Medicare certified hospital to develop, implement, maintain, and evaluate its own QAPI program, which must be hospital-wide, ongoing, and focused on indicators related to the improvement of health outcomes.³⁴³ Each hospital will be required to maintain and

334. 42 C.F.R. § 482.21 (2002).

335. Linda T. Kohn et al., *To Err Is Human: Building a Safer Health System*, COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, at 1 (National Academy Press, 1999).

336. Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435 (Jan. 24, 2003) (codified at 42 C.F.R. pt. 482).

337. *Id.*; see also 42 C.F.R. § 482.21 (2001), as amended.

338. 42 C.F.R. § 488.5(a).

339. *Id.* § 488.14.

340. *Id.* § 488.11.

341. Medicare Program, 68 Fed. Reg. at 3442-43.

342. *Id.* at 3435.

343. 42 C.F.R. § 482.21 (2002).

demonstrate evidence of its QAPI program and related efforts for review by CMS.³⁴⁴ The regulations set forth five standards related to the development of a hospital's QAPI program.

Standard one, Program Scope, provides that the hospital must demonstrate that its QAPI program examines and initiates measurable improvements, on an ongoing basis, in indicators that, based on objective evidence, will improve health outcomes and identify and reduce medical errors.³⁴⁵ In addition, standard one requires the hospital to measure, analyze, and track quality indicators, such as "adverse patient events, and other aspects of performance that assess processes of care, hospital service, and operations."³⁴⁶ CMS has declined to publish areas on which hospitals should focus their QAPI efforts because a closed list stifles innovation, does not allow hospitals to directly address their peculiar strengths and weaknesses, and would be subject to constant modification as the state of the art progresses and as the standards of care evolve.³⁴⁷ Consequently, CMS drafted the QAPI regulations to make the program scalable for hospitals of differing size and financial means and to allow for individual hospital flexibility, following a prescribed selection and evaluation process. First, the hospital must identify the hospital's critical patient care and services components.³⁴⁸ Next, the hospital must apply performance measures that are predictive of quality outcomes that would result from delivery of the patient care and services.³⁴⁹ Finally, the hospital must use a continuous method of data collection and evaluation that identifies or triggers further opportunities for improvement.³⁵⁰

Standard two, Program Data, provides a framework and defines expectations for hospitals regarding the quality indicator data necessary for a QAPI program.³⁵¹ In particular, this standard refers to information submitted to, or received from, the hospital's QIO (if it has one).³⁵² Hospitals that do not use QIOs may satisfy the conditions of participation by identifying measures of performance for the activities each such hospital identifies as a priority.³⁵³ The hospital must use the data to monitor the effectiveness and safety of services and quality of care, and to identify opportunities for improvement and changes that will lead to improvement and error prevention.³⁵⁴

Standard three, Program Activities, defines the conduct to take place in the QAPI program, and clarifies that the hospital's responsibility under its QAPI

344. Medicare Program, 68 Fed. Reg. at 3442-43.

345. 42 C.F.R. § 482.21(a).

346. *Id.* § 482.21(a)(2).

347. Medicare Program, 68 Fed. Reg. at 3437; *but see id.* at 3435 (describing throughout the preamble numerous sources for topics suitable for hospital quality improvement attention).

348. *Id.* at 3439.

349. *Id.*

350. *Id.*

351. 42 C.F.R. § 482.21(b) (2002).

352. *Id.*

353. *Id.*

354. *Id.*

program is to focus resources on improvement, considering prevalence and severity of incidence, or both, of high-risk, high-volume or problem prone areas, and giving priority to improvement activities that affect health outcomes, patient safety, and quality of care.³⁵⁵ A hospital's QAPI activities should track adverse patient events, analyze their causes, and implement preventive actions and mechanisms of feedback and learning throughout the hospital.³⁵⁶ This must include incidents of medical errors and adverse patient events.³⁵⁷ Each hospital is also required to take action designed to improve performance, and to measure its success and track its performance to assure that improvements are sustained.³⁵⁸

Standard four, Performance Improvement Projects, requires that each hospital must conduct performance improvement projects as part of its QAPI program.³⁵⁹ The number of performance improvement projects a hospital undertakes must be "proportional to the scope and complexity of the hospital's services and operations."³⁶⁰ The regulations expressly permit a hospital to develop and implement an information technology system as one of its performance improvement projects.³⁶¹ Hospitals must document each performance improvement project undertaken, the reasons for conducting the project, and the measurable progress achieved on the project.³⁶²

QIO cooperative projects will satisfy this standard's requirement for performance improvement projects.³⁶³ Projects undertaken pursuant to this standard must involve a degree of effort comparable to that of a QIO project.³⁶⁴ Hospitals must ensure that the clinical topics selected for performance improvement projects, and the priorities assigned to such clinical topics, evaluate the following criteria: (1) prevalence, incidence and disease impact relative to the affected population; (2) scientific consensus regarding improvement of patient outcomes; (3) measurability of processes or outcomes; and (4) the opportunity to improve care.³⁶⁵

Standard five, Executive Responsibilities, holds the hospital's leadership responsible and accountable for QAPI activities.³⁶⁶ The hospital's governing body, medical staff, and administrative officials are responsible and accountable

355. *Id.* § 482.21(c).

356. *Id.*

357. *Id.*

358. *Id.*

359. *Id.* § 482.21(d).

360. *Id.* § 482.21(d)(1).

361. *Id.*

362. *Id.*

363. Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435, 3439-41 (Jan. 24, 2003) (codified at 42 C.F.R. pt. 482).

364. *Id.*

365. *Id.* at 3442.

366. 42 C.F.R. § 482.21(e).

for ensuring that the hospital defines, implements and maintains an ongoing program for quality improvement and patient safety, including the reduction of medical errors. Further, these individuals must ensure that the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, that clear expectations for safety are established, and that all improvement actions are evaluated. In addition, they must ensure that adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients. Finally, these individuals must determine the number of distinct improvement projects to be conducted annually.³⁶⁷

The QAPI regulation identifies the minimum efforts necessary to satisfy the conditions of participation. The risk is therefore clear: a hospital that exerts less than the minimum effort may lose its Medicare certification. CMS intends information technology to ultimately be shared on a nationwide basis (within the constraints of HIPAA and analogous State laws) to construct a dynamic best practices approach to delivery of medical care.³⁶⁸ Benchmarking will be a large part of the process and will undergo periodic restatement to reflect development of the state of the art and evolution of the standard of care applicable to the clinical process under study.³⁶⁹ The heightened use of information technology, in the view of CMS, will revolutionize the delivery of medical care, and will prevent the preventable error.³⁷⁰

B. JCAHO Periodic Performance Review

The Joint Commission on Accreditation of Health Care Organizations ("JCAHO") has announced its Shared Visions-New Pathways initiative.³⁷¹ This new initiative adds an intermediate accreditation review, the periodic performance review ("PPR"), at the 18-month midpoint between triennial onsite surveys.³⁷² Under this initiative, each hospital will self-evaluate its compliance with all applicable accreditation standards, and based on the PPR will prepare a plan of action ("POA") designed to address any findings in the PPR.³⁷³

Hospitals have three options for the intermediate review under the new JCAHO initiative. Option one is to conduct a full PPR, prepare a POA, and submit to JCAHO the PPR results, POA and subsequent measures of success ("MOS") related to any non-compliance. Option two is to conduct a full PPR, prepare a POA and MOS, but attest that, based on advice of counsel, the hospital will not submit PPR results or POA to JCAHO (although any MOS are made available at time of next triennial survey). Option three allows a hospital to

367. *Id.*

368. Medicare Program, 68 Fed. Reg. at 3440.

369. *Id.* at 3444.

370. *Id.* at 3440.

371. 22 PERSPECTIVES 1, Oct. 2003 (JCAHO newsletter).

372. *Id.*; see generally <http://www.jcaho.org/accredited=organizations/SVNP/> (providing links to numerous JCAHO resources).

373. 22 PERSPECTIVES 1, Oct. 2003 (JCAHO newsletter).

conduct a PPR and attest that, based on advice of counsel, the hospital will instead undergo an independent JCAHO compliance assessment survey and POA development, and will report its POA to JCAHO and make any MOS available at time of next triennial survey.³⁷⁴

Hospitals must comply with this initiative to maintain JCAHO accreditation.³⁷⁵ The approach to compliance will differ from hospital to hospital based on several considerations, including the hospital's ability to protect the information adduced during a self-evaluation. In Indiana, self-critical analysis is not subject to the peer review privilege if it is not related to the provision of patient care,³⁷⁶ so any findings that constitute admissions could create risk from litigation in the future. Thus, hospitals must assess the risks and benefits associated with the PPR. Clearly, there are advantages to conducting a full PPR (*e.g.*, the hospital will be continuously accredited throughout the period between triennial onsite reviews), but it also creates risks relating to disclosure of self-critical analysis. While options two and three do not provide that same accreditation guarantee, they do preserve the dissemination of self-critical analysis a hospital prepares. Unless a hospital can take sufficient prophylactic measures, the self-disclosure of self-critical analysis may lead to substantial risks that outweigh the benefits from the PPR process.

VIII. *IN RE MANAGED CARE*³⁷⁷

Approximately 700,000 physicians are represented in a national class action lawsuit, *In re Managed Care Litigation*, initiated in March of 2001 against thirteen entities representing the nation's largest insurers, including Aetna, Inc., Aetna-USHC, Inc., and Cigna.³⁷⁸ The American Medical Association in conjunction with several state and local medical societies and individual representatives of the physician population alleged that the insurers violated the Racketeer Influenced and Corrupt Organizations Act³⁷⁹ and state prompt-pay laws³⁸⁰ in processing claims since 1990. Aetna and Cigna have settled the claims, but the remaining insurers are still defending the case.

374. *Id.*

375. *Id.*

376. Privileged Communications of Health Care Provider Peer Review Committees, IND. CODE § 34-30-15-1 to -23 (1999).

377. *In re Managed Care Litigation*, MDL No. 1334, 00-1334-MD-MORENO (S.D. Fla. 2003).

378. The following are all named defendants in the suit: Humana, Inc.; Aetna, Inc.; Aetna-USHC, Inc.; Cigna; Coventry Health Care, Inc.; Health Net, Inc.; Humana Health Plan, Inc.; PacifiCare Health Systems, Inc.; Prudential Insurance Company of America; United Health Group; United Health Care; Wellpoint Health Networks; and Anthem, Inc. *Id.* at *1.

379. 18 U.S.C. §§ 1961-68 (2002).

380. *See, e.g.*, IND. CODE §§ 27-13-36.2-1 to -7 (2003) (providing for prompt payment of claims for services furnished to patients of health maintenance organizations); *id.* § 27-8-5.7-5 (providing for prompt payment of claims for services furnished to patients of preferred provider organizations).

Aetna settled the *In re Managed Care* class' claims by means of a settlement agreement providing for, among other things, payment to individual physicians.³⁸¹ In the settlement agreement, Aetna agreed to modify a number of its business practices. In particular, the insurer has agreed to modify its utilization review processes, define parameters for timely claims payment, establish dispute resolution procedures, and undertake various other business practice initiatives.³⁸² In addition, Aetna paid approximately \$100 million into a settlement fund to be distributed to class members who elected to participate in the settlement (approximately \$142.56 per physician).³⁸³ As part of the settlement, Aetna also created a charitable foundation "dedicated to promoting high quality health care [through] initiatives that assist physicians to improve [or] enhance the quality of care received by patients."³⁸⁴

Cigna HealthCare also executed a settlement agreement that resolved the claims against it in the *In re Managed Care Litigation* class action.³⁸⁵ Among other things, Cigna will pay \$30 million into a settlement fund for individual physician class members to be paid based on each physician's experience with specified billing codes,³⁸⁶ and \$15 million into a foundation "dedicated to promoting high quality health care [with] particular emphasis [on] initiatives that assist Physicians to improve/enhance the quality of care received by patients and to enhance the delivery of care to the disadvantaged members of the public."³⁸⁷ Cigna will also pay \$55 million for the plaintiff class' attorneys' fees, costs and expenses.³⁸⁸

IX. MANAGED CARE: USUAL AND CUSTOMARY CHARGES— OIG REGULATIONS

The OIG has permissive exclusion authority—the authority to exclude a health care provider or individual from the Medicare program—over any individual or entity that it finds to have

381. The settlement agreement was preliminarily approved on May 30, 2003, a Final Approval Order and Judgment was entered on October 24, 2003, and a Supplemental Final Approval Order was entered on November 6, 2003. *In re Managed Care Litigation*, MDL No. 1334, 00-1334-MD-MORENO (S.D. Fla. 2003). To be eligible for settlement payments, individual physicians were required to submit a "Proof of Claim" no later than September 30, 2003. *Aetna Settlement Agreement* § 8.5. Documents and additional information related to the Aetna settlement are available on the Internet at <http://www.managed-care-litigation.com/>.

382. *Aetna Settlement Agreement* § 7.

383. *Id.* § 8.2.

384. *Id.* § 8.1.

385. The settlement agreement was preliminarily approved on September 4, 2003, and a Final Approval Hearing was held on December 18, 2003. *In re Managed Care Litigation*, MDL No. 1334, (S.D. Fla. 2003). A Final Approval Order was entered on February 2, 2004.

386. *Cigna Settlement Agreement* § 2.

387. *Cigna Settlement Agreement*, Exhibit 9, at 3.

388. *Id.* § 14.

submitted or caused to be submitted bills or requests for payment (where such bills or requests are based on charges or cost) under [Medicare or Medicaid] containing charges . . . for items or services furnished *substantially in excess* of such individual's or entity's *usual charges* . . . for such items or services, unless the Secretary finds there is *good cause*³⁸⁹

Since 1987, when Congress codified this power, the OIG has done very little to use it to exclude any person from the Medicare program,³⁹⁰ largely due to the vague nature of the statute's core terms, "substantially in excess," "usual charges," and "good cause." For the third time, the OIG has published a proposed rule that would, among other things, define these three key terms.³⁹¹ Historically, "usual charges" was reflected in a hospital's charge master³⁹² as the full billed charge for services. In the proposed rule, the OIG would define the term "usual charges" to mean amounts billed to self-pay patients and patients covered by indemnity insurers with which the provider has no contractual arrangement, and any fee-for-service rates it contractually agrees to accept from any payor including any discounted fee-for-service managed care rates.³⁹³ The OIG's rationale for this change is that, because managed care negotiated rates may constitute a large percentage of a hospital's overall revenue, "usual charges" (as that term is used in the OIG's statutory permissive exclusion authority) must reflect the discounts that a hospital provides to its managed care organizations.³⁹⁴

OIG would not consider certain specified charges to be "usual," including charges for services furnished to uninsured patients free of charge or at a substantially reduced rate, capitated payments, certain hybrid fee-for-service

389. 42 U.S.C. § 1320a-7(b)(6)(A) (2002) (emphasis added) (authorizing the Secretary of the Department of Health and Human Services to enforce the permissive exclusion power); 53 Fed. Reg. 12993 (Apr. 20, 1988) (delegating such authority to the OIG).

390. Virtually no case law references the exclusionary authority relating to excessive charges, although the petitioner in *Green v. Sullivan*, 731 F. Supp. 835 (E.D. Tenn. 1990), sought, unsuccessfully, to have a mandatory exclusion recast as a permissive exclusion under § 1320a-7(b). In a case heard in Indiana, a plaintiff sought to have a contract declared invalid because it violated § 1320a-7(b)(6). *Zimmer v. NuTech Med., Inc.*, 54 F. Supp. 2d 850, 853 (N.D. Ind. 1999). The court determined invalidity on other grounds. *Id.* at 863-64.

391. Medicare and Federal Health Care Programs: Fraud and Abuse; Clarification of Terms and Application of Program Exclusion Authority for Submitting Claims Containing Excessive Charges, 68 Fed. Reg. 53,939 (Sept. 15, 2003) (to be codified at 42 C.F.R. pt. 1001). The OIG published, but never finalized, proposed rules addressing the definitions of the key terms of its exclusion authority in 1990 and 1993. 55 Fed. Reg. 12205 (Apr. 2, 1990); 62 Fed. Reg. 46,676 (Sept. 8, 1997).

392. A hospital's charge master reflects the price charged for each of the thousands of individually-coded services the hospital offers.

393. Medicare Program, 68 Fed. Reg. at 53,944 (to be codified at 42 C.F.R. § 1001.701 (a)).

394. *Id.* at 53,941.

arrangements, and fees set by Medicare or Medicaid.³⁹⁵ In determining “usual charge,” the OIG has proposed two different methodologies: computing the average of a provider’s charge for each particular item or service, or computing the median charge for such item or service.³⁹⁶ Notably, claims for physician services under Medicare Part B are excluded from the proposed rule because “the fee schedule amounts for physician services . . . are functionally equivalent to a prospective payment methodology.”³⁹⁷

Whether a provider submits a claim for payment that is “substantially in excess” of its usual charge will be a mathematic calculation under the OIG’s proposed rule.³⁹⁸ If a claim for service seeks payment that is more than 20% in excess of the provider’s “usual charge,” the OIG’s proposed rule would deem that charge to be “substantially in excess” of the usual charge.³⁹⁹ OIG has given no concrete basis for the seemingly arbitrary 20% threshold, and has offered only the explanation that “anecdotal evidence” supports that figure.⁴⁰⁰

In the event that a provider charges Medicare an amount that is “substantially in excess” of its “usual charge” but has “good cause,” the provider will not be subject to the OIG’s permissive exclusion authority.⁴⁰¹ OIG has indicated that “good cause” exists where a provider sets forth a “reasonable set of underlying facts and circumstances” necessitating the higher charge, such as unusual circumstances or medical complications experienced by the provider.⁴⁰²

As a general rule, the OIG’s proposal would equate payments with charges, but should not significantly affect payments received under the Medicare program. The determination whether a provider is charging Medicare substantially in excess of its usual charges only applies where Medicare pays the lower of cost or charges or the appropriate fee schedule.⁴⁰³ Because, as a general rule, providers’ charges are higher than the Medicare fee schedule, the proposed rule should typically not come into play. Nonetheless, if the proposed rule is finalized in its present form, providers will need to determine, on an ongoing basis, whether their charges exceed the 20% threshold, on a service by service basis, to prevent inadvertently “overcharging” the Medicare program. Moreover, because providers update their charge masters, managed care organizations continually negotiate new agreements with providers, and the Medicare program continually modifies its fee schedules, the exercise proposed by the OIG will become time consuming and potentially quite expensive.

395. *Id.*

396. *Id.*

397. *Id.* at 53,940.

398. *Id.* at 53,941.

399. *Id.* at 53,942.

400. *Id.*

401. *Id.* at 53,942-43.

402. *Id.*

403. 42 U.S.C. § 1320a-7(b)(6)(A) (2002).

X. IMMIGRATION: VISASCREEN CERTIFICATION FOR HEALTH CARE WORKERS

Shortages in health care professionals, most notably nurses, have caused U.S. employers to look outside the country's borders to fill the gap.⁴⁰⁴ Consequently, the immigration laws are an increasingly important consideration in health care staffing and human resource management. The recent modification of the VisaScreen requirement⁴⁰⁵ is a noteworthy development in immigration law applicable to the health care industry.

On July 25, 2003, the Department of Homeland Security ("DHS") published its final rule related to the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 ("IIRIRA")⁴⁰⁶ and the Immigration and Nationality Act ("INA").⁴⁰⁷ The IIRIRA requires that certain foreign healthcare workers have their credentials evaluated and certified before they will be allowed to work in their professions in the United States.⁴⁰⁸ Although IIRIRA has always required a credentials evaluation for foreign healthcare workers seeking permanent residency, under the new final rule it is also required of those seeking non-immigrant status in the United States.⁴⁰⁹ The rule lists seven categories of health care workers to which the VisaScreen applies: nurses, physical therapists, occupational therapists, speech-language pathologists and audiologists, medical technologists (also known as clinical laboratory scientists), medical technicians (also known as clinical laboratory technicians), and physicians' assistants.⁴¹⁰

The IIRIRA provides that the Commission on Graduates of Foreign Nursing Schools ("CGFNS"), through its International Commission on Healthcare Professionals ("ICHP") division, administers the VisaScreen verification.⁴¹¹ The statute does not specifically list all of the healthcare professions affected by the VisaScreen requirement (although physicians are specifically exempted), so employers and employees in unlisted healthcare professions are unclear as to the status of some professionals.⁴¹² A recent guidance memo issued by the Citizenship and Immigration Service does state that currently only those professionals described by the final rule's seven categories are subject to the VisaScreen requirements.⁴¹³

404. J. Berger, *From Philippines, with Scrubs: How One Ethnic Group Came to Dominate the Nursing Field*, N.Y. TIMES, Nov. 24, 2003, at B1.

405. Certificates for Certain Health Care Workers, 68 Fed. Reg. 43,901 (July 25, 2003) (the "VisaScreen").

406. Pub. L. No. 104-208, 110 Stat. 3009, 636-37 (1996) (codified at 8 U.S.C. § 1182(a)(5)(x) (2002)).

407. 8 U.S.C. §§ 1101-1537 (2003).

408. IIRIRA § 343.

409. 42 C.F.R. § 212.15 (2002).

410. *Id.* § 212.15(c).

411. 8 U.S.C. § 1182(a)(5)(C) (2002).

412. *See id.*

413. Memorandum from William Yates, Associate Director for Operations, Citizenship and Immigration Services, Department of Homeland Security (Sept. 22, 2003), *available at*

When originally introduced, the VisaScreen provisions of the IIRIRA established a new ground of inadmissibility for applicants seeking entry to the United States to work in health care.⁴¹⁴ The law dictates that an applicant is inadmissible unless he or she presents a certificate verifying that his or her education, training, license, and experience meet all requirements for entry to the United States and that the applicant is competent in both spoken and written English.⁴¹⁵

XI. LABOR: DEVELOPMENTS IN THE INDIANA WAGE PAYMENT STATUTE⁴¹⁶

In *Highhouse v. Midwest Orthopedic Institute*,⁴¹⁷ the Indiana Court of Appeals ruled on a case concerning the Indiana Wage Payment Statute. This case was granted transfer by the Indiana Supreme Court and a ruling is expected some time in 2004. A review of the issues and the appellate court's decision is appropriate.

Dr. Michael Highhouse had entered into an employment agreement with Midwest Orthopedic Institute ("MOI") in 1996.⁴¹⁸ Roughly three years into the contract, Dr. Highhouse gave MOI ninety days notice that he was terminating the employment agreement and would resign from MOI effective June 30, 1999, the end of the contract term.⁴¹⁹ Thereafter a dispute arose as to what monies were owed to the physician after his resignation.

Two specific issues required the trial court's interpretation. The first was whether the physician was owed any post-termination bonus payments under the employment agreement. The employment agreement provided that Dr. Highhouse would receive an annual bonus based upon his "productivity, collection of accounts, office expenses . . . and the net income of [various] offices [in] Indiana."⁴²⁰ Although Dr. Highhouse received his quarterly bonus for May 1999, he did not receive any further bonus payments following his resignation, while MOI continued to collect payments for services furnished by Dr. Highhouse prior to his resignation.⁴²¹

On appeal, MOI argued that the plain language of the employment agreement prohibited Dr. Highhouse from receiving bonuses after resigning. In support of its position, MOI cited the termination without cause section of the employment agreement that said Dr. Highhouse would only receive his regular compensation if MOI terminated the agreement early and gave ninety-day notice. However, the court found that this provision did not apply where Dr. Highhouse terminated the

<http://uscis.gov/graphics/lawsregs/handbook/FHCWmemo092203.pdf>.

414. Pub. L. No. 104-208, § 343, 110 Stat. 3009 (1996).

415. 8 U.S.C. § 1182(a)(5)(C).

416. IND. CODE §§ 22-2-5-1 to -3 (2003).

417. 782 N.E.2d 1006 (Ind. Ct. App. 2003).

418. *Id.* at 1009.

419. *Id.* at 1008.

420. *Id.* at 1009.

421. *Id.*

agreement, and noted that the agreement was silent on that point.⁴²² The court agreed with Dr. Highhouse that his right to bonus payments vested at the time he performed the services related thereto.⁴²³ Therefore, the court ruled that Dr. Highhouse was due bonus payments he earned prior to his resignation.⁴²⁴

The second issue was whether these monies owed to Dr. Highhouse were truly “bonuses,” as referred to in the employment agreement, or “wages” as defined in the Indiana Wage Payment Statute.⁴²⁵ If the monies were “wages,” then the physician would also be entitled to a mandatory award of liquidated damages pursuant to the Indiana Wage Payment Statute.⁴²⁶ Specifically, the statute requires an employer to pay wages to an employee who voluntarily leaves employment on the “next usual and regular day for payment of wages” following his or her departure.⁴²⁷ The Indiana Wage Payment Act defines wages 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.”⁴²⁸

In past cases, Indiana courts found that a payment will constitute a wage despite being called a bonus if it relates directly to the time an employee works; is paid on a regular, periodic basis, and was not predicated on the financial success of the employer.⁴²⁹ In finding that the bonus payments were actually “wages,” the court cited the mandatory language in the employment agreement: “Employer shall also pay an annual bonus to Employee based upon Employee’s productivity”⁴³⁰ In addition, the court noted that MOI historically paid bonuses on a quarterly basis (*i.e.* paid on a regular, periodic basis).

The appellate court therefore found that the trial court erred by not granting Dr. Highhouse partial summary judgment on his claim that the bonuses constituted wages under the Indiana Wage Payment Statute.⁴³¹ However, as noted above, the Indiana Supreme Court’s ruling is expected in 2004 and is anticipated to provide additional guidance as to the definition of “wages” in Indiana.

422. *Id.* at 1011.

423. *Id.*

424. *Id.* at 1011, 1012.

425. *Id.* at 1012.

426. *Id.*

427. IND. CODE § 22-2-5-1 (1998).

428. *Id.* § 22-2-9-1(b).

429. *Highhouse*, 782 N.E.2d at 1013 (citing *Gurnik v. Lee*, 587 N.E.2d 706, 710 (Ind. Ct. App. 1992)).

430. *Id.* at 1014.

431. *Id.*