SURVEY OF RECENT DEVELOPMENTS IN HEALTH LAW

ICE MILLER LLP*

INTRODUCTION

This survey summarizes recent developments in case law, legislation, and administrative actions that affect the health care industry. Not meant to be an exhaustive review, this survey details the "hot" topics in the health care industry this survey year.[1]

I. FRAUD AND ABUSE

A. E-Prescribing and Electronic Health Records Safe Harbor Regulations

The Medicare Modernization Act of 2003[2] directed the Secretary of Health and Human Services ("HHS") to create exemptions from the Anti-kickback statute[3] and Stark law,[4] to permit certain entities to provide nonmonetary remuneration in the form of hardware, software, and information technology and training services, in connection with the transmission of electronic prescription information.[5] On August 8, 2006, the Department of Health and Human Services ("HHS") and Centers for Medicare and Medicaid Services ("CMS") published final regulations which implemented the statutory requirement.[6]

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* The following Ice Miller LLP attorneys contributed to the research and drafting of this article: Sarah Cotterill, Tami Earnhart, Lisa Gethers, Blaire Henley, Taryn Smith, Ann Stewart, Brad Williams, and Kevin Woodhouse.

1. October 1, 2005 to September 30, 2006.

2. Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified in scattered sections of 42 U.S.C. § 1395w-101 (2000)).

3. 42 U.S.C. § 1320a-7b(b) (2000). The Anti-kickback statute prohibits the knowing or willful offer, payment, solicitation or receipt of any remuneration in return for patient referrals, or the ordering or recommendation of an item or service, covered under a federal healthcare program. *Id.* The statute permits the Secretary to establish exceptions, known as "safe harbors," for certain non-abusive practices which, if conditions are met, will not be treated as violations. *Id.* § 1320a-7b(b)(3)(E).

4. 42 U.S.C. § 1395nn (2000). The statute prohibits physician referrals of patients to an entity for certain "designated health services" if the physician has a financial relationship (including certain ownership, investment, or compensation arrangements) with the entity.

5. Medicare Prescription Drug, Improvement, and Modernization Act 2003, Pub. L. No. 108-173, § 1860D-4(e)(6), 117 Stat. 2066 (2003); 42 U.S.C. § 1395w-104(e)(6) (2000).

6. Medicare and State Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the Anti-kickback Statute, 71 Fed. Reg. 45,110 (Aug. 8, 2006) (Anti-kickback statute safe harbors), adding 42 C.F.R. § 1001.962(x) (2006); Medicare Program; Physicians Referrals to Health Care Entities with Which They Have Financial Relationships; Exceptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 71 Fed. Reg. 45,140 (Aug. 8, 2006) (Stark law exceptions), adding 42 C.F.R. §411.357(v) (2006).

The new regulations actually go beyond the statutory mandate. In addition to the required exemptions for e-prescribing technology, the regulations also create a separate Stark law exception, and an Anti-kickback statute safe harbor, to encourage the adoption and use of "interoperable"[7] Electronic Health Records[8] ("EHR") software, information technology, and training services.

The e-prescribing regulations require that the donation be nonmonetary, consisting of items or services in the form of hardware, software, or information technology services, which are necessary and are used solely to transmit and receive e-prescription information.[9] The EHR regulations are similar, but provide that (1) only donations of software, information technology and training systems (not hardware) are protected, and (2) recipients must contribute fifteen percent of the donor's cost.[10]

Under both regulations, donors may not take action to limit or restrict the compatibility of the items or services with other electronic prescribing or EHR systems.[11] Donors cannot restrict the use of the items or services for any patient without regard to payor status.[12] Recipients may not make the receipt of such items or services a condition of doing business with the donor.[13] Donors may not condition eligibility for the items or services, or the amount or nature of the items or services, in a manner that takes into account the volume or value or referrals or other business generated.[14] Donors may not provide items or services that the recipient already has. The arrangement must be in writing, signed by the parties, specify the items or services being provided and the donor's cost, and cover all items or services provided by the donor.[15]

The EHR regulations expire on December 21, 2013, consistent with the

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7. "Interoperable" is defined as "able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings[,] and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered." 42 C.F.R. § 1001.952(y) (note) (2006); *id.* § 411.351.

8. "Electronic health record means a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions." *Id.* § 1001.952(x) (note); *id.* § 411.351.

9. *Compare id.* § 1001.952(x); *id.* § 411.351 (The "used solely" requirement means that e-prescribing hardware and software cannot include general office functions such as scheduling or billing.), *with id.* § 1001.952(y); *id.* § 411.351(w) (EHR technology need only be "used predominantly" to create, maintain, transmit, or receive electronic health records.).

10. *Id.* § 1001.952(y)(11); *id.* § 411.351(w)(4).

11. *Id.* § 1001.952(x), (y).

12. *Id.*

13. *Id.*

14. However, the EHR regulations permit donors to take into account the total number (but not the volume or value) of prescriptions written by the recipient. *Id.* § 1001.952(y)(5); *id.* § 411.357(w)(6).

15. *Id.* § 1001.952(x)(3)-(8); *id.* § 411.357(v)(3)-(8).

Administration's goal of adopting EHR technology by 2014.[16]

B. OIG Voluntary Disclosure Initiative

On April 24, 2006, Inspector General Daniel R. Levinson issued "An Open Letter to Health Care Providers."[17] The letter announced a new initiative to promote the agency's 1998 Self-Disclosure Protocol,[18] which could afford providers some relief from Civil Monetary Penalty ("CMP")[19] liability under the physician self-referral and Anti-kickback statutes.[20]

The 2006 letter leaves in place the standards concerning corporate integrity agreements ("CIAs") established by the Office of Inspector General ("OIG") in 2001.[21] OIG will continue to settle appropriate overpayment cases by entering into less-onerous Certification of Compliance Agreements ("CCAs") which are shorter-lived and do not require costly monitoring by outside independent review organizations.

The 2006 initiative is limited to overpayments implicating the Stark law and Anti-kickback statute, which arise from hospital financial relationships with physicians. The principal benefit offered by the policy is reduced exposure to CMPs.[22] The 2006 letter provides that, for providers participating in the Self Disclosure Protocol, OIG will generally settle CMP claims based upon a multiple of the value of the financial benefit conferred by the hospital by the physician, which is far less than the maximum possible penalty.[23]

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16. *Id.* § 1001.952(y)(13); *id.* § 411.357(w)(13); *see* Office of Inspector General, Message from the Inspector General (2006), http://oig.hhs.gov/publications/docs/semiannual/2006/semiannual%20Final%20FY%202006.pdf (discussing the 2014 goal).

17. Office of Inspector General, An Open Letter to Health Care Providers (Apr. 24, 2006), http://oig.hhs.gov/fraud/docs/openletters/Open%20Letter%20to%20Providers%202006.pdf [hereinafter 2006 Open Letter].

18. 63 Fed. Reg. 58,399 (Oct. 30, 1998). The Self Disclosure Protocol sets out a procedure for provider self-audit, reporting and repayment of alleged overpayments. The program was considered flawed because, among other things, (1) it required costly sampling and analysis to yield a statistically significant (ninety percent confidence level) result, (2) it offered no specific benefit in return for the disclosure, and (3) as an OIG policy, it did not affect the U.S. Department of Justice's prosecutorial discretion.

19. 42 U.S.C. § 1320a-7a (2000).

20. *See supra* notes 2-3.

21. Office of Inspector General, An Open Letter to Health Care Providers (Nov. 20, 2001), http://oig.hhs.gov/fraud/docs/openletters/openletter111901.htm.

22. 2006 Open Letter, *supra* note 17.

23. *Id.* OIG may impose a CMP on each claim for payment for a service rendered in violation of the Stark law of not more than $15,000. 42 U.S.C. § 1395nn(g)(3) (2000). Each violation of the Anti-kickback statute is subject to a CMP of up to $50,000, plus an assessment of up to three times the amount claimed for each item or service arising from the violation. 42 *Id.* § 1320a-7a(a). The OIG may also exclude violators from participation in federal health care programs. *Id.*

Providers participating in the program must give "full cooperation and complete disclosure of the facts and circumstances surrounding the violation."[24] The degree of a provider's cooperation will be considered in OIG's determination whether to require a CMP.[25]

As with earlier versions, the policy does not guarantee any particular benefit to a prospective participant. The policy does not bind the U.S. Department of Justice ("DOJ"). Indeed, before accepting a provider into the program, OIG will confer with DOJ to ensure that it is aware of each disclosure and has an opportunity to comment.[26]

C. Mandatory False Claims Act Policies

Section 6032 of the Deficit Reduction Act of 2005[27] imposed new compliance obligations on large providers which became effective January 1, 2007. As of that date, states must amend their respective plans for medical assistance to include a requirement applicable to every entity that receives at least five million dollars annually in Medicaid payments. State plans must require that covered entities establish written policies that provide detailed information concerning the federal False Claims Act[28] and applicable state statutes providing civil or criminal penalties for false claims.

The required policies must cover, and be provided to, all contractors and agents of the entity, as well as the entity's employees. Written policies must include measures for detecting waste, fraud and abuse, and set out the rights of employees to be protected as whistleblowers. Notwithstanding that the section title is "Employee Education About False Claims Recovery,"[29] the text of the section as passed does not mandate that employers provide actual training.

On December 13, 2006, CMS issued a letter to state Medicaid directors providing limited guidance.[30] The letter makes clear that the five million dollar threshold will be applied to entities as a whole, without regard to the number of locations providing service or the types of services provided. The letter does not clarify what is meant by the "detailed information" which written policies must include but states that CMS will not provide model language illustrating the required policies.[31]

Entities may disseminate written policies in paper or electronic form, so long as they are "readily available." Although the section references employee

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24. 2006 Open Letter, *supra* note 17.

25. *Id.*

26. *Id.*

27. Pub. L. 109-171, § 6032, 120 Stat. 4, 73-74 (codified at 42 U.S.C. § 1396a(a)(68) (2000)).

28. 31 U.S.C. § 3729 (scattered sections) (2000).

29. Pub. L. No. 109-17, § 6032, 120 Stat. 4, 73-74 (2005).

30. Letter from the Centers for Medicare & Medicaid Services to State Medicaid Directors, http://www.cms.hhs.gov/smdl/downloads/SMD121306.pdf.

31. *Id.*

handbooks, the letter provides that an entity need not create a handbook if none exists.

D. Indiana False Claims Act

Section 6031 of the Deficit Reduction Act[32] provides financial incentives for states to enact false claims laws. States with acts meeting the federal requirements[33] qualify for a ten percent increase in the state's share of amounts recovered in a state action brought under the law. Indiana promptly adopted such a law in the 2005 legislative session,[34] as did several other states.

To qualify for the increased recovery, state laws, must among other things, preserve the *qui tam* provisions of the federal version,[35] and provide for civil penalties not less than the amount contained in the federal version. Approval of state laws rests with OIG.

In August 2006, after many states had already crafted relevant legislation, OIG published guidelines for evaluating whether state false claims laws meet the section 6031 requirements.[36] In December 2006, the Secretary rejected seven out of the ten newly-adopted state statutes submitted for approval, including Indiana's statute.[37] In a letter to Indiana authorities dated December 21,[38] the Secretary determined that Indiana's statute did not adequately mirror the federal version with respect to the definition of "knowing" conduct.[39] Indiana's statute failed because it applies to a person who acts "knowingly or intentionally," but does not define the term "knowingly" to include reckless conduct.[40]

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32. Pub. L. No. 109-171, § 6031, 120 Stat. 4, 72-73 (codified at 42 U.S.C. § 1396d (2000)).

33. 42 U.S.C. § 1396d(b).

34. IND. CODE § 5-11-5.5-1 (2005). For an analysis of the statute's provisions, see Ice Miller LLP, *Summary of Recent Developments in Health Law*, 39 IND. L. REV. 1051, 1069 (2006).

35. Individuals with evidence of prohibited conduct (referred to as "relators") may file a complaint on behalf of the United States against the alleged wrongdoer. The complaint is kept under seal for a period of at least sixty days and is not served on the defendant during that period. During the period the complaint is under seal, the government must investigate the claim and determine whether it will intervene in the action and thereafter control it. If the government declines to intervene, the relator may proceed with the action. 31 U.S.C. § 3730 (2000).

36. OIG's Guidelines for Evaluating State False Claims Acts, 71 Fed. Reg. 48,552 (Aug. 21, 2006).

37. *Few State Whistleblower Laws Meet Requirements for Incentive Bonus, OIG Finds*, 11 BNA HEALTH CARE FRAUD REPORT 8 (Jan. 3, 2007).

38. Letter from Daniel R. Levinson, Inspector General, to Allen K. Pope, Director, Indiana Medicaid Fraud Control Unit, http://oig.hhs.gov/fraud/docs/falseclaimsact/Indiana.pdf.

39. The federal False Claims Act provides that a person acts "knowingly" with respect to information if he "acts in deliberate ignorance of the truth or falsity of the information," or "acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b) (2000).

40. IND. CODE § 5-11-5.5-2 (2005). Such a definition of "knowingly" would not be consistent with Indiana's Model Penal Code-based general definition of the term. *See* IND. CODE § 35-41-2-2(b) (2004) ("A person engages in conduct 'knowingly' if, when he engages in the

The Secretary's disapproval does not interfere with enforcement of the Indiana statute, but will affect the State's share of recoveries in actions brought under it.

E. Nuclear Medicine as Designated Health Services Under Stark

On November 21, 2005, CMS issued a final rule which amends the definition of "designated health services" under the Stark law to include diagnostic nuclear medicine.[41] In the final rule, CMS revised the definition of both "radiology and certain other imaging services" and "radiation therapy services and supplies" to remove the exclusionary language that had previously excluded diagnostic nuclear medicine from the definition of "designated health services."[42] The final rule is effective January 1, 2007.

II. DEFICIT REDUCTION ACT OF 2005

On February 8, 2006, the President signed the Deficit Reduction Act of 2005 ("DRA").[43] The DRA is expected to slow the pace of spending in the Medicare and Medicaid programs by roughly $40 billion. The DRA contains a number of provisions that will significantly affect Medicare and Medicaid reimbursement, some of which are summarized below.

A. Medicare Part A

1. Hospital Quality.—Section 5001(a) of the DRA expands a provision of the Medicare Modernization Act of 2003 ("MMA")[44] which ties Medicare inpatient hospital reimbursement to the hospital reporting certain quality data based on ten quality indicators.[45] The DRA provides that hospitals that do not report the quality data will have their payment update reduced by two percentage points beginning in fiscal year 2007.[46] The DRA also calls for the Secretary to expand the number of quality indicators that must be reported by hospitals.[47] The Secretary may replace or change quality measures as appropriate and all quality

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conduct, he is aware of a high probability that he is doing so."). Recklessness constitutes a separate and distinct mental state ("plain, conscious, and unjustifiable disregard of harm that might result and the disregard involves a substantial deviation from acceptable standards of conduct"). IND. CODE § 35-41-2-2(c) (2004). In order to conform to the federal requirement without undoing these provisions, the General Assembly would have to create a special definition of "knowingly" which is unique to the False Claims Act.

41. 70 Fed. Reg. 70,116, 70,283 (Nov. 21, 2005).
42. *Id.*
43. Pub. L. No. 109-171, 120 Stat. 4 (codified in scattered sections of 42 U.S.C.).
44. Pub. L. No. 108-173, 117 Stat. 2066 (2003).
45. Pub. L. No. 109-171, § 5001(a), 120 Stat. 4 (codified at 42 U.S.C. § 1396d (2000)).
46. 42 U.S.C. § 5001(a)(3)(viii)(I).
47. *Id.* § 5001(a)(3)(viii)(III).

data submitted under this requirement must be available to the public.[48]

2. Value-Based Purchasing Program.—Section 5001(b) of the DRA also requires the Secretary to develop a plan to implement a "value-based" purchasing program for the inpatient prospective payment system ("IPPS") payments to acute care hospitals.[49] The plan must consider: (1) the on-going development, selection, and modification process for measures of quality and efficiency in hospital inpatient settings; (2) the reporting, collection, and validation of quality data; (3) the structure of value-based payment adjustments, including the determination of thresholds or improvements in quality that would substantiate a payment adjustment, the size of the payment adjustment, and the sources of funding for the value-based purchasing payments; and (4) the disclosure of information on hospital performance.[50]

3. Gainsharing Demonstration Projects.—Section 5007 of the DRA directs the Secretary to establish a gainsharing demonstration project.[51] The gainsharing demonstration projects will "test and evaluate methodologies and arrangements between hospitals and physicians designed to govern the utilization of inpatient hospital resources and physician work to improve the quality and efficiency of care provided to Medicare beneficiaries and to develop improved operational and financial hospital performance with sharing of remuneration."[52] The gainsharing demonstration projects must arrange for remuneration as a share of savings, operate pursuant to a written plan agreement, include a patient notification process, monitor quality and efficiency of care, certify that elements of the program are subject to independent review, and contain referral limitations.[53] Previously, questions arose regarding whether gainsharing arrangements can be structured in compliance with the Anti-kickback statute,[54] the Stark Law,[55] and the Civil Money Penalty ("CMP") provision which prohibits hospital payments to physicians which reduce or limit care.[56] The DRA, however, explicitly provides that gainsharing demonstration projects will not violate the Anti-kickback statute, the Stark Law or the CMP.[57]

B. Medicare Part B

1. Imaging Services.—The Medicare Physician Fee Schedule update for calendar year 2006[58] contained a payment discount of the technical component

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48. *Id.* § 5001(a)(3)(viii)(VI)-(VII).
49. *Id.* § 5001(b).
50. *Id.* § 5001(b)(2).
51. *Id.* § 5007.
52. *Id.* § 5007(a).
53. *Id.* § 5007(b)(1)-(6).
54. 42 U.S.C. § 1320a-7b(b) (2000).
55. *Id.* § 1395nn.
56. *Id.* § 1320a-7a(b).
57. Pub. L. No. 109-171, § 5007(c)(1), 120 Stat. at 34.
58. 70 Fed. Reg. 70,116, 70,216 (Nov. 21, 2005).

of certain multiple imaging procedures performed on contiguous body parts during a single visit. Under the payment discount, Medicare pays the full technical component for the most expensive imaging procedure and then applies a twenty-five percent discount to all other procedures performed during a single session for calendar year 2006.[59] The DRA exempted these reduced payment for multiple imaging procedures from the budget neutrality calculation.[60]

The DRA also caps reimbursement for the technical component of certain imaging services payable under the Medicare Physician Fee Schedule to the payment amounts under the Medicare Hospital Outpatient Prospective Payment System.[61] The payment cuts apply to "imaging and computer-assisted imaging services, including x-ray, ultrasound (including echo-cardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computing tomography, and fluoroscopy, but [will exclude] diagnostic and screening mammography."[62] The payment cuts are effective January 1, 2007.

2. Limits on ASC Payments.—Section 5103 of the DRA provides that payment rates for services performed in an ambulatory surgery centers may not exceed the payment rates for the same services performed in a hospital outpatient department under the Medicare Hospital Outpatient Prospective Payment System.[63] This provision is effective January 1, 2007 and until the Secretary establishes a revised payment system for ASCs.[64]

3. Physician Fee Schedule.—Section 5104 of the DRA calls for a zero percent update to Medicare payments for physician services for calendar year 2006 instead of the proposed 4.4 percent reduction in payments for physician services by Medicare.[65]

C. Medicare Parts A & B

Section 5201 of the DRA eliminates the payment update to the Medicare home health prospective payment rates for 2006.[66]

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59. *Id.* The Physician Fee Schedule for Calendar Year 2006 contained a provision that would have increased the twenty-five percent discount to a fifty percent discount in 2007. However, in the final Medicare Physician Fee Schedule Update for Calendar Year 2007, CMS maintained the twenty-five percent discount for 2007. 71 Fed. Reg. 69,659, 69,624 (Dec. 1, 2006).

60. Pub. L. No. 109-171, § 5102(a), 120 Stat. at 39. The exclusion of the multiple imaging procedure discount from the budget neutrality calculation means that any savings derived will not be counted in the pool of available funds for Medicare payments to physicians.

61. *Id.* § 5102(b), 120 Stat. at 39.

62. *Id.*

63. *Id.* § 5103, 120 Stat. at 39.

64. A revision of the payment system is called for in the MMA by January 2008. For discussion of the proposed rule, see *infra* Part III C.

65. Pub. L. No. 109-171 § 5104, 120 Stat. at 40-41.

66. *Id.* § 5201, 120 Stat. at 46.

D. Medicaid

Additionally, the DRA makes a number of significant changes to Medicaid reimbursement, specifically, to pharmacy reimbursement and Medicaid rebate programs.[67] The DRA also makes significant changes to the Medicaid asset transfer rules and eligibility provisions.[68] The DRA contains a number of Medicaid fraud and abuse provisions, discussed in Part I. Finally, the DRA contains a number of provisions which expand the ability of states to impose premiums and cost sharing requirements on Medicaid recipients, including cost sharing for prescription drugs and copayments for non-emergency care provided in the emergency room.[69]

III. REIMBURSEMENT

In addition to the reimbursement changes in the DRA, there have been other significant changes in Medicare reimbursement.

A. Inpatient Prospective Payment System Changes

In an effort to better align payments for inpatient hospital services with costs of care and address concerns that the existing payment system encourages investment in specialty hospitals and "cherry picking" of more profitable cases, on August 1, 2006, CMS issued a final rule which significantly changes Medicare reimbursement in the Inpatient Prospective Payment System ("IPPS") for fiscal year 2007.[70] The final rule assigns weights to DRGs based on hospital costs rather than charges, effective October 1, 2006.[71] These changes will be phased in over a three year period. CMS also added twenty new DRGs to better reflect severity.[72] Under the proposed rule, CMS proposed to adjust DRGs for patient severity. However, in the final rule, CMS announced that it would continue to study DRG classification options to adjust for patient severity with more comprehensive changes in 2008 following further evaluation and study by an outside contractor.[73]

B. Long Term Acute Care Hospital Payment Changes

On May 12, 2006, CMS issued a final rule that changes the payment for long term acute care hospitals ("LTCHs").[74] The final rule specified that there would

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67. *Id.* § 6001-6003, 120 Stat. at 54-61.

68. *Id.* § 6011-6016, 120 Stat. at 61-67.

69. *Id.* § 6041-6044, 120 Stat. at 81-92.

70. Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2007 Rates, 71 Fed. Reg. 47,870 (Aug. 18, 2006) (to be codified at scattered sections of 42 C.F.R.).

71. *Id.*

72. *Id.*

73. *Id.*

74. Prospective Payment System for Long-Term Care Hospitals RY 2007, 71 Fed. Reg. 27,798 (May 12, 2006) (to be codified at 42 C.F.R. pt. 412).

be a zero percent update to LTCH payments for Rate Year ("RY") 2007.[75] The new rule also revised the labor-related share of the LTCH prospective payment system federal rate to account for geographic differences in the area wage levels.[76]

CMS also revised the payment adjustment formula for short stay outliers ("SSOs"). Previously, CMS adjusted payments for discharges "by the lesser of the 120 percent of the estimated cost of the case, 120 percent of the LTC-DRG specific per diem amount multiplied by the [length of stay] of that discharge, or the full LTC-DRG payment."[77] Under the new final rule, CMS reduced the adjustment from 120% of the patient cost to 100% of the patient cost and added a fourth component to the "lesser of" list for payment adjustments: "a blend of the IPPS-comparable per diem payment amount (capped at the full IPPS comparable payment amount), and the 120 percent of the LTC-DRG per diem payment amount."[78]

The new rule also provides that Medicare will pay an additional amount for high cost cases.[79] CMS also eliminated the surgical DRG expection to the three day or less interrupted stay policy.[80] The three day or less interrupted stay policy provides that where a LTCH patient is discharged to an "acute care hospital, IRF, [skilled nursing facility (SNF)], or the patient's home and [is] readmitted to the [long-term care hospital] within [three] days, Medicare makes only one LTCH PPS payment and does not provide for a separate payment for the services provided during the three day or less period.[81] The former rule contained an exception which allowed a separate payment to an acute care hospital in the event the treatment at the acute care hospital was for inpatient surgery.[82] Under the new rule, CMS phased out this exception.

C. ASC Payment Changes

In the Medicare Modernization Act of 2003 ("MMA"), Congress directed CMS to develop and implement a new payment methodology for ambulatory surgery centers ("ASCs") by January 1, 2008.[83] On August 8, 2006, CMS proposed a new payment system for ASCs that would base payments on the procedure classification and payment systems Medicare uses to pay hospitals for outpatient services.[84]

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75. *Id.* at 27,819.
76. *Id.* at 27,828.
77. *Id.* at 27,845.
78. *Id.* at 27,851.
79. *Id.* at 27,838.
80. *Id.* at 27,872.
81. *Id.*
82. *Id.*
83. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 626, 117 Stat. 2066, 2068 (2003).
84. *See generally* Hospital Outpatient Prospective Payment System and CY 2007 Payment

> The proposed rule is intended to encourage quality, efficient care in the most appropriate outpatient setting given the rapid spending growth for services and the large variations in the use of services and to take needed steps to more logically align payment rates across payment systems to eliminate payment incentives favoring one care setting over another.[85]

Under the new rule, CMS is proposing to pay ASCs 62 percent of the hospital payment for procedures performed in an ASC.[86] Additionally, CMS is changing how it determines what procedures it will reimburse when furnished in the ASC setting. Presently, CMS has an "inclusive" list of roughly 2500 procedures that it has approved for the ASC setting. Under the proposed rule, CMS would allow payment for procedures in an ASC setting, except those procedures that CMS determines are not appropriate or safe when performed in an ASC setting, thus creating an "exclusionary" list.[87] CMS has also, under the proposed rule, proposed to cap payment for "office-based" procedures to be the lesser of the Medicare physician fee schedule payment or the ASC rate under the new payment system.[88]

IV. Medicare Enrollment

On April 21, 2006, CMS published a final rule regarding provider and supplier enrollment requirements.[89] The new regulations set forth requirements for initial enrollment in the Medicare program and require providers and suppliers to update and report changes to certain information previously submitted on the enrollment application.[90] The final rule was effective June 20, 2006. In addition to the final rule, CMS has revised its Medicare Enrollment Application, specifically CMS Forms 855A, B, I, R, and S.[91] The new Medicare Enrollment Applications must be used effective April 2006.

V. Clinical Trials

In 2006, the Centers for Medicare & Medicaid Services ("CMS") announced that it is reconsidering its national coverage decision ("NCD") on the Clinical

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Rates, 71 Fed. Reg. 49,506 (Aug. 23, 2006) (codified at scattered parts of 42 C.F.R.).

85. CMS, Fact Sheets: Proposal for a Revised Payment System for Services Provided in Ambulatory Surgical Centers (Aug. 8, 2006), http://www.cms.hhs.gov/media/press/factsheet.asp?Counter=1940.

86. *Id.*

87. *Id.*

88. *Id.*

89. Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment, 71 Fed. Reg. 20,754 (Apr. 21, 2006) (to be codified at scattered sections of 42 C.F.R.).

90. 42 C.F.R. § 424.500 (2006).

91. CMS, Enrollment Applications (Apr. 2007), http://www.cms.hhs.gov/MedicareProviderSupEnroll/03_EnrollmentApplications.asp.

Trial Policy,[92] which describes the circumstances under which Medicare will cover certain items and services provided during the course of a clinical trial.

Previously, Medicare had not paid for items and services related to clinical trials because of their experimental nature. On July 10, 2006, however, CMS opened a reconsideration of its national coverage determination on clinical trials.[93] The purpose of the reconsideration is to further refine the policy, to rename it the Clinical Research Policy ("CRP"), to address several ambiguities, including the link between the CRP and the Coverage with Evidence Development concept, and the authority to allow Medicare to pay for the costs of limited investigational items.[94]

The current Clinical Trial Policy was developed in response to a June 7, 2000, executive memorandum, issued by President Clinton, directing Medicare to pay for routine patient costs in certain clinical trials.[95] The 2000 Clinical Trial Policy, implemented September 19, 2000, requires trials to be "qualified" prior to payment of routine costs.[96] The policy also provides for certain trials to be deemed qualified; i.e., those that are approved and funded by a federal agency or have an IND approval from the FDA or are IND exempt.[97] An additional option, the self-certification option, was never implemented.

On October 27, 2006, CMS published in the Federal Register its Notice of the December 13, 2006 Medicare Coverage Advisory Committee ("MCAC") meeting to consider issues associated with this NCD reconsideration.[98] Because CMS decided to convene an MCAC, it has not yet issued a proposed decision memorandum on the issue and expected completion date of the National Coverage Analysis ("NCA") has been amended to July 9, 2007.

Specifically, CMS identified ten issues it intends to address as part of its reconsideration of the Clinical Trial Policy. These include the need to:

> (1) Clarify payment criteria for clinical costs in research studies other than clinical trials; (2) Devise a strategy to ensure that Medicare covered clinical studies are enrolled in the National Institute of Health ("NIH") clinical trials registry website;[99] (3) Develop criteria to assure that any Medicare covered clinical research study includes a representative

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92. Meeting of the Medicare Coverage Advisory Committee, 71 Fed. Reg. 63,021 (Oct. 27, 2006).

93. OMS, Medicare Reuses Guidance for National Coverage Determinations with Evidence Development (July 12, 2006), http://www.cms.hhs.gov/apps/media/press/release.asp?Counter =1897.

94. *Id.*

95. *See* Medicare Clinical Trial Policies Overview, http://www.cms.hhs.gov/ClinicalTrial Policies/ (last visited June 10, 2007).

96. *Id.*

97. *Id.*

98. Meeting of the Medicare Coverage Advisory Committee, 71 Fed. Reg. 63,021 (Oct. 27, 2006).

99. *See* http://www.clinicaltrials.gov (last visited Apr. 5, 2007).

> sample of Medicare beneficiaries, by demographic and clinical characteristics; (4) Clarify the definitions of routine clinical care costs and investigational costs in clinical research studies including clinical trials; (5) Remove the self-certification process that was never implemented; (6) Clarify the scientific and technical roles of Federal agencies in overseeing IND [investigational new drug] Exempt trials; (7) Determine if coverage of routine clinical care costs is warranted for studies beyond those covered by the current policy[;] (8) Clarify how items/services that do not meet the requirements of [Section] 1862(a)(1)(A) [of the Social Security Act[100]] but are of potential benefit can be covered in clinical research studies . . .;[101] (9) Clarify whether and under what conditions an item/service non-covered nationally may be covered in the context of clinical research to elucidate the impact of the item or service on health outcomes in Medicare beneficiaries; and (10) Discuss Medicare policy for payment of humanitarian use device (HUD) costs.[102]

Although the current Clinical Trial Policy broadened the scope of Medicare payments and was instrumental in expanding access to clinical trials for Medicare beneficiaries, its general terms left substantial uncertainty in the research community regarding which costs are in fact eligible for reimbursement under Medicare. A CMS change to its current coverage policy will likely have a significant impact on manufacturers, providers, and patients with respect to coverage, reimbursement, billing, compliance, and patient access to new technology.

VI. PRICE TRANSPARENCY

On August 22, 2006, President George W. Bush signed an executive order which directs federal agencies that administer or sponsor a healthcare program to increase price and quality transparency by January 1, 2007.[103] The order directs federal agencies and their contractors to utilize, where available, health information technology systems and products so that health data can be easily shared.[104] The order also requires agencies to collect and share with beneficiaries information about prices paid to healthcare providers by insurers or health

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100. Section 1862(a)(1)(A) of the Social Security Act requires that "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A) (2000).

101. Medicare has separately just released final guidance on "Coverage with Evidence Development" that includes provisions for coverage of items and services that may not meet the requirements of Section 1862(a)(1)(A) under "Coverage with Study Participation."

102. MCAC Meetings, Clinical Trial Policy, http://www.cms.hhs.gov/med/viewmcac.asp?where=index&mid=38.

103. Exec. Order No. 13410, 71 Fed. Reg. 51,089 (Aug. 22, 2006), *available at* http://www.whitehouse.gov/news/releases/2006/08/print/20060822-2.html.

104. *Id.*

insurance plans for procedures performed along with the overall cost of services for common episodes of care and treatment of common chronic diseases.[105] The order also requires agencies to collect and share with beneficiaries information about the quality of services provided by doctors, hospitals, and other healthcare providers.[106] The President said the executive order is the "first step" in a larger plan to provide open health quality and price information and invited other employers to make similar commitments.[107]

VII. EMTALA

Effective October 1, 2006, CMS revised hospital responsibilities under EMTALA.[108] First, the rule expands the type of health care professional who may certify false labor. Under the new rule,

> [A] woman experiencing contractions is in true labor unless a physician, certified nurse-midwife, or other qualified medical person acting within his or her scope of practice as defined in hospital medical staff bylaws and State law, certifies that, after a reasonable time of observation, the woman is in false labor.[109]

Hospitals, therefore, may revise their definition of "qualified medical personnel" to include certified nurse midwives and nurse practitioners.[110]

The rule also clarifies the application of EMTALA requirements to hospitals without dedicated emergency departments. Under 42 CFR § 489.24(b), only a hospital with a dedicated emergency department has an EMTALA responsibility with respect to an individual for whom no appropriate transfer is sought but who comes to the hospital seeking examination or treatment for a medical condition.[111] However, in recent years with the proliferation of specialty hospitals, there has been some confusion regarding EMTALA application to hospitals with specialized capabilities but who are without dedicated emergency departments. The final rule clarifies that hospitals with specialized capabilities[112] that do not have a dedicated emergency department are bound by the same responsibility to accept an appropriate transfer under EMTALA as hospitals with a dedicated emergency department.[113]

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105. *Id.*

106. *Id.*

107. *Id.*

108. Changes to the Hospital Inpatient Prospective Payment Systems and CY 2007 Rates, 71 Fed. Reg. 47,870 (Aug. 18, 2006) (to be codified at scattered sections of 42 C.F.R.).

109. *Id.* (to be codified at 42 C.F.R. pt. 489.24(b)).

110. *Id.*

111. 42 C.F.R. § 489.24(b) (2006).

112. "Specialized capabilities" is defined in 42 C.F.R. § 489.24(f) (2006).

113. Changes to the Hospital Inpatient Prospective Payment Systems and CY 2007 Rates, 71 Fed. Reg. 47,870 (Aug. 18, 2006) (to be codified at 42 C.F.R. § 489.24). CMS noted, in the final rule, that this only clarified, it did not change, their position that EMTALA applies to hospitals with

VIII. MEDICAL STAFF CREDENTIALING AND PEER REVIEW

A. JCAHO Medical Staff Credentialing and Privileging Standards

The Joint Commission on Accreditation of Healthcare Organizations ("JCAHO") issued proposed revisions to the Medical Staff Credentialing and Privileging Standards.[114] The revisions amend the existing credentialing and privileging standards to ensure that the practitioner's proficiency is assessed in the "six areas of 'General Competencies' adopted from the Accreditation Council for Graduate Medical Education (ACGME) and the American Board of Medical Specialties (ABMS) joint initiative."[115] The six "General Competencies" include patient care, medical knowledge, practice-based learning and improvement, interpersonal and communication skills, professionalism, and system-based practice.[116] The major factors used to support the six General Competencies in the process of credentialing and privileging are "licensure, relevant training, experience, and current competence to perform the requested privilege."[117] The revised standards identify other reasonable criteria, which may be added by the organized medical staff, to include patient care, treatment and service skills expected in staff members with the applicant's skills and training.[118]

Most significantly, the proposed revisions address three main areas through the imposition of six new standards: privilege-specific resource availability, performance monitoring, and continuous practice evaluation. First, the proposed revisions, as indicated in the introduction, recognize that privileges are setting-specific and therefore are based not only on an applicant's qualifications, but should also be based on "the procedures and type of care, treatment and services that can be performed or provided within the proposed setting."[119] Under proposed Standard 1.0, the healthcare organization must have a mechanism to determine whether the resources necessary to support requested privileges are currently available, or will be available within a specified time frame.[120] The healthcare organization would have to "determine whether or not sufficient budgetary, spatial, equipment, and staffing resources are in place to support each requested privilege."[121]

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specialized capabilities that do not have a dedicated emergency department. *Id.*

114. Joint Commission on Accreditation of Healthcare Organizations, Proposed Revisions to the Medical Staff Credentialing and Privileging Standards (hereinafter "JCAHO Proposed Revisions"), *available at* www.abanet.org/health/05_health_links/News/2005-11_JCAHOCred-and-Priv.pdf (last visited June 9, 2007).

115. *Id.* at *1.

116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.* at *2.

120. *Id.*

121. *Id.*

Next, the proposed revisions contain a new section on "performance monitoring."[122] "Performance monitoring" allows a healthcare organization "to evaluate the privilege-specific competence of the practitioner who presents to the [healthcare entity] appropriately credentialed, but without an established record of competently performing the requested privilege at that facility" or evaluate currently privileged practitioners who are the subject of patient quality and safety concerns.[123] Under proposed Standard 4.0, hospitals are required to develop a performance monitoring process which would require, among others, criteria for evaluating the performance of applicants without a current performance record, criteria for evaluating the performance of applicants who are the subject of patient safety and quality concerns, triggers that indicate the need for performance monitoring, and the actions designed to resolve the performance issues.[124] Proposed Standard 5.0 would require hospital to develop an information review and analysis that is clearly defined and consistently applied for each requesting practitioner.[125] Proposed Standard 6.0 deals with the privilege decision notification and requires a defined process for notification of privileging decisions and appeal rights.[126]

The theme of the proposed revisions is the continuous monitoring of a practitioner's performance so that patient quality of care and safety issues are immediately and adequately addressed.[127] Proposed Standard 7.0 requires hospitals to factor continuous professional practice evaluation into the decision to maintain, revise, or revoke privileges.[128] The criteria used in this decision-making process "may include the review of operative and other clinical procedure(s) performed and their outcomes . . . ; pattern of blood use; requests for tests and procedures; length of stay pattern; mortality rates; risk management data; and the practitioner's use of consultants, pharmaceuticals, and other treatment modalities."[129] Proposed Standard 8.0 requires that a health care organization have "a clearly defined process for receiving, investigating, and addressing clinical practice concerns" and that reported concerns are uniformly investigated and addressed.[130]

B. Peer Review

In 2006, a district court in Texas issued decisions in the *Poliner v. Texas Health Systems* case that dramatically altered the landscape of peer review.[131] To

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122. *Id.* at *9.
123. *Id.*
124. *Id.*
125. *Id.* at *11.
126. *Id.*
127. *Id.* at *12.
128. *Id.*
129. *Id.*
130. *Id.* at *13.
131. Poliner v. Tex. Health Sys., No. Civ. A.3:00-CV-1007-P, 2006 WL 770425, at *1 (N.D.

fully understand the importance of this case, however, one must understand the prior decisions which made such a verdict possible.

Lawrence Poliner, M.D., along with his professional corporation, filed suit against Presbyterian Hospital in Dallas and several physicians in 2000, alleging the defendants "improperly and maliciously used the peer-review process to summarily suspend [his] privileges, thereby causing damage to his interventional cardiology practice."[132] Ultimately the case would turn on the decision of Dr. Knochel, the chairman of the Internal Medicine Department, to demand that Dr. Poliner agree to an abeyance of his privileges or face a summary suspension.[133]

In 1998, several nurses completed incident reports concerning Dr. Poliner's treatment of patients.[134] The reports concerned a patient who died following a cath procedure and another patient who suffered a stroke following a cath procedure.[135] A third nurse reported that Dr. Poliner had used a contaminated sheath.[136] These reports were then forwarded to the hospital's Clinical Risk Review Committee.[137] While these reports were still under review, concerns arose regarding a fourth patient of Dr. Poliner.[138] The reviewing physician believed Dr. Poliner performed an angioplasty on the wrong artery, creating a life threatening situation for the patient.[139]

In May, Dr. Knochel, along with Drs. Harper and Levin, met with Dr. Poliner. In that meeting, Dr. Knochel asked Dr. Poliner to agree to an abeyance of his cath lab privileges, pending the committee's review of the four complaints.[140] Dr. Poliner alleged he received the letter at 2:00 p.m. and was told to sign the letter by 5:00 p.m. that day, or suffer an immediate suspension.[141] Dr. Poliner signed the letter of abeyance, which would become the foundation of his breach of contract and defamation claims.

Dr. Knochel then created an ad hoc committee, which ultimately determined Dr. Poliner rendered substandard care in 29 of 44 reviewed cases.[142] In June, the committee voted to recommend suspension of Dr. Poliner, who unsuccessfully appealed the determination via hospital channels. The case did not turn on a determination of whether Dr. Poliner rendered substandard care. Instead, the case

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Tex. Mar. 27, 2006); Poliner v. Tex. Health Sys., No. 3:00-CV-1007-P, 2006 WL 3342618 (N.D. Tex. Nov. 17, 2006) (slip opinion).

132. Poliner v. Tex. Health Sys., No. Civ. A.3:00-CV-1007-P, 2006 WL 770425, at *1 (N.D. Tex. Mar. 27, 2006).

133. *Id.*

134. Poliner v. Tex. Health Sys., No. Civ. A.3:00-CV-1007-P, 2003 WL 22255677, at *2 (N.D. Tex. Sept. 30, 2003).

135. *Id.*

136. *Id.* at *3.

137. *Id.* at *9.

138. *Id.* at *11.

139. *Id.* at *12.

140. *Id.*

141. *Id.* at *13.

142. *Id.* at *14.

turned on the procedure followed, or as it turned out not followed, in addressing the reports of substandard care. Thus, the court dismissed all defendants involved only in the June suspension and subsequent appeals, holding those defendants followed appropriate procedures and were entitled to immunity under the Health Care Quality Improvement Act ("HCQIA").[143]

Prior to trial, the court dismissed all defendants but the hospital and Drs. Knochel, Harper, and Levin, as they were the only defendants involved in the abeyance letter.[144] Further, the court denied these defendants motions for summary judgment on the claims related to the abeyance letter as the defendants failed to meet the HCQIA requirements for immunity, holding the defendants failed to show that they took the action with the reasonable belief that they were furthering patient safety, that the action was taken after "a reasonable effort to obtain the facts," and that Dr. Poliner was afforded "adequate notice and hearing procedures."[145] The court also refused to grant summary judgment on statute of limitations grounds, despite the fact that the plaintiffs filed their claims more than one year after the defamatory publications were made.[146] Dr. Poliner claimed he could file suit after the statute of limitations ran because each publication of the summary suspension, for example on applications for hospital privileges, constituted an additional tort.[147] The court agreed and denied summary judgment as Dr. Poliner was able to show publication of the summary suspension within one year of filing suit.[148] Finally, the court refused to grant summary judgment on the contract claims, as Texas law stated hospital bylaws could create a contract for procedural rights between a physician and hospital.[149]

The case was ultimately submitted to a jury, which awarded Dr. Poliner a total recovery of $366,211,159.[150] Post-verdict, the court ordered the parties to mediate.[151] The parties, however, were unable to come to an agreement and the court closed the mediation.[152] The plaintiffs then moved to have the judgment entered.[153] In opposition to that motion, the defendants "renewed their motion for judgment notwithstanding the verdict."[154]

The defendants challenged the jury's conclusion that the "[d]efendants were

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143. *Id.*

144. *Id.* at *40.

145. *Id.* at *39.

146. *Id.* at *57-58.

147. *Id.* at *57.

148. *Id.* at *58.

149. *Id.* at *30 (granting summary judgment for all defendants on antitrust and deceptive trade practices claims).

150. Poliner v. Tex. Health Sys., No. 3:00-CV-1007-P, 2006 WL 770425, at *2 (N.D. Tex. Mar. 27, 2006).

151. *Id.*

152. *Id.*

153. *Id.*

154. *Id.*

not entitled to HCQIA immunity."[155] The defendants alleged that no evidence supported the jury's findings that the defendants summarily suspended Dr. Poliner without a reasonable belief that Dr. Poliner represented a danger to patient safety.[156] The defendants also took issue with the jury's determination that the summary suspension was issued prior to adequate notice or an opportunity for a hearing.[157] In support of the jury's verdict, the court pointed to testimony from Dr. Knochel indicating that he did not possess information, at the time of the abeyance, that Dr. Poliner posed a danger to his patients.[158] Further, Dr. Poliner's experts testified "that no reasonable hospital could have taken the action it did against Dr. Poliner except by knowingly or recklessly disregarding the medical evidence."[159] The court also noted Dr. Knochel did not offer Dr. Poliner a less severe option, instead requiring Dr. Poliner to agree to an abeyance or suffer a suspension of all privileges.[160] The court also found it important that the defendants refused to discuss the relevant patient cases with Dr. Poliner prior to the summary suspension and also focused on the evidence that Dr. Knochel told Dr. Poliner he was not permitted to consult an attorney.[161] Thus, the court found a jury could reasonably conclude that the hospital did not have a reasonable belief that Dr. Poliner posed a danger to patients and the action was not taken after a "reasonable effort to obtain the facts of the matter."[162] The refusal to permit Dr. Poliner to consult with an attorney also supported a finding that the defendants failed to provide Dr. Poliner with adequate notice and hearing procedures. In sum, sufficient evidence existed for the jury's determination that the defendants were not entitled to HCQIA immunity.[163] This same evidence supported the jury's determination that the defendants were not entitled to immunity under state law.[164]

The court also refused to overturn the breach of contract verdict, explaining that hospital bylaws created a contract entitling Dr. Poliner to certain procedural safeguards, which the defendants failed to provide.[165] In making this determination, the court again noted there was sufficient evidence to find Dr. Poliner did not agree to the abeyance but was instead forced to sign it under duress.[166] The same evidence that supported the denial of HCQIA immunity, namely the refusal to discuss the cases and Dr. Knochel's testimony, supported

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155. *Id.* at *4.
156. *Id.*
157. *Id.*
158. *Id.*
159. *Id.*
160. *Id.*
161. *Id.*
162. *Id.* at *5.
163. *Id.*
164. *Id.*
165. *Id.* at *8.
166. *Id.*

the breach of contract claim.[167]

The defendants also claimed they made no defamatory statements.[168] The court disagreed, explaining that the jury's finding that Dr. Poliner did not consent to the abeyance meant that Dr. Poliner was summarily suspended.[169] As the hospital bylaws stated the hospital could summarily suspend a physician who posed a danger to patients, the summary suspension amounted to a defamatory statement that Dr. Poliner was a dangerous physician.[170] Further, the jury found Dr. Poliner was not a dangerous physician, thus establishing the falsity of the statements.[171] The defendants published the fact of the summary suspension to third parties, thus Dr. Poliner satisfied all elements of a defamation claim.[172]

The defendants did successfully limit the plaintiffs' recovery by arguing the plaintiffs were entitled to only one recovery, under either the contract or tort theories.[173] The court held the plaintiffs were entitled to only one recovery because "[t]here was no evidence that the contract breach caused Dr. Poliner to suffer an injury to reputation/career and mental anguish separate and distinct from those caused by the tortious conduct."[174]

After mediation proved unsuccessful, the court entered judgment.[175] Prior to entering judgment, the court first addressed the defendants' motion for a new trial and remitter. The court denied a motion for a new trial, as the jury verdict was not based on prejudice or bias. The court did, however, recognize that the verdict was excessive.[176] Ultimately, the court held Dr. Poliner could recover $22.5 million on his defamation claim against the hospital and Dr. Knochel—Drs. Levin and Harper settled prior to the entry of judgment.[177] This included the following $21 million in non-economic actual damages: $6 million against Dr. Knochel for injury to career and reputation and $6 million for mental anguish; $4.5 million against the hospital for injury to career and reputation and $4.5 million for mental anguish.[178] The damages also included $7894.92 in lost earnings and approximately $1,542,106 in punitive damages.[179] Finally, the judgment ordered that the defendants pay 8.35% interest on the compensatory damage award form the date the suit was filed to October 13, 2006, a period of over six years.[180]

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167. *Id.* at *12.

168. *Id.*

169. *Id.*

170. *Id.*

171. *Id.*

172. *Id.*

173. *Id.* at *18.

174. *Id.*

175. As the plaintiffs were entitled to only one recovery, the court entered judgment on the defamation claim as the jury awarded the most damages under this theory. *Id.*

176. Poliner v. Tex. Health Sys., 239 F.R.D. 468, 478 (N.D. Tex. 2006).

177. *Id.*

178. *Id.*

179. *Id.*

180. *Id.*

Further, the defendants were required to pay post-judgment interest in the amount of 4.9% from October 14, 2006 to the date of satisfaction.[181]

This case not only provides a cautionary tale regarding the importance of adhering to the hospital's peer review procedures but also underscores the importance of the perceptions of the jury and judge. Shedding some light on the excessive verdict, the judge explained that while Dr. Poliner "presented himself as a committed and dedicated doctor who was good at and enjoyed his [job]," the "[d]efendants came across as arrogant, uncaring, and completely unconcerned with damaging Dr. Poliner's career."[182] In fact, the court explained that:

> [t]here is no doubt the jury awarded Dr. Poliner a tremendous amount of money in damages. The jury's attitude and award [were] influenced by Defendants' unwillingness to acknowledge their own wrongdoing and their callous attitude toward Dr. Poliner at the time of the abeyance/suspension and at trial. Defendants' insistence on taking the position that Dr. Poliner voluntarily agreed to the abeyance caused Defendants to lose credibility with the jury.[183]

IX. LABOR AND EMPLOYMENT

A. Exempt Status of Medical Coders and Respiratory Therapists Fair Labor Standards Act ("FLSA")[184] Opinion Letters 2005-35 and 2006-26

The Department of Labor ("DOL") issued two opinion letters since last year's *Survey of Recent Developments in Health Law*[185] involving the exempt status of certain positions within the health care industry under the learned professional exemption.[186] FLSA Opinion Letter 2005-35[187] addressed the exempt status of medical coders and FLSA Opinion Letter 2006-26[188] addressed the exempt status of respiratory therapists. Both opinion letters concluded that the positions at issue were not exempt under the FLSA.[189]

The focus of both of these opinion letters is the nature of the education required for the positions. In both letters, the DOL noted that the individuals holding the respective positions could possess either a bachelor's or an associate's

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181. *Id.*

182. *Id.*

183. *Id.* at 476.

184. 29 U.S.C. § 201 (2000).

185. *See generally* Ice Miller LLP, *Survey of Recent Developments in Health Law*, 39 IND. L. REV. 1051 (2006).

186. 29 C.F.R. § 541.300(a) (2007).

187. U.S. Dep't of Labor, FLSA Opinion Letter 2005-35 (Oct. 3, 2005) [hereinafter FLSA Opinion Letter 2005-35].

188. U.S. Dep't of Labor, FLSA Opinion Letter 2006-26 (July 24, 2006) [hereinafter FLSA Opinion Letter 2006-26].

189. *Id.*

degree.[190] The DOL also noted that individuals wishing to hold the position of either medical coder or respiratory therapist do not need to possess a bachelor's degree to obtain the necessary state board certifications and/or licenses. Consequently, the DOL found that neither position required "knowledge of an advanced type in a field of science or learning customarily acquired by a prolonged course of specialized intellectual instruction."[191]

Importantly, the DOL emphasized that the requirements of the particular health care facility are not controlling. The relevant question is whether the "specialized academic training is a standard prerequisite for entrance into the profession."[192] Accordingly, even though the hospital targeted respiratory therapists with bachelor's degrees in its hiring practices, the respiratory therapists did not fall under the learned professional exemption because the bachelor's degree was not a standard prerequisite for the profession as a whole.[193]

B. Charge Nurses as Supervisors Under the National Labor Relations Act ("NLRA")

On September 29, 2006, the National Labor Relations Board ("the Board") set forth new guidelines for determining who is a "supervisor," and thus not entitled to union representation under the NLRA.[194] In *Oakwood Healthcare, Inc.*,[195] the Board announced the new guidelines and determined that permanent charge nurses at a Michigan hospital qualified as supervisors under the NLRA. However, in *Beverly Enterprises—Minnesota, Inc.*,[196] the Board applied these guidelines to determine that charge nurses at a nursing home in Minnesota were *not* supervisors.[197] Although the precise contours of the Board's new interpretation have yet to be determined, the guidelines arguably broaden the management-aligned category of "supervisor," and narrow the category of employees entitled to union representation.

The NLRA defines "supervisor" as:

> any individual having authority, in the interest of the employer, to hire, transfer, suspend, lay off, recall, promote, discharge, assign, reward, or discipline other employees, or responsibly to direct them, or to adjust their grievances, of effectively to recommend such action, if in connection with the foregoing the exercise of such authority is not of a merely routine or clerical nature, but requires the use of independent

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190. According to the DOL, only twelve percent of the accredited respiratory care programs in the country are at the baccalaureate level. FLSA Opinion Letter 2006-26.

191. 29 C.F.R. § 541.300(b)(4) (2007).

192. 29 C.F.R. § 541.301(d) (2007).

193. FLSA Opinion Letter 2006-26.

194. Oakwood Healthcare, Inc., 348 N.L.R.B. 37 (2006), 2006 WL 2842124, at *19.

195. *Id.* at *19, *43.

196. 348 N.L.R.B. 39 (2006), 2006 WL 2842126, at *8.

197. *Id.* at *7.

judgment.[198]

The U.S. Supreme Court has set forth a three-part test for determining supervisory status under this definition:

> Employees are statutory supervisors if (1) they hold the authority to engage in any 1 of the 12 listed supervisory functions [in NLRA § 2(11)], (2) their "exercise of such authority is not of a merely routine or clerical nature, but requires the use of independent judgment," and (3) their authority is held "in the interest of the employer."[199]

The Board issued the guidelines outlined in *Oakwood Healthcare* for determining who counts as a "supervisor" for purposes of the NLRA in response to the U.S. Supreme Court's decision in *NLRB v. Kentucky River Community Care*,[200] which rejected the Board's assessment of whether certain nurses qualified as supervisors under the NLRA.[201]

C. *The* Oakwood Healthcare, Inc. *Decision*

The bargaining unit in *Oakwood Healthcare* included 181 registered nurses who worked in a hospital. Of these 181 nurses, twelve were registered nurses who worked permanently as charge nurses. In addition, several other registered nurses rotated into the charge nurse position.[202] Charge nurses were responsible for overseeing their patient care units and assigning other registered nurses, licensed practical nurses, nursing assistants, technicians, and paramedics to patients. Charge nurses also monitored the patients in the unit, met with doctors and the patients' family members, and followed up on "unusual incidents."[203] The petitioning union argued that all of the registered nurses—including the permanent and rotating charge nurses—were employees and not supervisors.[204] The employer contended that both the permanent and rotating charge nurses were supervisors and should be excluded from the bargaining unit.[205]

Ultimately, the Board concluded that the permanent charge nurses, were "supervisors" for purposes of the NLRA.[206] Before reaching this conclusion, the Board clarified (and broadened) its interpretation of some of the terms used in the NLRA to define supervisory authority: "assign," "responsibly to direct," and "independent judgment."[207]

1. "Assign."—"Assign" now extends beyond assignments of employees to

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198. 29 U.S.C. § 152(11) (2000).
199. NLRB v. Ky. River Cmty. Care, Inc., 532 U.S. 706, 713 (2001).
200. 532 U.S. 706 (2001).
201. *Id.* at 707.
202. Oakwood Healthcare, Inc., 348 N.L.R.B. 37 (2006), 2006 WL 2842124 at *1-2.
203. *Id.* at *2.
204. *Id.*
205. *Id.*
206. *Id.* at *12.
207. *Id.* at *4-11.

job classifications, work sites, and work hours to include assignments of significant overall duties and tasks to employees.[208] The Board held that the word "assign" refers to "the act of designating an employee to a place (such as a location, department, or wing), appointing an employee to a time (such as a shift or overtime period), or giving significant overall duties, i.e. tasks, to an employee."[209] In addition, the Board noted that, in the health care setting, the term assign "encompasses the charge nurses' responsibility to assign nurses and aids to particular patients."[210]

2. "Responsibly to Direct."—Under *Oakwood Healthcare*, "responsibly to direct" applies not only to direction of entire departments but also to one-on-one task direction with authority to take corrective action. The Board now emphasizes accountability for the performance of the employees being directed.[211] The Board stated that, "[i]f a person on the shop floor has 'men under him,' and if that person decides 'what job shall be undertaken next or who shall do it,' that person is a supervisor, provided that the direction is both 'responsible' (as explained below) and carried out with independent judgment."[212] In addition, the Board held that the term "responsible" means that "the person directing and performing the oversight of the employee must be accountable for the performance of the task by the other, such that some adverse consequence may befall the one providing the oversight if the tasks performed by the employee are not performed properly."[213]

3. "Independent Judgment."—Prior to *Oakwood Healthcare*, the Board took the position that "independent judgment" excluded "ordinary professional or technical judgment in directing less skilled employees to deliver services."[214] However, the new decision holds that "independent judgment" can be exercised even if it is exercised using professional or technical expertise, shifting the focus from the kind of discretion to the degree of discretion.[215] To be "independent," judgment must be "free of the control of others" and not "dictated or controlled by detailed instructions, whether set forth in company policies or rules, the verbal instructions of a higher authority, or in the provisions of a collective-bargaining agreement."[216] With respect to charge nurses, the Board stated, "if the registered nurse weighs the individualized condition and needs of a patient against the skills or special training of available personnel, the nurse's assignment involves the exercise of independent judgment."[217]

4. Application of Definitions.—Applying these definitions to the nurses at

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208. *Id.* at *4.
209. *Id.*
210. *Id.*
211. *Id.* at *7-8.
212. *Id.* at *7.
213. *Id.* at *8.
214. *See* NLRB v. Ky. River Cmty. Care, Inc., 532 U.S. 706, 713 (2001).
215. *Oakwood Healthcare*, 2006 WL 2842124, at *8.
216. *Id.* at *9-10.
217. *Id.* at *10.

issue in *Oakwood Healthcare*, the Board concluded that the permanent charge nurses constituted "supervisors" for purposes of the NLRA.[218] The Board first held that the employer had not shown that the charge nurses exercised the supervisory function of "responsibly directing" other employees because it had not proved that the charge nurses were held accountable for the performance of the employees they directed.[219] However, it went on to hold that the employer had shown that the charge nurses exercised the supervisory "assigning" function and exercised "independent judgment" in making such assignments.[220]

Specifically, the Board held that the permanent charge nurses exercised the "assign" function when they assigned patients to nurses or assigned nurses to specific geographic locations within the hospital.[221] The Board also concluded that the permanent charge nurses performed this assignment with the exercise of "independent judgment" because the assignment involved was "based upon the skill, experience, and temperament of other nursing personnel and on the acuity of the patients."[222] Thus, the Board held, the permanent charge nurses were "supervisors" for purposes of the NLRA and should be excluded from the bargaining unit.[223]

D. The Golden Crest Healthcare *Decision*

A companion decision issued in conjunction with *Oakwood Healthcare* applied the new guidelines, confusing the issue of whether charge nurses are "supervisors" by finding in a fact-sensitive inquiry that not all charge nurses at a nursing home in Montana are supervisors for purposes of the NLRA.[224] In *Golden Crest Healthcare*, the charge nurses occasionally asked certified nursing assistants ("CNAs") to stay past the end of their shifts.[225] They also oversaw the CNAs' job performance, acted to correct the CNAs when they were not providing adequate patient care, and directed the CNAs to perform certain tasks.[226]

The Board concluded that the employer had not shown that the charge nurses

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218. *Id.* at *12.

219. *Id.*

220. *Id.* at *12-17.

221. *Id.* at *13.

222. *Id.* at *16.

223. *Id.* at *17. With respect to the rotating charge nurses, the Board concluded that the employer had not proven that they exercised these supervisory functions with "regularity." Thus, the rotating charge nurses did not devote a "substantial" part of their work time to supervisory tasks, as required by the NLRA. *Id.* at *18.

224. *See* Beverly Enterprises-Minn. Inc. (*Golden Crest Healthcare Ctr.*), 348 N.L.R.B. 39 (2006), 2006 WL 2842126; *see also* Croft Metals, Inc., 348 N.L.R.B. 38 (2006), 2006 WL 2842125, at *5-9 (applying the *Oakwood Healthcare* factors and holding that lead persons at an aluminum and vinyl products manufacturing plant in Mississippi were also employees, and not supervisors as defined by the NLRA).

225. *Golden Crest Healthcare Ctr.*, 348 N.L.R.B. 39, 2006 WL 2842126, at *4.

226. *Id.* at *6.

exercised the supervisory functions of "assigning" or "responsibly directing."[227] First, the Board determined that the charge nurses did not actually have the authority to *require* the CNAs to stay past the end of their shifts.[228] Second, the Board concluded that the charge nurses did not "responsibly" direct the CNAs because no evidence indicated that the charge nurses were held accountable for their performance in directing CNAs.[229] Thus, the Board concluded, the charge nurses were *not* supervisors for purposes of the NLRA and could be included in the bargaining unit.[230]

E. Does Joint Employment Exist for Temporary Employees Under the Worker's Compensation Act After Wishard Memorial Hospital v. Kerr*?*

In 2006, the Indiana Court of Appeals issued *Wishard Memorial Hospital v. Kerr*.[231] This decision makes practitioners question whether joint employers in the healthcare setting will be afforded the benefit of the exclusive remedy provision in the Indiana Worker's Compensation Act[232] as the Legislature intended.[233]

Kerr was a registered nurse who was working at Wishard Memorial Hospital.[234] Care Staff, Inc. hired Kerr and assigned her to work in Wishard hospital's psychiatric emergency room. The staffing agreement between Care Staff and Wishard listed specific dates and times during a thirteen-week period in which Kerr was to work at Wishard.

On October 1, 2002, Kerr slipped and fell on a newly waxed floor as she left Wishard after completing her shift.[235] Kerr applied for and received worker's compensation benefits from Care Staff. She also filed a negligence complaint against Wishard and sought personal injury damages.[236] Wishard filed a motion to dismiss based on lack of subject matter jurisdiction alleging that Kerr's cause of action was barred by the exclusivity provision of the Indiana Worker's Compensation Act because Kerr was Wishard's employee.[237] Under the statute, an injured employee is entitled to worker's compensation benefits only, and may not sue the employer for damages.[238]

The trial court concluded that Wishard did not employ Kerr and, therefore,

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227. *Id.* at *1.
228. *Id.* at *4-5.
229. *Id.* at *7.
230. *Id.* at *8.
231. Wishard Mem'l Hosp. v. Kerr, 846 N.E.2d 1083 (Ind. Ct. App. 2006).
232. IND. CODE § 22-3-2-2 (2004).
233. *Id.* § 22-3-6-1(a).
234. *Wishard Mem'l Hosp.*, 846 N.E.2d at 1086.
235. *Id.* at 1087.
236. *Id.*
237. *Id.*; IND. CODE § 22-3-2-2 (2004).
238. IND. CODE § 22-3-2-2.

that the Act did not bar her from bringing action against Wishard.[239] Wishard appealed the decision. On appeal, the court recognized that the Indiana Worker's Compensation Act provides the exclusive remedy to an employee when he or she is injured by accident "arising out of and in the course and scope of employment."[240] It also acknowledged that the Act contemplates that one employee may simultaneously have two employers.[241] The Indiana Court of Appeals acknowledged that joint employment is possible when both employers are in direct control of the employee and the employee is made accountable to both.[242] Nonetheless, it then went on to make the factual determination that an employment relationship did *not* exist between Kerr and Wishard.[243]

The court weighed seven factors in making its factual determination that Kerr was not an employee of Wishard. These factors, established by the Indiana Supreme Court in 1991, are (1) the right to discharge; (2) the mode of payment; (3) supplying tools or equipment; (4) belief of the parties in the existence of an employer-employee relationship; (5) control over the means used in the results reached; (6) length of employment; and (7) establishment of the work boundaries.[244] These factors were weighed against each other as a part of a balancing test with the greatest weight given to the right to exercise control of the employee.[245]

The court analyzed and balanced each factor in great detail and determined that six of the seven factors were nearly evenly split, both for and against a finding of joint employment.[246] The court determined that Wishard's right to discharge Kerr, the tools and equipment that Wishard supplied Kerr and her work boundaries weighed in favor of finding Kerr was Wishard's employee. The method of payment, the belief of the parties that an employment relationship existed, and the short length of employment weighed against finding joint employment. Since these six factors "cancelled" each other out, the court looked to the most important factor of control.[247]

The court ultimately determined that the evidence was neutral regarding whether Wishard "controlled" Kerr to the extent that she should be considered a Wishard employee.[248] Because Kerr was in a highly skilled and trained profession, the court recognized that Wishard would have less ability to control and supervise the details of her job duties, but it found that Wishard's policies and procedures were no greater than the standards and skills required of any licensed registered nurse. In addition, although Wishard required Kerr to

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239. *Wishard Mem'l Hosp.*, 846 N.E.2d at 1087.
240. *Id.* (citing IND. CODE § 22-3-2-6 (2004)).
241. *Id.* (citing IND. CODE § 22-3-3-31 (2004)).
242. *Id.* at 1088 (citing Degussa Corp. v. Mullens, 744 N.E.2d 407, 413 (Ind. 2001)).
243. *Id.* at 1094.
244. *Id.* at 1087-88 (citing Hale v. Kemp, 579 N.E.2d 63, 67 (Ind. 1991)).
245. *Id.* at 1090.
246. *Id.* at 1094.
247. *Id.*
248. *Id.* at 1092.

complete orientation and pass clinical skills testing specific to its work, these sessions were conducted by CareStaff rather than by Wishard.[249]

Finally, the court found Wishard failed to present evidence regarding the employment status of the physicians working in Wishard's psychiatric emergency room.[250] The court reasoned that if the physicians directing Kerr's work were Wishard employees, rather than independent contractors, it would be sufficient to decide that Wishard was controlling Kerr's work. Because the court had no evidence about the physician's status, it found that Wishard failed to meet its burden of establishing that Kerr was its employee.[251] The court strictly construed the statute against limiting Kerr's right to bring suit and found that there was no joint employment entitling Wishard to the exclusivity remedy of the Act.[252]

In determining that no joint employment existed between Kerr and Wishard, the court acknowledged that "dual employment" issues in the worker's compensation context have generated inconsistent rulings from Indiana courts.[253] Balancing seven different factors does not seem to lead to predictable results in these types of cases.[254] This is precisely why the Legislature amended the Act in 2001. In fact, in 2005, the Indiana Court of Appeals heard a case with similar facts and affirmed the trial court ruling that dual employment existed.[255] In the 2005 case, the court found that employees working for health facilities through a staffing agency were considered employees of *both* entities and subject to the exclusive remedies provision in the Worker's Compensation Act.[256]

The court's decision might have been different if it referred to the statutory provisions addressing joint employment. In 2001, the Legislature amended the definition section of the Act to clarify its intent and resolve any confusion regarding joint employment and exclusive remedy protection for both the lessor and the lessee of employees under the Act.[257] Indiana Code section 22-3-6-1(a) states that "[b]oth a lessor and a lessee of employees shall each be considered joint employers of the employees provided by the lessor to the lessee . . ." for purposes of the exclusive remedy provision of the Act.[258] It appears that no party before the court of appeals since the 2001 amendment has raised this statutory change to the court's attention. Consequently, despite the change in the law in 2001, which was designed to resolve the joint employment issue, courts continue

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249. *Id.* at 1091.

250. *Id.*

251. *Id.* at 1092.

252. *Id.* at 1094.

253. *Id.* at 1088.

254. *Id.*

255. *See generally* Jennings v. St. Vincent Hosp. & Health Care Ctr., 832 N.E.2d 1044 (Ind. Ct. App.), *trans. denied*, 855 N.E.2d 1001 (Ind. 2006). It is interesting to note that the judge assigned to write the *Kerr* opinion was also the judge who dissented in *Jennings* which was the most recent case involving joint employment before the court of appeals.

256. *Id.* at 1054.

257. IND. CODE § 22-3-6-1(a) (2004).

258. *Id.*

to weigh the seven factors to determine whether an employment relationship exists, resulting in inconsistent decisions.[259]

X. ANTITRUST

On November 29, 2005, the Federal Trade Commission ("FTC") found that North Texas Specialty Physicians' ("NTSP") activities on behalf of its participating physicians amounted to an unlawful horizontal price-fixing conspiracy in violation of Section 1 of the Sherman Act.[260]

NTSP is an association of over 500 members consisting of independent physicians and physician groups in the Fort Worth, Texas area.[261] NTSP primarily negotiates and reviews payor contracts on behalf of its members. All but one of the payor contracts are non-risk-sharing, fee-for-service contracts. The challenged conduct in this case was the negotiation of the non-risk contracts.

The FTC began its analysis by acknowledging that *Arizona v. Maricopa County Medical Society*,[262] provides the basis for outright per se condemnation of conduct that parallels the conduct in issue. However, the FTC applied the "inherently suspect" analysis from *Polygram Holdings, Inc. v. FTC*.[263] The FTC found that the *Polygram* analysis was appropriate because the U.S. Supreme Court has cautioned application of a per se standard to a professional setting where the economic impact is not immediately obvious and because physician networks have been found to have some procompetitive efficiencies.[264] Under *Polygram,* a defendant can avoid condemnation of a suspect practice by offering justifications that are both "cognizable" under the antitrust laws and facially "plausible."[265] Therefore, NTSP was required to advance a "cognizable" and "plausible" justification for the challenged conduct.[266] NTSP was not able to do this. The FTC noted that had NTSP shown financial or clinical integration as described in *The Health Care Statements*,[267] its conduct would have qualified for "rule of reason" analysis.

The FTC concluded that in the negotiation of its non-risk contracts NTSP

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259. *Jennings*, 832 N.E.2d at 1044; *see, e.g.*, GKN v. Magness, 744 N.E.2d 397 (Ind. 2001); Degussa Corp. v. Mullens, 744 N.E.2d 407 (Ind. 2001); Turner v. Richmond Power & Light Co., 756 N.E.2d 547 (Ind. Ct. App. 2001); Nowicki v. Cannon Steel Erection Co., 711 N.E.2d 536 (Ind. Ct. App.1999).

260. *In re* North Texas Specialty Physicians Corp., Docket No. 9312, Opinion of the Commission, at 3 (decision and order entered November 29, 2005), *available at* http://www.ftc.gov/os/adjpro/d9312/index.htm [hereinafter Opinion].

261. *Id.*

262. 457 U.S. 332, 356-57 (1982).

263. 416 F.3d 29 (D.C. Cir. 2005).

264. Opinion, *supra* note 260, at 11.

265. *Id.* at 13.

266. *Id.* at 13-14.

267. The FTC and Department of Justice Health Care Statements provide guidance about the agencies' enforcement intentions on issues that arise in the health care industry.

engaged in conduct designed to enhance the collective bargaining power of its members. The FTC found that this conduct included polling its member physicians on minimum acceptable reimbursement rates, reporting the results to its physicians, and using the results to calculate average minimum acceptable reimbursement rates which served as the basis for its minimum contract prices. The FTC found that the NTSP's use of a poll facilitated a price-fixing agreement among its members.[268] NTSP's polling results essentially set a minimum fee schedule that intended to increase prices overall. NTSP also made the existence of the minimum fee schedule clear to the payors and informed them that NTSP would not enter into or forward any offers below the minimum.[269]

The FTC also looked at the physician participation agreement.[270] The agreement required the physicians to forward any payor offers he/she received to NTSP, who had a right of first negotiation. Under the agreement, the physicians agreed that they would refrain from pursuing offers from a payor until they were notified by NTSP that it was discontinuing negotiations with the payor.[271] The FTC found that the agreement rendered NTSP the sole bargaining agent of NTSP competing physicians and thus facilitated price fixing among NTSP physicians.[272] The FTC found that NTSP rejected and did not deliver any non-risk contracts that fell below its minimum reimbursement schedule.[273] The FTC also noted that the "terms of the [agreement] and the manner in which NTSP has utilized them hinder the ability of payors to assemble a marketable physician network in the Fort Worth area without submitting to the collective bargaining of NTSP."[274]

NTSP also had powers of attorney with most of its members which allowed NTSP to negotiate contracts on the member's behalf. The FTC found that NTSP used the powers of attorney in a manner similar to the agreement, which again allowed NTSP to solidify its power as a bargaining agent and thus facilitated price fixing.[275]

The FTC found that on several occasions NTSP used its agency powers to refuse to deal or to terminate member contracts. The FTC found that NTSP "illegally utilized refusals to deal and termination of contracts to enhance the bargaining power of the participating physicians and command higher prices."[276]

The FTC then looked at the justifications offered by NTSP. The FTC found that none met the cognizable and facially plausible test. First, NTSP argued that its risk panel physicians "use financial and clinical integration techniques to develop team-oriented improvements in cost and quality" and that NTSP has a right to "limit" its involvement to non-risk contracts so that their participation

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268. Opinion, *supra* note 260, at 18.
269. *Id.*
270. *Id.* at 20.
271. *Id.*
272. *Id.* at 21.
273. *Id.*
274. *Id.*
275. *Id.* at 22.
276. *Id.* at 23.

will ensure the spillover of the efficient treatment patterns established in the risk contract.[277] The FTC rejected NTSP's justification. NTSP also argued that its polling, communications with physicians and payors, and its refusal to messenger contracts had procompetitve effects on their own.[278] The FTC rejected this argument noting that arguments to the effect that "competition itself is inefficient" are not cognizable under the antitrust laws.[279]

Ultimately, the FTC concluded that NTSP's challenged restraints constituted unlawful horizontal price-fixing. The FTC issued an order which requires that NTSP cease and desist from engaging in anticompetitive price-fixing conduct which includes

> (1) entering into, adhering to, participating in, maintaining, implementing, or otherwise facilitating any combination, conspiracy, agreement, or understanding on behalf of any physician with any payor; (2) to deal, refuse to deal, or threaten to refuse to deal with any payor; (3) regarding any term, condition, or requirement upon which any physician deals, or is willing to deal, with any payor, including, but not limited to price terms; or (4) not to deal individually with any payor, or not to deal with any payor through any arrangement other than [NTSP].[280]

XI. TAX

The IRS recently began a compliance initiative directed at tax-exempt hospitals reflecting the increasing concern of both the IRS and Congress as to whether tax-exempt hospitals provide sufficient "community benefit" to justify their tax exempt status.[281] The IRS requested that selected hospitals complete Form 13790, the Community Benefit Compliance Check Questionnaire ("Questionnaire"), which focused on the hospital's community benefit activities and policies.[282]

The Questionnaire presented over eighty questions including questions regarding the hospital's patient mix, emergency room issues, the structure and composition of the governing board of the hospital, medical staff privileges,

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277. *Id.* at 28.

278. *Id.* at 31.

279. *Id.* at 31-32.

280. *Id.* at 4.

281. The community benefit standard is the standard under which hospitals receive their tax-exempt status under I.R.C. § 501(c)(3) (2006). The community benefit standard was adopted by the IRS in a 1969 revenue ruling (Rev. Rul. 69-545, 1969-2 C.B. 117). Additionally, in General Counsel Memorandum 39862 (Nov. 21, 1991) the IRS identified additional factors as evidence of community benefit.

282. The Questionnaire is available at http://www.IRS.gov (last visited June 9, 2007).

medical research issues, the extent of medical education and training at the hospital, the extent of uncompensated care, the hospital's billing practices, the provision of community programs, and the executive compensation practices of the hospital. Although the Questionnaire was "voluntary," hospitals that failed to complete the Questionnaire would be subject to further examination.[283]

283. Memorandum from George Quinn to the Wisconsin Hospital Association Executive, *IRS Compliance Questionnaire—A Sign of Things to Come?* (June 8, 2006), *available at* www.wha.org/communitybenefits/irsquestionnaire6-8-06.pdf.