

SURVEY OF RECENT DEVELOPMENTS IN HEALTH CARE LAW

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INTRODUCTION

Healthcare in Indiana, as in the rest of the United States, is governed by an evolving and changing body of law, both state and federal, covering a vast number of topics. Although not an exhaustive review, this Survey summarizes recent developments in various areas of health law including: fraud and abuse, quality, tax, reimbursement, and labor and employment.

I. GENERAL HEALTH LAW

In 2008, there were several interesting cases impacting health care providers. Two notable cases include *Poliner v. Texas Health System*¹ and *United States ex rel. Bates and Patrick v. Kyphon, Inc.*² involving peer review and a *qui tam* complaint, respectively. These cases are summarized below.

A. Peer Review

The 2007 *Survey of Recent Developments in Health Law* in the *Indiana Law Review* reported on the decisions from a district court in Texas in the *Poliner v. Texas Health System*³ case, and described the dramatic impact these decisions had on the landscape of peer review.⁴ However, following publication of the 2007 Survey, the defendants appealed to the Fifth Circuit.⁵ The court issued a decision reversing the district court on July 23, 2008.⁶

Poliner is based upon a lawsuit with numerous claims brought by Lawrence Poliner, M.D. and his professional corporation against Texas Health Systems and several physicians, alleging that the defendants “improperly and maliciously used the peer-review process to summarily suspend [his] privileges, thereby causing damage to his interventional cardiology practice.”⁷ In September 2003, the United States District Court for the Northern District of Texas, Dallas Division, “granted in part and denied in part [d]efendants’ motion for summary judgment

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1. 537 F.3d 368 (5th Cir. 2008), *cert. denied*, 129 S. Ct. 1002 (2009).

2. No. 05-CV-6568CJS(f) (W.D.N.Y., filed Oct. 25, 2005).

3. 537 F.3d 368 (5th Cir. 2008), *cert. denied*, 129 S. Ct. 1002 (2009).

4. Ice Miller LLP, *Survey of Recent Developments in Health Law*, 40 IND. L. REV. 931, 946-51 (2007).

5. *Poliner*, 537 F.3d at 375.

6. *Id.* at 384.

7. *Poliner v. Tex. Health Sys.*, No. Civ. A.3:00-CV-1007-P, 2006 WL 770425, at *1 (N.D. Tex. 2006), *rev'd*, 537 F.3d 368 (5th Cir. 2008), *cert. denied*, 129 S. Ct. 1002 (2009).

on all of [p]laintiffs' claims."⁸ The claims not dismissed on summary judgment were submitted to a jury, who found that defendants' actions were not immune from civil liability under the federal Health Care Quality Improvement Act (HCQIA) or state peer review statutes, and in favor of plaintiffs on all of their other claims.⁹ "The jury awarded compensatory and exemplary damages against [d]efendants in the total amount of \$366,211,159.30."¹⁰

Following an unsuccessful mediation, plaintiffs moved to have the judgment entered, and the defendants moved to renew their motion for judgment notwithstanding the verdict, arguing that the defendants were entitled to immunity under the HCQIA or state peer review statutes.¹¹ The court found that sufficient evidence existed in support of the jury's decision that the defendants were not entitled to immunity under HCQIA or state law.¹² The court, in a separate order, addressed the defendants' motion for a new trial and remittitur, but ultimately denied the motion for a new trial.¹³ Although the motion was denied, the court did reduce the verdict to approximately \$22.5 million, because it found the jury's verdict to be excessive.¹⁴

The United States Court of Appeals for the Fifth Circuit later reversed the lower court's decision on based on the defendants being entitled to immunity under the HCQIA.¹⁵ The court held, "Because [d]efendants are immune under the HCQIA, we have no occasion to consider [d]efendants' other substantial arguments that we must reserve and render judgment based on state law immunity and because Poliner failed to prove the substantive elements of his claims."¹⁶

In arriving at the decision that the defendants were immune under the HCQIA, the court examined the factors set out in HCQIA¹⁷ and concluded that the professional review actions taken by the defendants were done "in the reasonable belief that the action was in the furtherance of quality health care," that defendants made "a reasonable effort to obtain" the facts, that defendants satisfied the notice and hearing requirements, and that the peer review action taken by defendants was taken "in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts."¹⁸ The court elaborated on the application of these elements, stating that (1) the HCQIA

8. *Id.*

9. *Id.* at *2.

10. *Id.*

11. *Id.*

12. *Id.* at *5.

13. *See Poliner v. Tex. Health Sys.*, 239 F.R.D. 468 (N.D. Tex. 2006), *rev'd*, 537 F.3d 368 (5th Cir. 2008), *cert. denied*, 129 S. Ct. 1002 (2009).

14. *Id.* at 478.

15. *Poliner v. Tex. Health Sys.*, 537 F.3d 368, 385 (5th Cir. 2008), *cert. denied*, 129 S. Ct. 1002 (2009).

16. *Id.* at 385 (footnote omitted).

17. *Id.* at 376-77 (citing 42 U.S.C. § 1112(a) (2006)).

18. *See id.* at 378-85.

was “intended to create an objective standard of performance, rather than a subjective good faith standard,”¹⁹ (2) HCQIA does not require that the peer review action result in an actual improvement in the quality of care,²⁰ (3) the “good or bad faith of the reviewers is irrelevant,”²¹ (4) an ultimate decisionmaker is not required to investigate the matter independently but is only required to make a “reasonable effort to obtain the facts,”²² and (5) “HCQIA immunity is not coextensive with compliance with an individual hospital’s bylaws.”²³ Poliner appealed, but on March 23, 2009, the United States Supreme Court denied the certiorari.²⁴

The most recent *Poliner* decision provides some reassurance for health care providers in that immunity under the HCQIA can be extended to those who perform professional review actions which conform to the applicable standards and serve as a shield from damages. The decision applies the presumption found in § 11112(a) of title 42²⁵ that “a professional review action shall be presumed to have met the [applicable standards] . . . unless the presumption is rebutted by a preponderance of the evidence.”²⁶

B. Medtronic-Kyphon Settlement

One of the most interesting False Claims Act²⁷ cases impacting healthcare providers in 2008 is the Medtronic settlement.²⁸ The settlement demonstrates the risks associated with a healthcare provider’s reliance on reimbursement advice from a medical device manufacturer.²⁹

On October 25, 2005, former Kyphon employees Charles Bates, III and Craig Patrick filed a *qui tam* complaint against Kyphon, Inc.³⁰ alleging violations of the False Claims Act.³¹ Bates and Patrick later amended the complaint to include

19. *Id.* at 376.

20. *Id.* at 378.

21. *Id.* (quoting *Brader v. Allegheny Gen. Hosp.*, 167 F.3d 832, 840 (3d Cir. 1999)).

22. *Id.* at 380 (internal quotes omitted).

23. *Id.*

24. *Poliner v. Tex. Health Sys.*, 129 S. Ct. 1002 (2009) (mem.).

25. *See Poliner*, 537 F.3d at 377.

26. 42 U.S.C. § 11112(a) (2006).

27. 31 U.S.C. § 3729 (2006).

28. Subsequent to the filing of the *qui tam* action, Kyphon was acquired by Medtronic in 2007.

29. DEP’T OF JUSTICE, MEDTRONIC SPINE, FORMERLY KYPHON, INC., TO PAY U.S. § 75 MILLION TO RESOLVE ALLEGATIONS OF DEFRAUDING MEDICARE (2008), *available at* <http://www.usdoj.gov/opa/pr/2008/May/08-civ-455.html>.

30. *United States ex rel. Bates & Patrick v. Kyphon*, No. 05-CV-6568CJS(f) (W.D.N.Y., filed Oct. 25, 2005). Subsequent to the filing of the *qui tam* action, Kyphon was acquired by Medtronic in 2007.

31. *Id.*

claims against Sisters of Charity Hospital.³² Bates was a former Kyphon sales representative while Patrick was a former Kyphon reimbursement manager.³³ According to the *qui tam* complaint, Kyphon illegally marketed its kyphoplasty procedure by encouraging physicians to perform the procedure and to claim reimbursement unnecessarily treating the procedure as an inpatient service.³⁴

The lawsuit described kyphoplasty as a minimally-invasive surgery used to treat vertebral compression fractures most commonly caused by osteoporosis in the elderly population.³⁵ The kyphoplasty restores the size and strength of the fractured, collapsed vertebra. According to the complaint, the procedure involves the insertion of an inflatable balloon into the vertebra in order to restore partially vertical height and to create a cavity in which to inject a viscous bone cement.³⁶ The cement in turn strengthens the broken vertebra, secures the vertebra in its original height and position, and supports the surrounding bone to prevent further collapse.³⁷ This procedure is usually performed by orthopedic surgeons and interventional radiologists under general anesthesia or conscious sedation.³⁸ Kyphoplasty can generally be done on an outpatient basis and inpatient stays are only expected in rare cases where the patient is frail or other medical issues require further monitoring following the procedure.³⁹

Despite the minimal invasiveness of the procedure, the complaint alleged that approximately eighty-ninety percent of the 150,000 kyphoplasty procedures performed from 1999 to 2005 were unnecessarily performed as inpatient, rather than outpatient, procedures as a result of Kyphon's misleading marketing practices.⁴⁰

On May 20, 2008, Medtronic Spine, LLC (Medtronic) announced a \$75 million settlement of the *qui tam* lawsuit.⁴¹ In addition to paying the \$75 million fine, Medtronic also agreed, as part of the settlement, to enter into a corporate integrity agreement (Agreement) with the United States Department of Human Services, Office of Inspector General.⁴² The Agreement contained measures to ensure compliance with Medicare regulations and policies in the future.⁴³ As a result of the settlement, the *qui tam* relators received a total of \$14.9 million as their statutory share of the proceeds.⁴⁴ The Medtronic-Kyphon settlement ranks

32. First Amended Complaint at 1, United States *ex rel.* Bates & Patrick v. Kyphon, Inc. and Sisters of Charity Hospital, No. 05-CV-6568CJS(f) (W.D.N.Y., filed Jan. 5, 2006).

33. *Id.* ¶¶ 14-17.

34. *Id.* ¶ 4.

35. *Id.* ¶¶ 54-59.

36. *Id.* ¶¶ 64-65.

37. *Id.* ¶¶ 65-66.

38. *Id.* ¶ 21.

39. *Id.* ¶ 68.

40. *Id.* ¶ 5.

41. See DEP'T OF JUSTICE, *supra* note 29.

42. *Id.*

43. *Id.*

44. *Id.*

as the fifty-eighth largest False Claims Act settlement to date.⁴⁵

II. FRAUD & ABUSE

A. Stark IV

On August 19, 2008, the Centers for Medicare & Medicaid Services (CMS) issued the final Hospital Inpatient Prospective Payment Systems rule for fiscal year 2009 (Final Rule) which, in part, finalized several new Stark regulations.⁴⁶

1. *Changes to Physician “Stand in the Shoes” Regulations.*—In the Stark Phase III final regulations effective December 4, 2007, CMS implemented a “stand in the shoes” rule under which referring physicians were treated as standing in the shoes of their physician organization for purposes of applying the direct and indirect compensation exceptions.⁴⁷ As a result, many compensation arrangements between entities providing designated health services (DHS) and physician groups that previously were indirect compensation arrangements or did not meet the definition of an indirect compensation arrangement under Stark (and thus may not have been subject to Stark at all), were treated as direct compensation arrangements between the DHS entities and the groups’ referring physicians.⁴⁸ Therefore, these arrangements were required to be restructured in order to satisfy all of the elements of a direct compensation exception.⁴⁹

In an attempt to simplify the application of the stand in the shoes regulations in the Final Rule, CMS finalized revisions to the physician “stand in the shoes” provisions that deem a physician who has an *ownership or investment interest* in a physician organization to “stand in the shoes” of that physician organization.⁵⁰ Physicians with only a “titular” ownership interest—physicians that do not have the “ability or right to receive the financial benefits of ownership or investment, . . . [such as] the distribution of profits, dividends, proceeds of sale, or similar returns on investment”—and non-owner physician employees or independent contractors would not be deemed to “stand in the shoes” of their physician organizations.⁵¹ Further, CMS clarified that the physician “stand in the shoes” provisions do not apply to arrangements that satisfy the academic medical centers exception.⁵²

Nonetheless, in the preamble to the Final Rule, CMS noted that the revised regulations *permit* non-owner physicians and titular owners to stand in the shoes

45. Top 100 False Claims Act Cases, <http://www.taf.org/top100fca.htm> (last visited July 5, 2009).

46. Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 48,434, 48,688-48,754 (Aug. 19, 2008) (to be codified at C.F.R. pt. 411).

47. *Id.* at 48,695 (citing 42 C.F.R. § 411.357(p) (2008)).

48. *Id.*

49. *Id.*

50. *Id.* at 48,753 (to be codified at 42 C.F.R. § 411.354(c)(1)(ii)).

51. *Id.* (to be codified at 42 C.F.R. § 411.354(c)(3)(ii)(C)).

52. *Id.* at 48,698.

of their physician organizations.⁵³ Per CMS, the purpose of this “permissive” regulation is to allow parties the flexibility to structure compensation arrangements in a manner that satisfies a direct compensation arrangement (as opposed to an indirect compensation arrangement exception or no exception at all) in order to comply with Stark.⁵⁴ CMS indicated that it believes that “[t]his approach is consistent with [its] longstanding view that parties are entitled to use any available exception of which they satisfy all of the applicable requirements.”⁵⁵

CMS noted that as a result of the Phase III “stand in the shoes” rule, many arrangements between DHS entities and physician organizations had to be restructured or initially structured by December 4, 2007, to meet an exception for direct compensation arrangements.⁵⁶ Accordingly, in the Final Rule, CMS clarified that “such arrangements do not need to be restructured” again to comply with the revised stand in the shoes regulations until the expiration of the original term or renewal term of the agreement.⁵⁷ Additionally, the parties can elect to continue having the non-owner physicians stand in the shoes of their physician organization, as was required under Stark III, in order to avoid restructuring an arrangement.⁵⁸

2. *New Limitations Placed on Services Performed for Hospitals and Other DHS Entities (including “Under Arrangements”).*—The Stark law prohibits both a physician from making referrals for DHS to an entity with which the physician (or an immediate family member) has a financial relationship and prohibits the entity from billing Medicare for the DHS, unless an exception applies.⁵⁹ Under the Phase I definition of “entity,” an “entity” includes only the person or entity that *bills* Medicare for the DHS—not the person or entity that performs the DHS where such person or entity—is not also the person or entity billing for it.⁶⁰

In this version of the Final Rule, CMS amended the definition of “entity” to clarify that a person or entity is considered to be “furnishing” DHS if it “[i]s the person or entity that has *performed*” the DHS (notwithstanding that such entity did not actually bill the services).⁶¹ Note that where an “under arrangements” service provider “performs” a service that is billed by another entity, both the “under arrangements” service provider and the billing entity are DHS entities with respect to that service.⁶² CMS does not define “perform” specifically, but it appears that the “hands-on” medical or clinical work would fall under this

53. *Id.* at 48,690.

54. *Id.* at 48,695.

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

59. 42 U.S.C. § 1395nn(a)(1) (2006).

60. 42 C.F.R. § 411.351 (2008).

61. Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. at 48,751 (to be codified at 42 C.F.R. § 411.351) (emphasis added)).

62. *Id.* at 48,721.

umbrella.

Thus, where an “under arrangements” service provider (e.g., a joint venture, physician group practice, or other physician organization) “performs” the services and, pursuant to a contractual arrangement, a hospital bills for those services, the services are DHS and the “under arrangements” service provider would be a DHS entity with respect to those services.⁶³ If the referral to the “under arrangements” service provider is made by a physician owner or investor in such provider, an ownership exception must be met to protect the referral.⁶⁴

CMS delayed the effective date of the amendment to the definition of “entity” until October 1, 2009, in order to afford parties adequate time to restructure arrangements.⁶⁵

3. *Percentage-Based Compensation Arrangements Prohibited for Office Space and Equipment Lease Arrangements Only.*—In the Final Rule, CMS revised the rental of office space,⁶⁶ rental of equipment,⁶⁷ fair market value compensation arrangement exceptions⁶⁸ (all of these are “direct” exceptions), and the indirect compensation arrangement exception⁶⁹ to prohibit the use of compensation formulae based on “[a] percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated” in leased space or by the use of leased equipment.⁷⁰

In the Final Rule, CMS clarified that it does not consider these changes in the Final Rule to prohibit the imposition or levy of a percentage of expenses (e.g., property taxes or utilities) by a third party or a lessor from charging a lessee a pro rata share of *expenses* incurred that are attributable to that portion of the medical office building or other space or equipment that is leased by a lessee.⁷¹ Although CMS only finalized the percentage-based compensation formulae prohibition with respect to space and equipment leases (the prohibition was not extended to arrangements for non-professional services such as management or billing services), CMS intends to continue monitoring percentage-based compensation arrangements between DHS entities and physicians and may further restrict such arrangements as appropriate.⁷²

CMS noted that the Final Rule’s restrictions on the use of percentage-based compensation formulae for determining rental charges for the lease of space and equipment “may require the restructuring or termination of arrangements for the rental of space and equipment.”⁷³ Therefore, CMS has delayed the effective date

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.* at 48,752 (to be codified at 42 C.F.R. § 411.357(a)).

67. *Id.* (to be codified at 42 C.F.R. § 411.357(b)).

68. *Id.* (to be codified at 42 C.F.R. § 411.357(l)).

69. *Id.* (to be codified at 42 C.F.R. § 411.357(p)).

70. *Id.* (to be codified at 42 C.F.R. § 411.357(a)).

71. *Id.* at 48,711.

72. *Id.* at 48,710.

73. *Id.* at 48,713.

of these regulations until October 1, 2009.⁷⁴

4. *Restrictions on Unit-of-Service (Per-Click) Payments in Space and Equipment Lease Arrangements.*—CMS revised the lease exceptions for office space and equipment, the fair market value exception, and the exception for indirect compensation arrangements to provide that Unit of Service (per-click) rental charges are not allowed “to the extent that such charges reflect services provided to patients referred [by the lessor to the lessee].”⁷⁵ The rulemaking clearly articulates,

The prohibition on per-click payments for space or equipment used in the treatment of a patient referred to the lessee by a physician applies regardless of whether the physician is the lessor or whether the lessor is an entity in which the referring physician has an ownership or investment interest. The prohibition also applies where the lessor is a DHS Entity that refers patients to a physician lessee or a physician organization lessee.⁷⁶

CMS delayed the effective date of these amendments until October 1, 2009, in order to afford parties adequate time to restructure arrangements.⁷⁷

5. *Expansion of Obstetrical Malpractice Insurance Subsidy Arrangements.*—In the Final Rule, CMS revised this exception by separating it into two subsections. First, section 411.357(r)(1) retains the provisions of the current exception.⁷⁸ New section 411.357(r)(2) allows hospitals, federally qualified health centers, and rural health clinics to provide an obstetrical malpractice insurance subsidy to a physician who regularly “engages in obstetrical practice as a routine part of his or her medical practice” that is: (1) “located in a rural area, primary care HPSA, rural area, or an area with a demonstrated need . . . as determined by the Secretary in an advisory opinion”; or (2) is comprised of patients “[a]t least [seventy-five] percent of the physician’s obstetrical patients reside in a medically underserved area or are part of a medically underserved population.”⁷⁹

6. *Ownership or Investment Interest in Retirement Plans.*—CMS revised the definition of ownership or investment interest out of concern that physicians may be using retirement plans as a vehicle “to purchase or invest in other entities . . . to which they refer patients for DHS.”⁸⁰

7. *Outer Limits on the Period of Disallowance.*—In the Final Rule, CMS provided that the “period of disallowance” begins when the “financial relationship fails to satisfy the requirements of an applicable exception.”⁸¹ A

74. *Id.*

75. *Id.* at 48,752 (to be codified at 42 C.F.R. § 411.357(b)).

76. *Id.* at 48,714.

77. *Id.*

78. *Id.* at 48,753 (to be codified at 42 C.F.R. § 411.357(r)(1)).

79. *Id.* (to be codified at 42 C.F.R. § 411.357(r)(2)(B)).

80. *Id.* at 48,737.

81. *Id.* at 48,700.

period of disallowance is the time in which a physician cannot refer DHS to an entity and an entity cannot bill Medicare because the financial relationship between the referring physician and the entity fails to meet all of the requirements of a Stark exception.⁸² When noncompliance is not due to a compensation matter, the period of disallowance ends when “the financial relationship satisfies all of the requirements of the applicable exception.”⁸³ In cases where the noncompliance is tied to compensation, the period of disallowance ends no later than the date on which all “excess compensation is returned to the party that paid it,” or the date on which all “additional required compensation is paid to the party to which it is owed.”⁸⁴

8. *Alternative Method for Compliance and New Guidance on Missing Signatures.*—The Final Rule also created a new paragraph to section 411.353, which provides that “payment may be made to an entity that submits a claim or bill for [DHS] if” the financial relationship between the entity and the referring physician “fully complied with an applicable exception [under section 411.357], except with respect to the signature requirement,” and provided that the necessary signatures are obtained within ninety days of the commencement of the financial relationship if the failure to comply with the signature requirement was “inadvertent,” or within thirty days if the failure to comply was “not inadvertent.”⁸⁵

In order to take advantage of the alternative method for compliance in section 411.353(g), the financial relationship at issue must satisfy all of the requirements of the applicable exception at the commencement of the financial relationship.⁸⁶ An entity may use this alternative method of compliance only once every three years with respect to the same referring physician.⁸⁷

9. *Claimants Bear Burden of Proof for Claims Denied Based on Prohibited Referrals.*—CMS finalized its proposal to clarify existing Medicare regulations to provide that,

in any appeal of a denial of payment for [DHS] that was made on the basis that the DHS was furnished pursuant to a prohibited referral [under Stark], the burden is on the [DHS] entity submitting the claim for payment to establish that the service was *not* furnished pursuant to a prohibited referral [under Stark].⁸⁸

In the Final Rule, CMS noted that this new regulation—section 411.353(c)(2)—clarifies that “in any case in which a claim is denied for failure to comply with [Stark], the ultimate burden of proof (that is, the burden of persuasion) is on the claimant to demonstrate compliance and not on [CMS or its

82. *See id.*

83. *Id.*

84. *Id.*

85. *Id.* at 48,751 (to be codified at 42 C.F.R. § 411.353(g)).

86. *Id.* (to be codified at 42 C.F.R. § 411.353(g)(1)(i)).

87. *Id.* (to be codified at 42 C.F.R. § 411.353(g) (2)).

88. *Id.* at 48,738 (to be codified at 42 C.F.R. § 411.353(c)(2)).

contractors] to demonstrate noncompliance.”⁸⁹ In the preamble, CMS clarified that the burden of proof rules relate only to the administrative appeals of Medicare claims denials under the appeals process.⁹⁰ Appeals of civil monetary penalties, exclusions or other remedies imposed based on a determination that a DHS entity or a physician knowingly violated the Stark Law involve other appeal processes that are not subject to this rule.⁹¹

10. Disclosure of Financial Relationships Report.—In the Final Rule, CMS also provided an update on the status of the “Disclosure of Financial Relationships Report” (DFRR).⁹² The DFRR arose out of the Stark Law and its implementing regulations.⁹³ In September 2007, CMS intended to send a mandatory DFRR to 500 specialty and general hospitals for the purpose of collecting information to be used analyzing the investment, ownership, and compensation relationships with regard to the hospitals and its physicians.⁹⁴ The mandatory disclosure process would have followed the previous year’s voluntary disclosure process, distributed to hospitals pursuant to the Deficit Reduction Act of 2006 (DRA).⁹⁵ However, prior to distribution of the mandatory DFRR, CMS was required to obtain approval from the Office of Management and Budget (OMB) and had been in discussions with OMB since late last year.⁹⁶

In the Final Rule, CMS indicated that it will proceed with its proposal to send the DFRR to 500 hospitals (both general acute care hospitals and specialty hospitals).⁹⁷

However, based on further review and comments [that CMS] may receive in response to the revised [Paperwork Reduction Act (PRA)] package that will be published separately in the Federal Register [at some later date], [CMS] may decide to decrease (but not increase) the number of hospitals [to which it will] send the DFRR.⁹⁸

Importantly, CMS did not adopt a regular reporting or disclosure process at this time, and thus, the DFRR will be used, for the time being, as a “one-time collection effort.”⁹⁹ CMS did, however, adopt its proposal that “the DFRR be completed, certified by the appropriate officer of the hospital, and received by [CMS] within [sixty] days of the date that appears on the cover letter or email

89. *Id.* at 48,739.

90. *Id.*

91. *Id.*; see also 42 C.F.R. § 411.353(c) (2008).

92. See *id.* at 48,740-41.

93. *Id.* at 48,740.

94. *Id.* at 48,740-41.

95. Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4 (2006) (codified as amended in scattered titles and sections of U.S.C.).

96. Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. at 48,745.

97. *Id.* at 48,743.

98. *Id.*

99. *Id.* at 48,744.

transmission of the DFRR.”¹⁰⁰ This is an increase from the original forty-five day required response time.

Failure to respond to the DFRR could result in a civil monetary penalty.¹⁰¹ However, prior to imposing such a penalty of up to \$10,000 for each day beyond the timeframe established for a response, CMS agreed to issue a letter to any hospital that does not return the completed DFRR.¹⁰² The letter will inquire as to why the hospital did not timely return the completed DFRR.¹⁰³ “In addition, a hospital may, upon a demonstration of good cause, receive an extension of time to submit the requested information.”¹⁰⁴

B. *OIG Actions*

1. *Advisory Opinion 08-01*.—On January 28, 2008, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued Advisory Opinion 08-01.¹⁰⁵ This was the first advisory opinion addressing the application of the anti-kickback statute to bulk replacement patient assistance programs (PAPs). Based on the specific facts of the arrangement, the OIG determined that while the arrangement raised a potential compliance risk as a possible inducement, it would still be approved due to the presence of several safeguards.¹⁰⁶

PAPs “have long provided important safety net assistance to patients of limited means who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs.”¹⁰⁷ The arrangement involved a non-profit, tax-exempt corporation (Partnership) that served “as a liaison between the pharmaceutical industry and free clinics and FQHCs [federally qualified health centers] to improve access to free pharmaceutical products for low-income persons” by participating in “various bulk replacement [PAPs] sponsored by pharmaceutical companies that provide in-kind donations in the form of free drugs.”¹⁰⁸

The Partnership sought to create an arrangement to make it easier for pharmaceutical companies to offer their bulk replacement PAPs to free clinics and FQHCs.¹⁰⁹ First, the Partnership limited utilization of the PAP drugs to uninsured patients with income below 200 percent of the federal poverty limit

100. *Id.* at 48,741.

101. *Id.*

102. *Id.*

103. *Id.*

104. *Id.*

105. OIG Advisory Opinion No. 08-01 (Jan. 28, 2008), available at <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-01C.pdf>

106. *Id.* at 2, 12.

107. OIG Special Advisory Bulletin on Patient Assistance Programs, 70 Fed. Reg. 70,623, 70,623-24 (Nov. 22, 2005).

108. OIG Advisory Opinion No. 08-01, *supra* note 104, at 2.

109. *Id.*

(including Medicare beneficiaries who are not enrolled in Part D).¹¹⁰ Second, the Partnership imposed uniform PAP operating standards on participating companies, which included: (1) maintaining separate, auditable records for all PAP drugs; (2) maintaining systems for separating PAP inventory from other purchased products; (3) implementing a computerized dispensing system that will generate electronic reports for monitoring compliance with the Partnership requirements; and (4) agreeing to submit to annual on-site compliance audits.¹¹¹ Additionally, the arrangement prohibited the free clinics and FQHCs from “selling any donated PAP drugs and from transferring any PAP drugs to any third party other than the qualifying patients.”¹¹² Finally, the arrangement required the Partnership to submit a monthly summary report to the pharmaceutical company sponsor of each participating PAP, “providing detailed information about the PAP drugs dispensed to eligible patients during the previous month.”¹¹³

The OIG concluded that the arrangement could potentially violate both the anti-kickback statute and the prohibition on inducements to Medicare beneficiaries contained in the civil monetary penalties, but nevertheless, OIG approved the arrangement due to several safeguards.¹¹⁴ Specifically, OIG identified the following safeguards: (1) the inventory segregation of the free drugs to be provided protected against free clinics and FQHCs from receiving any remuneration such as excess stock that could be diverted to other uses;¹¹⁵ (2) the arrangement was documented in detail and was auditable, which assured transparency;¹¹⁶ (3) the PAP sponsors did not control the selection of the free clinics or the FQHCs which prevented PAP sponsors from “cherry-picking” certain FQHCs to receive donated drugs;¹¹⁷ (4) the physicians who prescribed drugs for FQHC patients did “not receive any compensation that [would] take[] into account in any manner the physicians’ prescribing patterns for PAP sponsors’ products, and the FQHCs [did] not track any physician’s prescribing patterns of PAP drugs”;¹¹⁸ and (5) in its liaison capacity, the Partnership insulated the FQHCs from PAP sponsors.¹¹⁹

2. *Advisory Opinions 07-21, 07-22, 08-09, & 08-21: The Gainsharing Exception.*—In 2008, OIG issued four separate Advisory Opinions addressing several proposed arrangements involving gainsharing agreements.

a. *Advisory opinions 07-21 & 07-22.*—On December 29, 2007, the U.S. Department of Health and Human Services issued Advisory Opinions 07-21¹²⁰

110. *Id.* at 2-3.

111. *Id.* at 3-4.

112. *Id.* at 3.

113. *Id.*

114. *Id.* at 12.

115. *Id.* at 10.

116. *Id.*

117. *Id.* at 10-11.

118. *Id.* at 10.

119. *Id.* at 11.

120. OIG Advisory Opinion No. 07-21 (Dec. 28, 2007), available at <http://www.oig.hhs.gov/>

and 07-22,¹²¹ in which the OIG restated its position regarding gainsharing arrangements with respect to surgeons and anesthesiologists.¹²² In both arrangements, the hospitals engaged a third-party program administrator (Administrator) to collect and analyze data related to the proposed cost saving practices, and to manage the arrangement.¹²³ Both Administrators identified a number of specific cost-saving opportunities such as: (1) use as needed items; (2) product substitution; and (3) product standardization.¹²⁴

The OIG noted its overall concerns related to gainsharing arrangements, included: (1) “stinting on patient care”; (2) “cherry picking” healthy patients; (3) payments in exchange for referrals; and (4) unfair competition.¹²⁵

The OIG determined that both arrangements contained a variety of safeguards so as to protect against inappropriate reductions in services, including: (1) “the specific cost-saving actions and resulting savings were clearly and separately identified”; (2) the hospitals provided “credible medical support for the position that implementation of the recommendations did not adversely affect patient care”; (3) the Administrator used “objective historical data and clinical measures”; and (4) the product standardization ensures “that individual physicians still had available the same selection of devices and supplies under the [a]rrangement as before.”¹²⁶ Thus, the OIG concluded that neither arrangement violated the civil monetary penalties statute.¹²⁷

In addition, the OIG analyzed these arrangements under the anti-kickback statute. In that analysis, the OIG determined that the personal services safe harbor would not afford protection to the arrangements because the aggregate compensation was not set forth in advance.¹²⁸ Nevertheless, the OIG determined that it would not impose sanctions because: (1) the circumstances and safeguards reduced the likelihood that the arrangements would attract or increase referrals; (2) each group was the sole participant of their respective arrangement and each group was composed of their respective specialty; and (3) the activities required

fraud/docs/advisoryopinions/2007/AdvOpn07-21A.pdf.

121. OIG Advisory Opinion No. 07-22 (Dec. 28, 2007), *available at* <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-22A.pdf>.

122. *See* OIG Advisory Opinion No. 07-21, *supra* note 119, at 11; OIG Advisory Opinion No. 07-22, *supra* note 120, at 11.

123. OIG Advisory Opinion No. 07-21, *supra* note 119, at 2-3; OIG Advisory Opinion No. 07-22, *supra* note 120, at 2-3.

124. OIG Advisory Opinion No. 07-21, *supra* note 119, at 4-5; OIG Advisory Opinion No. 07-22, *supra* note 120, at 4.

125. OIG Advisory Opinion No. 07-21, *supra* note 119, at 8; OIG Advisory Opinion No. 07-22, *supra* note 120, at 7-8.

126. OIG Advisory Opinion No. 07-21, *supra* note 119, at 10-11; OIG Advisory Opinion No. 07-22, *supra* note 120, at 9-10.

127. OIG Advisory Opinion No. 07-21, *supra* note 119, at 15; OIG Advisory Opinion No. 07-22, *supra* note 120, at 14.

128. OIG Advisory Opinion No. 07-21, *supra* note 119, at 13; OIG Advisory Opinion No. 07-22, *supra* note 120, at 12.

of the groups under the arrangements carried some increased liability risks for physicians, for which compensation was reasonable.¹²⁹ Thus, the arrangements posed a low risk of fraud or abuse under the anti-kickback statute.

b. Advisory opinion 08-09.—On July 31, 2008, the U.S. Department of Health and Human Services, OIG issued Advisory Opinion 08-09, in which the OIG again¹³⁰ discussed its position regarding gainsharing.¹³¹ This time, however, OIG discussed its position with respect to an arrangement under which “a medical center . . . agreed to share with groups of orthopedic surgeons and a group of neurosurgeons a percentage of the medical center’s cost savings arising from the surgeons’ implementation of a number of cost reduction measures in certain surgical procedures.”¹³² Specifically, the medical center would pay the surgeon groups fifty percent of the medical center’s first-year cost savings directly attributable to specific changes in each of the surgeon groups’ operating room practices for spine fusion surgery.¹³³ While the medical center withheld payment under the arrangement until it received a favorable opinion from the OIG, the OIG explicitly stated that such nonpayment does not insulate parties from liability.¹³⁴

The medical center engaged an Administrator to collect and analyze historical data related to the cost-saving practices as well as to manage the arrangement.¹³⁵ The Administrator had thirty-six specific recommendations which can be grouped into two categories: (1) “use as needed biological” and (2) “product standardization.”¹³⁶

The OIG noted that these types of arrangements that share cost savings “could serve legitimate business and medical purposes” if properly structured by increasing “efficiency and reduc[ing] waste, thereby potentially increasing a hospital’s profitability.”¹³⁷ However, the OIG reiterated its longstanding concerns related to gainsharing arrangements as aforementioned.¹³⁸

129. OIG Advisory Opinion No. 07-21, *supra* note 119, at 13-14; OIG Advisory Opinion No. 07-22, *supra* note 120, at 13-14.

130. *See also* OIG Advisory Opinion No. 08-21 (Nov. 25, 2008), *available at* <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-21.2.pdf>. The OIG utilizing similar analysis reiterates its positions regarding gainsharing in the context of cardiac catheterization procedures. *Id.* at 12. Consistent with its prior gainsharing advisory opinions, the OIG found that the arrangement implicated both the civil monetary penalties statute and the anti-kickback statute. *Id.* at 16. However, the OIG concluded that it would not impose sanctions due to the presence of certain program safeguards. *Id.*

131. *Id.* at 3 n.4.

132. *Id.* at 1.

133. *Id.* at 5.

134. OIG Advisory Opinion No. 08-09 (July 31, 2008), *available at* <http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-09B.pdf>.

135. *Id.* at 3.

136. *Id.* at 4.

137. *Id.* at 7.

138. *Id.* at 11.

The OIG ultimately concluded that the arrangement provided sufficient safeguards such as (1) the transparency of the identifiable cost-saving actions, (2) credible support that patient care was unaffected, and (3) the medical center and surgeons provided written disclosures of the arrangement to patients, which precluded the OIG from seeking sanctions.¹³⁹

Additionally, the OIG analyzed the arrangement under the anti-kickback statute and determined that the personal services safe harbor would not protect the arrangement because the compensation was not set forth in advance.¹⁴⁰ However, the OIG consistently concluded that sanctions would not be imposed because of several safeguards including (1) the low likelihood that referrals would increase as a result of the arrangement, (2) the low likelihood that the arrangement would influence other physicians who refer patients to the surgeon groups, and (3) the increased liability risks for the surgeons.¹⁴¹ The OIG continued to emphasize the transparency of this gainsharing arrangement, but still cautioned against similar arrangements, including multi-year arrangements or those based on generalized, less specific cost savings formulae.¹⁴²

III. TAX

In 2007 and 2008, there were several tax developments that directly impacted the health care industry. These developments include the introduction of the new Form 990 by the Internal Revenue Service, final regulations relating to the requirements for tax exemption status under 501(c)(3) of the Internal Revenue Code, and an Interim Report on the Hospital Compliance Project. Below is a brief summary and analysis each of these recent tax developments.

A. *Final Form 990*

Since the summer of 2007, the world of tax exempt organizations, including tax exempt hospitals, has been intently focused on the changes associated with the redesign of the Form 990, *Return of Organizations Exempt from Income Tax*, by the Internal Revenue Service (IRS). After the closing of comment periods to drafts of the Form 990 and related instructions, the final version of the redesigned Form 990 (New Form 990) was released on December 20, 2007,¹⁴³ and instructions to the New Form 990 were released on August 19, 2008 (Instructions).¹⁴⁴

The New Form 990 represents one of the most significant changes in the tax exempt sector during the last thirty years. “The focus of the redesign . . . was on

139. *Id.* at 9-11.

140. *Id.* at 12.

141. *Id.* at 12-13.

142. *Id.* at 12.

143. I.R.S. News Release IR-2007-204 (Dec. 20, 2007).

144. I.R.S. News Release IR-2008-98 (Aug. 19, 2008); *see also* I.R.S., Chronological History: Redesign of the 2008 Form 990 and Corresponding Instructions (June 18, 2009), *available at* <http://www.irs.gov/charities/charitable/article/0,,id=185892,00.html>.

increasing reporting related to governance, executive compensation, related organizations, fundraising practices, and hospitals' amount of community benefit," according to Lois Lerner, IRS Exempt Organizations Division Director.¹⁴⁵ The subject matter that is addressed in the New Form 990 was developed based on a perceived need to aid the tax compliance interests of the IRS as well as the transparency and accountability needs of the states, the general public, and local communities served by tax exempt organizations.¹⁴⁶ The New Form 990 becomes applicable for tax years beginning in 2008 (i.e., returns filed in 2009). The effective date for the filing of certain information on Schedule H (Hospitals) and Schedule K (Bonds) has been delayed for one year.¹⁴⁷ Only the portions of these Schedules that provide certain identifying information must be completed for the 2008 tax year.¹⁴⁸

The implementation of the New Form 990 represents an increased compliance burden for most tax-exempt organizations, especially tax exempt hospitals. The New Form 990 will require the disclosure of a significant amount of new information, which will be available publically.¹⁴⁹ The New Form 990 consists of a core form (Core Form) and sixteen schedules (each referred to as a Schedule) that cover various topics.¹⁵⁰ Every organization that files the New Form 990 will complete the Core Form.¹⁵¹ Completion of the Schedules will be dependent upon the type of activities that the organization conducts.¹⁵² While much has changed with the New Form 990, three areas should be of particular interest to tax exempt hospitals: governance, compensation, and hospital activities, including community benefit and charity care activities that must be reported on Schedule H.¹⁵³

With respect to governance, a section of the Core Form is primarily devoted to questions about the governance of the organization that will likely influence the behavior of most tax-exempt organizations.¹⁵⁴ The questions require only a "yes" or "no" answer, but in effect, these questions encourage organizations to revisit their structural and policy choices and modify their conduct.¹⁵⁵ The

145. Christopher Quay & Fred Stokeld, IRS's Lerner Details Draft of Redesigned Form 990, 57 EXEMPT ORG. TAX REV. 9 (2007).

146. IRS Frequently Asked Questions, Why Did the IRS Redesign the Form? (Jan. 7, 2007), available at <http://www.irs.gov/charities/article/0,,id=176670,00.html>.

147. See TY 2008 Form 990—Forms and Instructions, Instructions for Schedule H and Instructions for Schedule K (Jan. 5, 2009), available at <http://www.irs.gov/charities/article/0,,id=185561,00.html>.

148. *Id.*

149. See 26 U.S.C. § 6104(d)(1) (2006).

150. I.R.S. News Release IR-2007-204 (Dec. 20, 2007).

151. *Id.*

152. *Id.*

153. See *id.*

154. See Instructions for Form 990, at 15-19, available at <http://www.irs.gov/pub/irs-pdf/990.pdf>.

155. See generally *id.*

policies addressed include a conflict of interest policy, a whistleblower policy, and a document retention policy.¹⁵⁶ This portion of the form also inquires as to whether the organization's process for approving compensation arrangements satisfies the requirements for the rebuttable presumption of reasonableness.¹⁵⁷

Significant with respect to the conflict of interest policy is the detail sought on conflicts enforcement practices, whether discovered before or after the transaction has occurred. This includes a description of the types of persons covered by the policy, the level at which the conflicts determination is made and at which actual conflicts are reviewed, as well as any restrictions imposed upon a person determined to have a conflict with respect to a particular transaction.¹⁵⁸ While the IRS believes that the listed policies and procedures generally improve tax compliance, it noted that many of the policies or procedures are not legally required.¹⁵⁹ If an organization does not already have the right policies or procedures in place with respect to these items (or similar ones discussed elsewhere on the New Form 990), then it may be prudent to adopt such policies.

An organization also must disclose how it makes certain information about itself—including its Form 1023, Form 990, governing documents, and various other information—available to the public.¹⁶⁰ Once again, the IRS is signaling that such information should be readily accessible and is inviting organizations to take action voluntarily rather than have the IRS compel them to do so.

Compensation is addressed in two areas of the New Form 990—in Part VII of the Core Form and in Schedule J, Compensation. In Part VII, organizations must report compensation for (1) current officers, directors, trustees, and key employees; (2) the five highest paid employees earning over \$100,000; (3) former officers, key employees, and the five highest paid employees (going back five years) earning over \$100,000; and (4) former directors or trustees who received more than \$10,000 of reportable compensation.¹⁶¹ A separate table demands compensation information for the highest-paid independent contractors.¹⁶²

In Schedule J, compensation information must be supplied for (1) any person listed in Part VII who receives reportable compensation greater than \$150,000 from the organization and any related organizations; (2) any former officer, key employee, or highest compensated employee receiving reportable compensation of \$100,000 or more; (3) any former director or trustee receiving reportable compensation greater than \$10,000; and (4) any individual who receives compensation from any source, other than the organization, for services rendered

156. *See id.*; *see also* 2008 Form 990: Return of Organization Exempt from Income Tax, OMB No. 1545-0047, at 6, ll. 13-14, available at <http://www.irs.gov/pub/irs-pdf/f990.pdf> [hereinafter 2008 Form 990] (providing disclosures on Part VI of the return).

157. 2008 Form 990, *supra* note 155, at 6, l. 15.

158. *Id.* at 6, l. 12.

159. Instructions for Form 990, *supra* note 153, at 15.

160. 2008 Form 990, *supra* note 155, at 6, l. 19.

161. *Id.* at 7, l. 1a (listing the disclosures required under Part II).

162. *Id.* at 8, § B, l. 1-2.

to the organization.¹⁶³ Schedule J also requires disclosures regarding specific types of compensation, some of which (e.g., first class travel or health club dues) the IRS has identified as occasionally problematic.¹⁶⁴ An organization must provide details about the process for setting the compensation of the chief executive officer and, in some cases, other officers.¹⁶⁵ Finally, Schedule J requires information about deferred compensation and nontaxable fringe benefits.¹⁶⁶

Schedule J, in combination with Part VII of the Core Form, will require disclosure of a great deal of information not previously collected by the IRS. There is no transition relief concerning this Schedule, so organizations should already have systems in place to identify the various highly compensated individuals and to track and record the benefits they provide to them.

Schedule H, Hospitals, should be of great interest to tax exempt hospitals even though the substantive questions on this schedule are optional for the 2008 tax year,¹⁶⁷ because it represents an entirely new compliance component for tax exempt hospitals. Schedule H must be completed by a filing organization that operates one or more hospitals.¹⁶⁸ The Instructions provide that the term "hospital" is limited to state-licensed hospitals.¹⁶⁹ In the New Form 990, Schedule H is divided into the following six parts: Part I—Charity Care and Certain Other Community Benefits at Cost; Part II—Community Building Activities; Part III—Bad Debt, Medicare & Collection Practices; Part IV—Management Companies and Joint Ventures; Part V—Facility Information; and Part VI—Supplemental Information.¹⁷⁰

Part I of Schedule H requests information regarding charity care and certain other community benefits provided by the organization.¹⁷¹ Part I raises numerous questions regarding the charitable care that the organization provides.¹⁷² The Schedule utilizes the community benefit reporting model advanced by Catholic Healthcare Association. Part I of Schedule H requires each line item of charity care/community benefit to include information regarding the number of the organization's charitable activities or programs related to that benefit, persons

163. See 2008 Form 990, Schedule J: Compensation Information, available at <http://www.irs.gov/pub/irs-pdf/f990sj.pdf>.

164. See *id.*

165. *Id.*

166. *Id.*

167. See 2008 Form 990: Instructions for Schedule H, at 1, available at <http://www.irs.gov/pub/irs-pdf/i990sh.pdf>. Only one part of the form that identifies hospital facilities will need to be completed when organizations file their returns in 2009. *Id.* (noting that only Part V must be completed).

168. See *id.*

169. *Id.* at 1.

170. *Id.* at 2-7.

171. See *id.* at 2.

172. See 2008 Form 990, Schedule H: Hospitals, available at <http://www.irs.gov/pub/irs-pdf/f990sh.pdf> [hereinafter 2008 Form 990, Schedule H].

served, total community benefit expense, direct offsetting revenue, net community benefit expense, and the percent of total expenses represented by such benefit.¹⁷³ The IRS has decided with the New Form 990 that Medicare shortfalls and bad debt should not be included in the calculation of community benefit—although such matters still may be reported in another area of the form.¹⁷⁴ According to the instructions to Part I, a hospital is required to use the “most accurate costing methodology” in reporting various costs on Schedule H.¹⁷⁵

Part II of Schedule H, allows an organization to describe its community building activities.¹⁷⁶ Examples of such activities include physical improvements and housing, economic development, community support, and environmental improvements.¹⁷⁷ Part III allows an organization to provide information about its bad debt and Medicare shortfalls.¹⁷⁸ The schedule also seeks information regarding collection practices.¹⁷⁹ Part IV of Schedule H requires that an organization identify and describe all management companies and joint ventures (regardless of their tax structure as partnerships or corporations) which it owns together with any of its officers, directors, trustees, key employees, or physicians.¹⁸⁰ In Part V of Schedule H, the IRS requests general information regarding the different facilities at which the organization provides medical or hospital care, including the activities and programs conducted at each such facility.¹⁸¹ This is the only Part of this Schedule that organizations will be required to complete for 2008.¹⁸² Part VI of Schedule H seeks certain supplemental information regarding the organization, such as how the organization assesses the health care needs of the communities it serves and how the organization informs and educates patients about their eligibility for assistance under federal, state, or local government programs or under the organization’s charity care policy.¹⁸³ Part VI also seeks any other information important to describing how the organization’s hospital facilities further its exempt purposes.¹⁸⁴

Schedule H demands more information from hospitals than ever before, and it is probable that reform advocates, members of Congress, and others will point to such information to support proposed changes to the tax-exempt healthcare sector. Overall, the New Form 990 presents a much more logical and systematic approach to the information reporting for tax exempt organizations. However,

173. See 2008 Form 990, Schedule H, *supra* note 171, at 1.

174. 2008 Form 990: Instructions for Schedule H, *supra* note 166, at 2.

175. *Id.* at 3.

176. *Id.*

177. See *id.* at 3-4.

178. *Id.* at 4.

179. *Id.* at 5 (discussing Section C of Part III).

180. *Id.* at 5-6.

181. See *id.* at 6.

182. *Id.* at 1, 6.

183. *Id.* at 6-7.

184. *Id.* at 7 (discussing line 7).

the volume of new information that must be produced by tax exempt organizations will undoubtedly be burdensome. Most significantly, tax exempt hospitals will need to evaluate their policies and operations to ensure that they can provide information on the New Form 990 that represents them in a favorable light.

B. Interaction Between Tax Exempt Status and Rules Regarding Excess Benefit Transactions

On March 28, 2008, the IRS released final regulations that clarify the substantive requirements for tax exemption under section 501(c)(3) of the Internal Revenue Code of 1986, as amended (Code), explain the relationship between those requirements and the imposition of excise taxes under Code section 4958, better known as the Intermediate Sanctions Law, and provide several examples of the interaction between Code sections 501(c)(3) and 4958.¹⁸⁵

For background purposes, the Intermediate Sanctions Law imposes excise taxes on “excess benefit transactions.”¹⁸⁶ An excess benefit transaction occurs when a tax exempt organization provides a benefit to a “disqualified person” that exceeds the fair market value of the consideration received for such benefit.¹⁸⁷ A disqualified person is “any person who was, at any time during the [five-year] period ending on the date of such transaction, in a position to exercise substantial influence over the affairs of the [tax exempt] organization,” any close family member of such individual, and any entity in which any such individual owns more than a thirty-five percent interest.¹⁸⁸

The IRS had previously issued proposed regulations addressing this topic on September 9, 2005.¹⁸⁹ The release of these regulations finalize the IRS’s application of certain factors when determining whether an exempt 501(c)(3) organization that has engaged in an excess benefit transaction should also lose its exempt status.¹⁹⁰ Specifically, the IRS will consider the following facts and circumstances:

(A) the size and scope of the [exempt] organization’s regular and ongoing activities that further exempt purposes before and after the excess benefit transaction or transactions occurred;

(B) the size and scope of the excess benefit transaction or transactions (collectively, if more than one) in relation to the size and scope of the [exempt] organization’s regular and ongoing activities that further exempt purposes;

185. See Treas. Reg. §§ 1.501(c)(3)-1, 53.4958-2 (as amended by T.D. 9390, 2008-18 I.R.B. 855).

186. See 26 U.S.C. § 4958(c) (2006).

187. *Id.* § 4958(c)(1).

188. *Id.* § 4958(f)(1).

189. See T.D. 9390, 2008-18 I.R.B. 855 (2008).

190. *Id.*

(C) whether the [exempt] organization has been involved in multiple excess benefit transactions with one or more person;

(D) whether the [exempt] organization has implemented safeguards that are reasonably calculated to prevent excess benefit transactions; and

(E) whether the excess benefit transaction has been corrected . . . or the [exempt] organization has made good faith efforts to seek correction from the disqualified person(s) who benefited from the excess benefit transaction.¹⁹¹

All of the foregoing factors will be “considered in combination with each other,” and the IRS “may assign greater or less weight to some factors than to others.”¹⁹²

The finalization of these regulations should serve to re-emphasize the importance to tax exempt organizations of having appropriate safeguards against excess benefit transactions and private inurement. Such safeguards should include an effective Intermediate Sanctions Policy to identify and prevent or correct the occurrence of excess benefit transactions.

C. IRS Interim Report on Hospital Compliance Project

On July 19, 2007, the IRS released an Interim Report on Tax Exempt Hospitals and Community Benefit Projects (IRS Interim Report) that summarized the responses from tax exempt hospitals to a questionnaire distributed by the IRS in May 2006.¹⁹³ That questionnaire was sent to over 500 tax exempt hospitals across the country, and it requested information regarding hospitals’ activities, governance, expenditures, and executive compensation practices.¹⁹⁴ The IRS Interim Report presents data gathered from the responses of 487 hospitals and focuses on how those hospitals provide and report benefits to the community pursuant to the community benefit standard.¹⁹⁵

The IRS Interim Report made three basic findings: (1) nearly all hospitals reported providing various types of community benefit; (2) no uniform definition of uncompensated/charity care emerged from various hospital responses; and (3) “there appear to be significant differences in the way other components of community benefit are reported.”¹⁹⁶ In conjunction with the IRS Interim Report, the IRS’s hospital project team recommended developing a separate Form 990 schedule for hospitals as a vehicle for addressing the lack of definitional and

191. Treas. Reg. § 1.501(c)(3)(ii) (as amended by T.D. 9390, 2008-18 I.R.B. 855).

192. *Id.* § 1.503(c)(3)-1(f)(2)(iii).

193. For a copy of the IRS Interim Report, see I.R.S., HOSPITAL COMPLIANCE PROJECT: INTERIM REPORT (Summary of REPORTED DATA) (2008), available at http://www.irs.gov/pub/irs-tege/eo_interim_hospital_report_072007.pdf.

194. *See generally id.*

195. *Id.* at 1.

196. I.R.S. News Release IR-2007-132 (July 19, 2007).

reporting uniformity.¹⁹⁷ The IRS responded with the new Schedule H, Hospitals, as part of the New Form 990, which was clearly influenced by the preliminary results of the IRS Interim Report.

The IRS issued a final report on the community benefit compliance check in early 2009.¹⁹⁸ The final report is outside the scope of this Survey, but it includes a more in-depth analysis of the responses, including information regarding executive compensation practices, and it provides information based on varying demographics, such as rural and urban communities and hospitals.¹⁹⁹

IV. REIMBURSEMENT & PAYMENT ISSUES

A. *New Provider Reimbursement Review Board Instructions*

On August 8, 2008, the Provider Reimbursement Review Board (Board) provided guidance following the much anticipated changes to the Medicare appeals process by issuing new rules, also referred to as instructions, to comply with new Centers for Medicare and Medicaid (CMS) regulations.²⁰⁰ The instructions outline new requirements under the regulations published by CMS in the *Federal Register* on May 23, 2008.²⁰¹ The new instructions supersede the prior rules and are applicable to all appeals pending as of, or filed on or after, August 21, 2008.²⁰² The Board instructions present additional issues providers must consider when preserving their appeal right before the Board. A brief summary and discussion of the changes to the appeal filing and pre-hearing process affected under the new instructions are discussed below.

1. *Appeal Filing Changes.*—Under the new rules the Board has issued several changes that appear minor in nature but can significantly impact whether the Board will grant jurisdiction to an appeal or whether the Board will consider a document to be timely received. One of the most significant changes was made to the actual Board filing process with respect to date and time of receipt. In order to be deemed timely filed, the previous rules allowed an appeal or document to be accepted by the Board based on the *day of mailing*. Under the new instructions, the filing deadline is now the date of *receipt*.²⁰³ This change

197. *Id.*

198. For a copy of the final report, see I.R.S. IRS EXEMPT ORGANIZATIONS (TE/GE) HOSPITAL COMPLIANCE PROJECT: FINAL REPORT (2009), available at <http://www.irs.gov/pub/irs-tege/frephospproj.pdf>.

199. See generally *id.*

200. PROVIDER REIMBURSEMENT REVIEW BD., CTRS. FOR MEDICARE & MEDICAID SERVS., PROVIDER REIMBURSEMENT REVIEW BOARD RULES (2008), available at <http://www.cms.hhs.gov/PRRBReview/Downloads/PRRRules2008.pdf>.

201. See Provider Reimbursement Determinations and Appeals, 73 Fed. Reg. 30,190 (May 23, 2008) (to be codified at 42 C.F.R. pts. 405, 413, 417). CMS published this Final Rule which outlines the changes to the Provider Reimbursement Review Board appeal process. *Id.*

202. PROVIDER REIMBURSEMENT REVIEW BD., *supra* note 200, at 1.

203. See Provider Reimbursement Determinations and Appeals, 73 Fed. Reg. at 30,192 (to be

is significant as it now places a stricter timeline on filing appeals and other time-sensitive documents to the Board. The effects of the changes are as follows. If an over-night carrier is used for delivery, the date of receipt will be the date as recorded by the carrier.²⁰⁴ If the U.S. Postal Service is used for delivery, the date of receipt is the date the Board's receiving entity enters the filing as "received."²⁰⁵

The new rules also place additional limitations on providers with respect to adding new appeal issues to active appeals already timely filed. Under the previous rules, providers had significant leeway to add new appeals issues at any time prior to the Board hearing. The new instructions change this filing deadline dramatically. Now, if a provider wishes to add a new appeal issue, they must do so within sixty days of the initial 180-day filing deadline.²⁰⁶ This change now gives providers a maximum of 240 days to add new issues to individual appeals. The Board's rationale for this change was based on the growing backlog of cases and concern that providers were intentionally leaving appeals open longer with the hope of capturing new appeal issues to add to the original filing.²⁰⁷ The new instructions significantly limit the addition of issues and now require providers to carefully consider the entirety of potential issues that arise from a final determination as part of their filing strategy.

Other appeal filing considerations relate to certain certifications that must be provided to the Board. In the Board instructions, the Board provides several templates that define specific information and specific statements that must be certified to the Board for either an individual provider or group appeal.²⁰⁸ The new instructions require that the designated representative sign a certification to the Board that the issue requested for appeal is not currently under appeal and that there is no common issue related provider (CIRP) issue.²⁰⁹ Under the CIRP rule, if two or more providers have a common appeal issue—are commonly owned or controlled and have the minimum \$50,000 amount in controversy requirement—the providers must file their appeal as a CIRP group.²¹⁰ While the

codified at 42 C.F.R. § 405.1801(a), (d)); *see also* PROVIDER REIMBURSEMENT REVIEW BD., *supra* note 200, at 2.

204. Provider Reimbursement Determinations and Appeals, 73 Fed. Reg. at 30,192.

205. *Id.*

206. *Id.* For each fiscal year, providers must submit a cost report to a Medicare Administrative Contractor (formerly referred to as a fiscal intermediary) who is responsible for auditing all costs submitted for payment to CMS. *Id.* at 30,191. After the audit is completed each provider is given a notice of program reimbursement (NPR) by their respective MAC which, among other things, outlines any adjustments to payments—often citing overpayments made to the provider. *See id.* If, after reviewing the NPR and adjustments, the provider wishes to appeal the issue, they have 180 days from the receipt of the NPR from which to initiate the appeal or they generally lose their appeal rights for the cost report year. *See id.* at 30,191, 30,203.

207. *Id.* at 30,192.

208. *See* PROVIDER REIMBURSEMENT REVIEW BD., *supra* note 200, at 45-62.

209. *Id.* at 58.

210. *Id.* at 9. Under the Board instructions, in order to initiate an individual appeal, a provider

CIRP rule has not changed in its scope under the new instructions, the Medicare Administrative Contractors (MAC) (formerly fiscal intermediaries) have noted they intend to deny jurisdiction for an appeal to the Board if the CIRP rule is not followed.

Finally, the Board instructions now require a more comprehensive description of the issue under appeal along with supporting documentation.²¹¹ The Board will no longer accept a general statement of an issue when requesting a hearing. Providers, in their initial hearing request, must provide the following information: (1) proof that all jurisdictional requirements have been met; (2) a thorough explanation of the issue under appeal; (3) the rationale for the appeal and underlying assertion as to why the provider believes the Medicare payment is incorrect—including supporting documentation or the provider's notation of the lack of necessary documentation required to accept the final payment determination; (4) an explanation as to how the determination should be determined differently; and (5) for items properly self-disallowed, a full descriptions of the nature of the controversy, the amount of reimbursement sought, and for cost reporting periods ending on or after December 31, 2008, proof that the self-disallowed item was filed under protest in the provider's cost report.²¹²

2. *Pre-hearing Considerations.*—Under the new instructions, the Board has introduced a significant change with the addition of the Joint Scheduling Order (JSO) which has implications for the appeals pre-hearing procedure.²¹³ In the past, the Board established all preliminary and final position paper due dates in addition to overseeing the pre-hearing process between the provider and MAC based on standard timeframes and the appeal filing date.²¹⁴ The Board is now offering two options for providers with respect to the pre-hearing process: (1) the Board will establish a standard timeline for document filing or (2) the parties may now jointly establish the pre-hearing deadlines in a proposed JSO.²¹⁵ The Board believes the JSO option will promote parties to work together to resolve issues more quickly, allow for stipulations, and promote judicial economy.

The JSO now allows parties to negotiate a detailed pre-hearing timeline setting out agreed upon dates for such important items as the filing of position

must have at least \$10,000 in controversy. *Id.* at 5. For a group appeal, the amount in controversy must be \$50,000. *Id.* at 8.

211. PROVIDER REIMBURSEMENT REVIEW BD., *supra* note 200, at 4.

212. *Id.* at 6, 46-63. A provider may self-disallow an item for payment on their cost report when they believe an item should be reimbursed but also are concerned that by requesting the payment from CMS, they would be in violation of a regulation or other legal authority. *Id.* at 6. If the provider maintains there should be a payment, however, they must file the cost report to CMS under protest. *Id.*; see also 42 C.F.R. § 405.1835(a)(1)(ii) (2006) (outlining the filing of a cost report under protest).

213. PROVIDER REIMBURSEMENT REVIEW BD., *supra* note 200, at 17-20; see also 42 C.F.R. § 405.1853 (2006).

214. PROVIDER REIMBURSEMENT BD., *supra* note 200, at 17.

215. *Id.*

papers and the exchange of information.²¹⁶ Under the JSO, the Board will still maintain authority over setting the final position paper due dates and scheduling the date of the hearing.²¹⁷ As part of the JSO request, the parties must identify all issues they agree to, conditionally agree to, and any issues that remain in dispute.²¹⁸ Providers must also provide the Board with expected discovery requests and a timeline for the exchange of information.²¹⁹ When approved, the JSO becomes the timeline that the Board will follow with respect to the pre-hearing procedure. If a provider or MAC fails to follow the negotiated JSO, they jeopardize their appeal rights before the Board.

B. Recovery Audit Contractors

The Recovery Audit Contractor (RAC) Program was instituted by CMS under authorization from the Medicare Modernization Act of 2003²²⁰ and was made permanent under the Tax Relief and Health Care Act of 2006.²²¹ Recovery Audit Contractors are independent organizations that contract with the federal government to audit improper over- and under-payments made to providers through the Medicare program.²²² Congress implemented the RAC Program as a means to support CMS in its efforts to prevent improper payments and safeguard against increased costs.²²³ In 2007, OMB estimated that, of the 1.2 billion claims processed by CMS for that year, improper payments accounted for Medicare costs of \$10.8 billion.²²⁴ The program was initiated under a three-year demonstration project beginning in 2005 that was first piloted in California, New York, and Florida and was eventually implemented in Arizona, Massachusetts, and South Carolina.²²⁵ An overview of the RAC Demonstration Project and implications for the final RAC Program is discussed below.

1. *RAC Demonstration Project, 2005-2008.*—The RAC Demonstration Project began in 2005 and ended on March 27, 2008.²²⁶ The Program was specifically designed to identify and correct past improper CMS payments and provide information to CMS regarding claims error rates that could be used to

216. *Id.* at 17-20.

217. *Id.* at 20.

218. *Id.* at 19-20.

219. *Id.* at 19.

220. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 306, 117 Stat. 2066, 2256-57.

221. Tax Relief and Health Care Act of 2006 § 302, 42 U.S.C. § 1395ddd (2006).

222. *See id.*

223. *See id.* § 1395ddd(a).

224. CTRS. FOR MEDICARE AND MEDICAID, THE MEDICARE RECOVERY AUDIT CONTRACTOR (RAC) PROGRAM: AN EVALUATION OF THE 3-YEAR DEMONSTRATION 1 (2008), available at <http://www.cms.hhs.gov/RAC/Downloads/RAC%20Evaluation%20Report.pdf> [hereinafter RAC PROGRAM].

225. *Id.*

226. *Id.* at 6.

prevent future improper payments.²²⁷ Through a competitive bidding process, three contractors were invited to participate in the RAC Demonstration Project and were divided among the piloted states.²²⁸ The RACs were paid by what has proven to be a controversial method of payment. While most agencies working with CMS are paid through appropriated funds, RACs were paid based on a contingency fee.²²⁹ That is, they were paid a percentage based on the number of improper claims the RACs identified and collected.

Results of the RAC Demonstration paint an interesting picture of what will likely occur once the RAC Program is implemented nationally in 2010.²³⁰ Upon completion of the demonstration on March 27, 2008, the RAC auditors had identified over \$1.03 billion in improper payments—ninety-six percent (\$992.7 million) were recovered overpayments made to providers while only four percent (\$37.8 million) were repaid to providers for underpayment.²³¹ With respect to hospital claims, critical areas that were examined included medical necessity and documentation related to proper coding.²³² Of the hospital overpayment claims reviewed, forty-one percent of all improper claims were due to a medically unnecessary setting, thirty-six percent were due to incorrectly coded claims, and eight percent were due to insufficient documentation.²³³

After the RAC Demonstration project was completed, CMS implemented new guidelines that will become effective with the final program.²³⁴ Key changes include: (1) RACs can only review claims going back to October 1, 2007; (2) all RACs must have a medical director; (3) RACs must have all issues they intend to examine approved by CMS and then must comply with the standards set forth by CMS; (4) RACs must post the issues on their website for providers to review; (5) RACs will only be able to request medical records based on a provider's NPI number for inpatient hospitals the RACs can only obtain ten percent of average monthly Medicare claims (maximum of 200 records) every forty-five days; and (6) RACs cannot review any claim or issue now under investigation or previously reviewed by the OIG.²³⁵

2. *The Implications of the Permanent RAC Program.*—After the RAC

227. *Id.* at 11.

228. *Id.* During the RAC Demonstration, Connolly was the RAC for New York and Massachusetts, HealthDataInsights was the RAC for Florida and South Carolina and PRG-Schultz was the RAC for California and Arizona. *Id.*

229. *Id.*

230. The national implementation is contemplated by the Medicare Modernization Act of 2003. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 306, 117 Stat. 2066, 2256-57.

231. RAC PROGRAM, *supra* note 227, at 2.

232. *Id.* at 56, app. E.

233. *Id.* at 18-19.

234. *See id.* at 25, tbl. 10.

235. *Id.*; *see also* CTRS. FOR MEDICARE AND MEDICAID, RAC MEDICAL RECORD REQUEST LIMITS (2009), available at <http://www.cms.hhs.gov/RAC/Downloads/RAC%20Medical%20Record%20Request%20Limits.pdf>.

Program was halted due to a bidding dispute in November 2008, CMS announced on February 6, 2009, that the final RAC contractors were named.²³⁶ Under the permanent RAC Program the country has been divided into four regions.²³⁷ The following RACs will be paid and are as follows: (1) in Region A, Diversified Collection Services will be the RAC and will be paid a contingency fee of 12.45%; (2) in Region B, CGI Technologies and Solutions will be the RAC and will be paid a fee of 12.50%; (3) in Region C, Connolly Consulting Associates will be the RAC and will be paid a fee of 9.00%; and (4) in Region D HealthDataInsights will be the RAC and will be paid 9.49%.²³⁸ The permanent RAC Program began in March 2009 in some areas of the country and will be nationally ramped up through 2010.

Hospitals and providers throughout the country are in various stages of trying to become RAC-ready. Hospitals have been encouraged to develop a centralized, multi-disciplinary group of healthcare providers and staff who can quickly respond to a RAC inquiry.²³⁹ Although providers in demonstration states have provided insight into how to prepare for a RAC data request, the demonstration project made it clear that providers should understand their rights and obligations and how to properly and quickly respond to a RAC inquiry.²⁴⁰ To begin, providers should know that RACs audit payment claims by one of two methods: (1) by mining claims data provided by to them by CMS and/or (2) by reviewing a sampling of patient charts delivered by the providers to the RAC upon request. If a provider receives a records request, hospitals have forty-five days to respond.²⁴¹ Hospitals can request an extension, but must do so before day forty-five.²⁴² Providers who fail to respond in a timely manner will have their claims denied. RACs have sixty days to review records and within the sixty day period must notify providers of the final determination by letter.

Preserving appeal rights as the result of the RAC audit is another important

236. See Andrea Kraynak, *RAC Protest Resolved: CMS to Continue RAC Program Implementation*, HEALTHLEADERSMEDIA.COM, Feb. 9, 2009, n.p., http://www.healthleadersmedia.com/content/227913/topic/WS_HLM2_FIN/RAC-Protest-Resolved-CMS-to-Continue-RAC-Program-Implementation.html.

237. For a map of these jurisdictions, see Ctrs. for Medicare and Medicaid Servs., *Proposed 2008 RAC Jurisdictions*, <http://www.cms.hhs.gov/RAC/Downloads/Four%20RAC%20Jurisdictions.pdf> (last visited July 6, 2009).

238. FedBizOpps.Gov, *Recovery Audit Contractor (RAC)*, https://www.fbo.gov/index?s=opportunity&mode=form&id=5c8c7d4b00249ba579d4d77d64bd0aea&tab=core&_cview=1&ck=1&au=&ck= (last visited July 6, 2009).

239. See, e.g., Bill Phillips et al., *10 Critical Actions to Minimize RAC Recoupment*, HEALTHLEADERS MEDIA.COM, Feb. 23, 2009, n.p., http://www.healthleadersmedia.com/content/228655/topic/WS_HLM2_FIN/10-Critical-Actions-to-Minimize-RAC-Recoupment.html.

240. See RAC PROGRAM, *supra* note 227, at 29.

241. Ctrs. for Medicare and Medicaid Servs., *Frequently Asked Questions, "How Long Does a Provider Have to Submit Medical Records When Requested by a Recovery Audit Contractor (RAC)?"*, <http://questions.cms.hhs.gov/> (search for question number 7725).

242. *Id.*

consideration. If hospitals are engaged in a RAC review, it is crucial to follow an established timeline to help navigate the required procedural obligations. An abbreviated version of the appeals process with important times is outlined below.

- Pre-Appeal: Providers should notify the RAC as soon as it has verified there is a dispute with the RAC's determination of an overpayment issue;
- Level 1 Review: Appeal to the FI/MAC for redetermination, Provider must file within 120 days of receiving the initial RAC determination letter requesting repayment; the MAC/FI has sixty days to issue determination after the request is made;
- Level 2 Review: Provider has 180 days from the FI/MAC redetermination to file an appeal with a Qualified Independent Contractor (QIC); the QIC has sixty days to issue a determination after the request is made;
- Level 3 Review: If denied by the QIC, the provider must file an appeal within sixty days to an Administrative Law Judge (ALJ). The ALJ has ninety days to issue a ruling;
- Level 4 Review: If denied by the ALJ, the provider must appeal within sixty days to the Medicare Appeals Council for review. The Appeals Council has ninety days to issue a determination;
- Level 5 Review: If denied by the Appeals Council, then the provider must move within sixty days for judicial review in a United States District Court.²⁴³

V. QUALITY

Two extremely important developments which relate to quality of health care include the new Red Flag Regulations as well as a final rule regarding the recognition of new Hospital Acquired Conditions. These developments require providers to be more diligent in the way they deliver care.

A. Red Flag Regulations

On December 4, 2003, President Bush signed the Fair and Accurate Credit Transactions Act (FACTA).²⁴⁴ FACTA was originally enacted to provide greater protection against consumer identity theft and directed six federal agencies to develop methods of detecting consumer identity theft.²⁴⁵ These six agencies

243. See Ctrs. for Medicare and Medicaid Servs., Original Medicare (Parts A and B Fee-For-Service) Appeals Process, <http://www.cms.hhs.gov/OrgMedFFSAppeals/Downloads/AppealsprocessflowchartAB.pdf> (last visited July 6, 2009).

244. See Fair and Accurate Credit Transactions Act of 2003, Pub. L. No. 108-159, 117 Stat. 1952, 2012.

245. See 15 U.S.C. § 1681m(e)(1)(A) & (2)(A) (2006). The six agencies Congress directed to develop guidelines were: (1) the Office of the Comptroller of the Currency, Treasury; (2) the Board of Governors of the Federal Reserve System; (3) the Federal Deposit Insurance Corporation; (4) the Office of Thrift Supervision, Treasury; (5) the National Credit Union Administration; and (6) the Federal Trade Commission. *Id.* § 1681m(2)(1) (listing the first three under the general

jointly promulgated final regulations that were initially to become effective November 1, 2008, but were later delayed and are presently effective as of May 1, 2009 (Red Flag Rules).²⁴⁶ The Red Flag Rules impose obligations on many health care providers to establish programs and greater oversight to prevent consumer identify theft.

The Red Flag Rules require “each financial institution or creditor to develop and implement a written Identity Theft Prevention Program (Program) to detect, prevent, and mitigate identity theft in connection with the opening of certain accounts or certain existing accounts.”²⁴⁷ The Rules define Red Flags as “a pattern, practice, or specific activity that indicates the possible existence of identify theft,” which the aforementioned program should protect against.²⁴⁸ They also provide guidelines “to assist financial institutions and creditors in the formulation and maintenance of [such] a Program that satisfies the requirements of the [rules].”²⁴⁹ Key definitions of the Red Flag Rules bring some health care entities within the rules’ purview. The Rules define “creditor” as “any [entity] who regularly extends, renews, or continues credits; any [entity] who regularly arranges for the extension, renewal, or continuation of credit; or any assignee of an original creditor who participates in the decision to extend, renew, or continue credit.”²⁵⁰ “Credit” is defined as “the right granted by a creditor to a debtor to defer payment of debt or to incur debts and defer its payment or to purchase property or services and defer payment therefore.”²⁵¹ Finally, “covered account” is defined as:

(i) An account that a financial institution or creditor offers or maintains, primarily for personal, family, or household purposes, that involves or is designed to permit multiple payments or transactions, such as a credit card account, mortgage loan, automobile loan, margin account, cell phone account, utility account, checking account, or savings account; and

(ii) Any other account that the financial institution or creditor offers or maintains for which there is a reasonably foreseeable risk to customers or to the safety and soundness of the financial institution or creditor from identity theft, including financial, operational, compliance, reputation, or litigation risks.²⁵²

heading of “Federal banking agencies”).

246. FED. TRADE COMM’N, FTC ENFORCEMENT POLICY: IDENTITY THEFT RED FLAGS RULE, 16 CFR 681.2 (2008), *available at* <http://www.ftc.gov/os/2008/10/081022idtheftredflagsrule.pdf>.

247. Identity Theft Red Flags and Address Discrepancies Under the Fair and Accurate Credit Transactions Act of 2003, 72 Fed. Reg. 63,718, 63,718 (Nov. 9, 2007).

248. 16 C.F.R. § 681.1(b)(9) (2009).

249. *Id.* pt. 681, app. A.

250. *Id.* § 681.1(b)(5) (citing 15 U.S.C. § 1681a(r)(5) (2006)).

251. *Id.* § 681.1(b)(4) (citing 15 U.S.C. § 1681a(r)(5) (2006)).

252. *Id.* § 681.1(b)(3).

In context, the definition of covered account implies a continuing relationship where a consumer receives a service or product that is billed retroactively. The widespread practice among health care institutions to bill for services after those services have been provided and the maintenance of accounts that allow for patients to defer and make multiple payments for these services will likely allow the FTC to characterize health care institutions who maintain these practices as “creditors” who extend “credit” under the Red Flag Rules. Moreover, the FTC may characterize patient accounts as “covered accounts,” as patient accounts are generally accounts maintained for personal and/or family purposes (e.g., health care needs) that are designed to allow multiple payments. Such characterizations will likely trigger the application of the Red Flag Rules to these health care institutions. Moreover, while there has been some speculation as to whether the FTC has jurisdiction over non-profit entities, including nonprofit hospitals, the FTC has taken the position that it will enforce the Red Flag Rules against nonprofit entities.²⁵³

Health care entities that determine they are covered by the Rules, finding they (1) are creditors and (2) have covered accounts, must follow the Red Flag Rules by implementing a Program. Each entity must tailor its Program to protect against the risk of identity theft based on its own operations and circumstances.²⁵⁴ For example, health care institutions covered by the rules would likely develop a Program to address medical identity theft.²⁵⁵ However, each Program must contain reasonable policies and procedures to:

- (i) Identify relevant Red Flags for covered accounts that the . . . [c]reditor officer or maintains, and incorporate those Red Flags into its Program;
- (ii) Detect Red Flags that have been incorporated into the Program of . . . the [c]reditor;
- (iii) Respond appropriately to any Red Flags that are detected . . . to prevent and mitigate identity theft; and
- (iv) Ensure the Program (including the Red Flags determined to be relevant) is updated periodically, to reflect changes in risks to customers and to the safety and soundness of the . . . creditor from identity theft.²⁵⁶

Health care entities implementing an initial Program, addressing all of the

253. Fed. Trade Comm’n, New “Red Flag” Requirements for Financial Institutions and Creditors Will Help Fight Identity Theft (June 2008), *available at* <http://www.ftc.gov/bcp/edu/pubs/business/alerts/alt050.shtm>.

254. 16 C.F.R. § 681.1(d)(1) (2009).

255. Identity Theft Red Flags and Address Discrepancies Under the Fair and Accurate Credit Transactions Act of 2003, 72 Fed. Reg. 63718, 63727 (Nov. 1, 2007).

256. 16 C.F.R. § 681.1(d)(2) (2009).

elements listed above, must receive the approval of the entities' "board of directors or an appropriate committee"; therefore, the Program and the board of directors, committee or "a designated employee at the level of senior management [i.e. compliance officer, risk manager or general counsel]" should be involved "in the oversight, development, implementation and administration of the Program."²⁵⁷ The entities must also train appropriate staff to implement the Program and ensure adequate oversight of its arrangements with service providers.²⁵⁸

The Red Flag Rules Program and oversight requirements will place additional obligations on many health care providers to develop additional policies and procedures to monitor patient accounts for identity theft. Moreover, the rules require more activity, involvement and accountability from governing boards of health care providers in regards to identify theft. Finally, health care providers must monitor their relationships with third parties that provide services to the health care providers and with whom these providers exchange patient account information. Many health care providers may already have in place certain provisions of agreements with third party services providers to protect certain patient information to comply with security and privacy obligations under the Health Insurance Portability and Accountability Act (HIPAA) and regulations that have been promulgated thereto. However, health care providers will have to impose additional oversight mechanisms and impositions on these third party service providers to protect against identity theft as required by the rules.

B. Hospital Acquired Conditions

On August 19, 2008, the Centers for Medicare & Medicaid Services (CMS) issued a final rule regarding additional recognized Hospital Acquired Conditions (HACs) and reportable quality measures.²⁵⁹ The effective date of the final rule is October 1, 2008.²⁶⁰ The final rule implements the HAC payment adjustment provision for all recognized HACs and imposes new reporting requirements for Inpatient Prospective Payment System (IPPS) hospitals who wish to receive the full 2010 payment update.

As part of its continued efforts to promote patient safety and health care quality, as well as support its value-based purchaser model, CMS developed strategies to combat expensive and preventable inpatient complications. In 2005, Congress, in its attempt to reduce the incidence of HACs, authorized CMS to adjust the IPPS to encourage hospitals to prevent medical errors. Legislation required CMS to identify at least two adverse HACs that were: (1) high cost, high volume, or both; (2) assigned to a higher paying diagnosis related group (DRG) when present as a secondary diagnosis; and (3) could reasonably have

257. *Id.* §§ 681.1(e)(1)-(2).

258. *Id.* §§ 681.1(e)(3)-(4).

259. Prospective Payment Systems for Inpatient Hospital Services, 73 Fed. Reg. 48,754 (Aug. 19, 2008) (to be codified at 42 C.F.R. pt. 412)

260. 42 C.F.R. § 412.22(e)(vi) (2008).

been prevented through the application of evidence-based guidelines.²⁶¹

CMS ultimately selected the following HACs for hospitals to report on beginning on October 1, 2007: (1) foreign object retained after surgery; (2) surgical site infection after coronary artery bypass graft surgery; (3) air embolism; (4) blood incompatibility; (5) catheter-associated urinary tract infection; (6) pressure ulcer (stages III and IV); (7) vascular catheter-associated infection; and (8) burns, electric shock, and certain types of falls and traumatic injuries.²⁶²

1. Newly Released HACs and the Payment Adjustment Provision.—Although the proposed rule for the FY 2009 rulemaking period sought comments on numerous HAC candidates, CMS ultimately chose to add two HACs, expand the HAC relating to surgical site infection, and clarify two recognized HACs. Under the final rule, manifestations of poor glycemic control and deep vein thrombosis and pulmonary embolism following total hip or knee replacement were recognized as an HACs.²⁶³ Additionally, the final rule expanded the surgical site infection HAC to include those following certain orthopedic procedures and bariatric surgery for obesity.²⁶⁴ Finally, the final rule refined diagnosis codes to include the payment provision in both the foreign object retention HAC and pressure ulcer HAC.²⁶⁵

The final rule also provided that as of October 1, 2008, any HAC adopted by CMS would only be paid at the higher DRG rate as a secondary diagnosis if it was present on admission.²⁶⁶ This is often referred to by CMS as the HAC payment adjustment provision. This payment adjustment provision allows Medicare to deny payment at the higher DRG rate when a HAC, not present on admission, is later claimed as a secondary diagnosis within the higher paying DRG. As part of this provision, hospitals would be required to report whether the secondary diagnoses were present on admission when submitting their claims.

The payment adjustment provision clearly targets reimbursement by linking payment for health care services to quality of care. Medical record documentation will be invaluable in establishing whether or not a particular condition was present on admission.

2. Expanding Reporting of Hospital Quality Data.—In the final rule, CMS expanded the list of reportable quality measures under the Reporting Hospital Quality Data for Annual Payment Update Program.²⁶⁷ Previously, this program required hospitals to report thirty quality measures on inpatient claims in order

261. Deficit Reduction Act of 2005, S. 1932, 109th Cong. § 5001(c) (2006) (enacted).

262. Medicare Program; Changes to Hospital Inpatient Prospective Payment System and Fiscal Year 2008 Rates, 72 Fed. Reg. 47,130 (Aug. 22, 2007) (to be codified at 42 C.F.R. pt. 411).

263. *Id.* at 47,215.

264. *Id.* at 47,244, 47,261.

265. *Id.* at 48,168.

266. Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, 73 Fed. Reg. 48,433, 48,444 (Aug. 19, 2008) (to be codified at 42 C.F.R. pt. 411).

267. *Id.* at 48,617.

to qualify for a full update to their Medicare payment rates. However, in the final rule, CMS added thirteen new reportable measures to this list and retired a pneumonia measure, bringing the total number of reportable quality measures to forty-two. The thirteen new reportable quality measures include: Surgical Care Improvement Project (SCIP) Measure, Readmission Measure, Nursing Sensitive Measure, Agency for Healthcare Research and Quality (AHRQ) Quality Indicators, and Cardiac Surgery Measure.²⁶⁸

According to the final rule, CMS will reduce the Medicare payment update amount by two percent for any hospital that fails to successfully report quality measures.²⁶⁹ In doing so, CMS has once again directed its enforcement at the bottom line. Hospitals who fail to fully comply with this emphasis on quality, efficiency, and transparency will see their reimbursement decline.

HACs are of great concern to both the public and health care providers. The occurrence of these conditions not only decreases the quality of care but also costs federal health care programs billions of dollars each year. Since paying for HACs is inconsistent with Medicare payment reforms, CMS is increasing financial consequences to encourage providers to reduce their occurrence.

VI. CHANGES TO HOSPITAL CONDITIONS OF PARTICIPATION

A. *Hospital Conditions of Participation Interpretive Guidelines*

On April 11, 2008, the CMS issued a Survey & Certification transmittal (S&C)²⁷⁰ to state survey agencies regarding the revised Medicare Conditions of Participation Interpretive Guidelines (Guidelines) for hospitals. The Guidelines serve as the basis for determining hospital compliance, and the S&C provides an advance copy of amendments to, and an accompanying explanation of, Appendix A of the State Operations Manual.²⁷¹

The new Guidelines correspond to the amended Hospital Conditions of Participation (CoPs) published on November 27, 2006. The Guidelines also reflect changes in the regulations from the 2008 Outpatient Prospective Payment System (OPPS), which became effective January 1, 2008. The Guidelines incorporate previously issued CMS guidance into the SOM for Hospitals.

The revised Guidelines reflect CMS' interpretations of the CoPs which address the following areas: history and physicals (H&Ps), post anesthesia evaluations, verbal orders, security of medications, infection control and

268. *Id.* at 48,609.

269. *Id.* at 48,768.

270. DEP'T OF HEALTH & HUMAN SERVS., HOSPITALS—RESTRAINT/SECLUSION INTERPRETIVE GUIDELINES & UPDATED STATE OPERATIONS MANUAL (SOM) APPENDIX A (2008), available at <http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter08-18.pdf> [hereinafter GUIDELINES].

271. DEP'T OF HEALTH & HUMAN SERVS., STATE OPERATIONS MANUAL (2004), available at <http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1201984&intNumPerPage=10>.

communicable diseases, and patient rights. Most noteworthy are CMS' interpretations and examples of restraints and seclusion, training requirements, and death reporting. Also included are many Guidelines on Medicare discharge appeal rights, informed consent, and medication and pharmacy, including medication management and disclosure requirements for physician-owned hospitals. The Guidelines were immediately upon the publication date.

1. *Restraint and/or Seclusion—Sections 482.13(e)-(g).*—The restraint and seclusion section of the Guidelines is quite expansive and provides numerous examples of what CMS deems a restraint or seclusion.²⁷² CMS also provides information about what constitutes a minimal assessment prior to the initiation of a restraint or seclusion of the patient.²⁷³ CMS states that “[t]he decision to use a restraint or seclusion is not driven by diagnosis, but by a comprehensive individual patient assessment.”²⁷⁴ The Guidelines also provide information regarding the hospital's inappropriate use of weapons, the use of drugs or medications which may or may not be a part of the patient's standard medical treatment, and the type of devices or methods used by practitioners that are not considered restraints.²⁷⁵

The Guidelines address significant details regarding the scope of training, who must be trained, and the qualifications of the trainers prior to use of the restraint or seclusion.²⁷⁶ There is considerable discussion regarding the method and manner of face to face evaluations of the patient.²⁷⁷ All of these requirements must be on file and set forth in the hospital's policies and procedures. The Guidelines dictate that states are free to set requirements by statute or regulation that are more restrictive than the federal regulations so long as they do not conflict with federal requirements. CMS has also included numerous resources for clinicians to provide further guidance.

2. *History and Physical Examinations—Section 482.24(c)(2).*—On November 27, 2006, CMS issued a revised rule requiring that H&Ps be completed no more than thirty days before, or twenty-four hours after, admission for each patient, or prior to a surgery or procedure requiring anesthesia.²⁷⁸ Additionally, an H&P or an update to an H&P, is required prior to surgery and for procedures requiring anesthesia services, regardless of whether care is being provided on an inpatient or outpatient basis.²⁷⁹

The new CoPs expand the permissible professional categories of individuals who may perform an H&P.²⁸⁰ The new rule allows physicians, oral maxillofacial

272. GUIDELINES, *supra* note 276, at 83.

273. *Id.* at 85.

274. *Id.* at 83.

275. *Id.* at 86.

276. *Id.* at 110.

277. *Id.* at 113.

278. Medicare and Medicaid Programs; Hospital Conditions of Participation, 71 Fed. Reg. 68,671, 68,673 (Nov. 27, 2006) (to be codified at 42 C.F.R. pt. 482).

279. *Id.* at 68,674.

280. GUIDELINES, *supra* note 276, at 148.

surgeons, or “other qualified licensed individual[s] in accordance with State law and hospital policy” to perform H&Ps.²⁸¹ The Guidelines interpret such “other qualified practitioners” as including nurse practitioners and physician assistants.²⁸²

The revised CoPs mandate that an H&P performed prior to admission (within at least thirty days before admission) must be updated within twenty-four hours of admission or prior to surgery, whichever comes first.²⁸³ The Guidelines explain that this update must be completed and documented by a licensed practitioner credentialed and privileged by the hospital’s medical staff.²⁸⁴ If the practitioner performing the update finds no change in the patient’s condition since the last H&P was completed, then the practitioner may indicate in the patient’s medical record that the H&P was reviewed, the patient was examined, and may enter “no change” in the patient’s medical record.²⁸⁵ However, if the practitioner finds that an H&P performed prior to admission was incomplete, then the practitioner must conduct and document a new H&P in the medical record within twenty-four hours after admission or registration.²⁸⁶ This must be done prior to the performance of a surgery or procedure requiring anesthesia.²⁸⁷

3. *Authentication of Verbal Orders—Section 482.24(c)(1).*—The CoPs emphasize that hospitals should use verbal orders sparingly, if at all. The Guidelines reiterate that verbal orders must not be a common practice as they increase the risk of miscommunication, which could contribute to error, resulting in an adverse patient event.²⁸⁸ Hospitals are expected to develop appropriate policies and procedures that govern the use of verbal orders and minimize their use.²⁸⁹ If there is no state law that designates a specific timeframe for the authentication of verbal orders, such orders must be authenticated within forty-eight hours.²⁹⁰

All orders, including verbal ones, must be dated, timed, and promptly authenticated by the ordering practitioner.²⁹¹ Verbal orders must be immediately documented in the patient’s medical record and signed by the individual receiving the order.²⁹² CMS expects the nationally accepted “read-back” verification practice to be used for every verbal order.²⁹³ Verbal orders may only be accepted by persons authorized to do so by hospital policy and procedure,

281. *Id.*

282. *Id.* at 149.

283. *Id.* at 150.

284. *Id.*

285. *Id.* at 151.

286. *Id.*

287. *Id.*

288. *Id.* at 166.

289. *Id.*

290. *Id.* at 181.

291. *Id.* at 179.

292. *Id.* at 176.

293. *Id.* at 179.

which must be consistent with federal and state law.²⁹⁴ The receiver of any verbal order must date, time, and sign the verbal order according to hospital policy.²⁹⁵ CMS expects that if verbal orders are received, then the hospital's policy must include a "read-back and verification process[es]."²⁹⁶ Where the ordering practitioner cannot authenticate his or her verbal order, another practitioner who is responsible for the patient's care may authenticate that verbal order.²⁹⁷

4. *Securing Medications—Section 482.25(b)(2)(i).*—Previously, the CoPs required that all drugs and biologicals be kept in a locked storage area.²⁹⁸ Further, all drugs categorized as Schedule II, III, IV, or V were required to be locked in a secure storage area available only to authorized personnel.²⁹⁹ The CoPs now require that all drugs and biologicals be kept in a secure area.³⁰⁰ CMS defines a "secure area" as one that prevents "unmonitored access by unauthorized individuals."³⁰¹ Labor and delivery suites in critical care units staffed twenty-four hours a day are considered secure areas so long as entries and exits are limited to appropriate staff, patients, and visitors.³⁰²

Operating room suites are considered secure only when the areas are staffed and care is being actively provided.³⁰³ The Guidelines go on to state that materials must not be stored in areas that are readily accessible to unauthorized personnel.³⁰⁴ It is also important to note that although the storage of non-controlled drugs and biologicals is a bit more flexible, controlled substances must be kept in locked storage.³⁰⁵ In the event a patient care area is not staffed, hospitals must be sure that both controlled and non-controlled substances are locked up at all times.³⁰⁶ If a hospital uses mobile nursing medication carts, anesthesia carts, epidural carts, or any other type of medication cart that contains controlled substances, all drugs must be locked to prevent unmonitored access.³⁰⁷

When a patient is self-administering his or her medications, hospitals are expected to address this aspect in their policies and procedures to ensure that the medications are secure at the patient's bedside.³⁰⁸

5. *Completion of Post-Anesthesia Evaluation—Section 482.52(b)(3).*—

294. *Id.*

295. *Id.* at 176.

296. *Id.* at 179.

297. *Id.*

298. 42 C.F.R. § 482.25(b)(2)(i) (2008).

299. *Id.* § 482.25(b)(2)(ii).

300. GUIDELINES, *supra* note 276, at 207.

301. *Id.*

302. *Id.*

303. *Id.* at 208.

304. *Id.* at 207.

305. *Id.*

306. *Id.*

307. *Id.* at 208.

308. *Id.*

Under the previous CoPs, only individuals who administered anesthesia could perform post-anesthesia evaluations.³⁰⁹ The revised CoPs now state that post-anesthesia evaluations and documentations may be done by any individual qualified to administer anesthesia.³¹⁰ This revision of the rules grants hospitals and staff much greater flexibility when completing post-anesthesia evaluations. It should also be noted that the new CoPs require post-anesthesia evaluations and documentations be completed within forty-eight hours of surgery.³¹¹

The Guidelines provide greater clarification on the new CoPs regarding post-anesthesia evaluations. CMS requires such an evaluation to be performed any time general, regional, or monitored anesthesia is administered to a patient.³¹² The Guidelines also provide clarification as to the definition of a “practitioner qualified to administer anesthesia,” including in its definition a qualified anesthesiologist, a doctor of medicine or osteopathy, a dentist, and a certified registered nurse anesthetist.³¹³ Anesthesiologist’s assistants may also complete the post-anesthesia evaluation and documentation so long as the anesthesiologist who is supervising the assistant is immediately available.³¹⁴ The Guidelines do not require a post-anesthesia evaluation and documentation to be performed on patients who receive conscious sedation.³¹⁵

B. Revisions to the Hospital Interpretive Guidelines for Infection Control

On November 21, 2007, CMS issued a S&C³¹⁶ to state survey agencies regarding revisions to the Hospital Interpretive Guidelines for Infection Control (Revisions). The Revisions were published in an effort to address the changing infectious disease threats, as well as new mechanisms to confront these threats, that have emerged in recent years.³¹⁷

The Revisions require hospitals “to develop, implement, and maintain an active, hospital-wide program for the prevention, control, and investigation of infections and communicable diseases.”³¹⁸ The program must “be conducted in accordance with nationally recognized infection control practices or guidelines, as well as applicable regulations of other federal or state agencies.”³¹⁹ Furthermore, the program must contain a surveillance component to identify

309. 42 C.F.R. § 482.52(b)(3) (2008).

310. GUIDELINES, *supra* note 276, at 321.

311. *Id.*

312. *Id.* at 322.

313. *Id.*

314. *Id.*

315. *Id.*

316. DEP’T OF HEALTH & HUMAN SERVS., REVISIONS TO THE HOSPITAL INTERPRETIVE GUIDELINES FOR INFECTION CONTROL (2007), *available at* <http://www.cms.hhs.gov/Survey/CertificationGenInfo/downloads/SCLetter08-04.pdf> [hereinafter REVISIONS].

317. *Id.* at 1.

318. *Id.* at 3.

319. *Id.*

infectious risks or communicable disease problems at any particular location within the hospital.³²⁰ The Revisions delineate the obligations of the hospital-appointed infection control officer and the protocols with which he or she must comply.³²¹ The Revisions also discuss the responsibilities of the Chief Executive Officer, Medical Staff, and Director of Nursing Services with regard to infection control.³²²

C. Enforcement of Requirements for Certain Hospital and Critical Access Hospital (CAH) Disclosures to Patients

On December 14, 2007, CMS issued a S&C³²³ to state survey agencies regarding the enforcement of disclosure requirements for certain hospitals and critical access hospitals (CAHs). This memorandum discusses patient disclosure obligations for physician-owned hospitals and CAHs.³²⁴ Under the final rule governing the hospital inpatient prospective payment system, all physician-owned hospitals and CAHs must provide written notice to a patient at the beginning of stay or visit that the hospital or CAH is physician-owned.³²⁵ The purpose of this rule is to enable patients to make an informed decision about his or her care. The notice must be made in a manner reasonably understood by all patients.³²⁶

The final rule amends 42 C.F.R. section 489.12 to enable CMS “to deny a provider agreement to a hospital or CAH applicant that does not have procedures in place to notify patients of physician ownership in the hospital.”³²⁷ Furthermore, CMS may terminate a provider agreement that does not comply with the new disclosure requirements.³²⁸ “Enforcement of the mandatory disclosure requirements is linked to the Patients’ Rights CoP for hospitals and the compliance with Federal, State and local laws and regulations CoP for CAHs.”³²⁹ Compliance with the disclosure requirements will be assessed when the hospital is surveyed for compliance.³³⁰

320. *Id.* at 4.

321. *Id.* at 7-13.

322. *Id.* at 13.

323. DEP’T OF HEALTH & HUMAN SERVS., ENFORCEMENT OF REQUIREMENTS FOR CERTAIN HOSPITALS AND CRITICAL ACCESS HOSPITALS (CAH) DISCLOSURES TO PATIENTS (2007), available at <http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter08-07.pdf> [hereinafter REQUIREMENTS].

324. *Id.* at 1.

325. *Id.*

326. *Id.*

327. *Id.* at 2.

328. *Id.*

329. *Id.*

330. *Id.* at 3.

VII. CHANGES TO HOSPICE CONDITIONS OF PARTICIPATION

On June 5, 2008, CMS issued a final rule revising the Hospice CoPs, which all hospices are required to meet to participate in the Medicare and Medicaid programs.³³¹ Effective December 2, 2008, the final rule addresses the comments received by CMS on the proposed rule published in 2005.³³² The revised CoPs are a flexible framework for continuous quality improvement in hospice care and reflect current standards of practice. Further, the CoPs focus on a patient-centered, outcome-oriented, and transparent process that promotes quality patient care while allowing for flexibility in meeting quality standards.³³³ The final rule marks CMS' first overhaul of regulations governing the hospice industry since 1983.³³⁴ These CoPs address patient rights and quality of care, as well as the relationship between hospices and the nursing facilities to whose patients they provide services.³³⁵

While many hospice patients are already active in their own treatment plans, this regulation is the first to set out a detailed list of patient rights. Specifically, the rule says that patients who choose hospice, or palliative care, over curative treatment are entitled to such things as participation in the development of his or her plan of care, the right to effective pain management, and the right to choose his or her attending physician.³³⁶

In addition to the patient rights' section, the CoPs created measures for the quality of care of hospice patients. For example, the CoPs require hospices to implement "an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement [(QAPI)] program."³³⁷ The CoPs allow hospices to develop their own QAPI program to cater to their own goals and needs instead of mandating a particular mechanism to implement this program.³³⁸ Furthermore, the CoPs require a comprehensive assessment to take place.³³⁹

Additionally, the CoPs create other quality measures, such as a requirement that patient needs be initially assessed within 48 hours of electing the hospice benefit.³⁴⁰ The rule also requires that a comprehensive assessment occur within five days of electing the hospice and that updated assessments be conducted at least every fifteen days thereafter.³⁴¹ Further, the CoPs create a requirement that

331. Medicare and Medicaid Programs: Hospice Conditions of Participation, 73 Fed. Reg. 32,087 (June 5, 2008) (to be codified at 42 C.F.R. pt. 418).

332. *Id.* at 32,088.

333. *Id.*

334. *Id.*

335. *Id.*

336. *See* 42 C.F.R. § 418.52 (2008).

337. *Id.* § 418.58.

338. Medicare and Medicaid Programs: Hospice Conditions of Participation, 73 Fed. Reg. at 32,118.

339. 42 C.F.R. § 418.54(c) (2008).

340. *Id.* § 418.54(a).

341. *Id.* § 418.54(d).

each patient receive a full drug profile that examines issues ranging from the effectiveness of current drug therapies to potential drug interactions to drug side effects.³⁴² A treatment team will consult with a qualified individual, such as a pharmacist, to ensure that drugs meet the needs of every hospice patient.³⁴³ Moreover, the CoPs recommend the use of a patient-centered interdisciplinary approach that recognizes the contributions of various skilled professionals and other support personnel and their interaction with each other to meet the patients' needs.³⁴⁴

The CoPs also establish certain requirements for relationships among hospices. For instance, the CoPs allow a hospice to contract with another Medicare-certified hospice for nursing, medical, social services, and counseling services under extraordinary or other non-routine circumstances, including travel of a patient outside of the hospice's service area.³⁴⁵ Moreover, the new CoPs remove a previous provision which required an inpatient facility only providing respite care to have a registered nurse on duty twenty-four hours a day.³⁴⁶ Instead, the patients' needs, acuity, and plan of care will drive the nursing and staffing requirements.

Finally, CMS created requirements for hospices with respect to their relationships with nursing facilities. Because a hospice's access to nursing facility patients is directly dependent on the nursing facility's operator, CMS created several additional requirements in an effort to reduce the potential for fraud and abuse. The CoPs require that a written agreement must be in place between a nursing facility and hospice if the hospice provides services in the facility.³⁴⁷ Furthermore, the CoP lists the minimum requirements for such agreements.³⁴⁸

Instead of ensuring quality through a problem-oriented, after-the-fact corrective approach of quality assurance, the CoPs suggest a shift towards a more quality-conscious, preemptive approach to hospice care. This approach will require hospice administrators to review current operating policies and procedures and create agreements with nursing facilities to ensure compliance.

342. *Id.* § 418.54(c)(b).

343. Medicare and Medicaid Programs: Hospice Conditions of Participation, 73 Fed. Reg. at 32,095.

344. *Id.* at 32,088.

345. *Id.* at 32,123; *see also* 42 C.F.R. § 418.64 (2008).

346. Medicare and Medicaid Programs: Hospice Conditions of Participation, 73 Fed. Reg. at 32,134.

347. *Id.* at 32,216; *see also* 42 C.F.R. § 418.112 (2008).

348. Medicare and Medicaid Programs: Hospice Conditions of Participation, 73 Fed. Reg. at 32,216.

VIII. ANTITRUST

A. *Clinical Integration*

In September of 2007, the FTC issued an advisory opinion informing the Greater Rochester Independent Practice Association, Inc. (GRIPA) that it would not challenge the organization's proposed operation as a non-exclusive physician network joint venture. The FTC found that the proposed program would involve substantial integration among its physician participants that had the potential to produce significant efficiencies in the provision of medical services, and that the joint contracting with payors on behalf of the GRIPA's physicians was subordinate and reasonably necessary.³⁴⁹

GRIPA is the fourth in a series of advisory opinions issued by the FTC focusing on clinical integration since clinical integration's first description in the FTC's 1996 *Statements of Antitrust Enforcement Policy in Health Care*.³⁵⁰ In each subsequent opinion, the FTC continues to refine its guidance on the types of programs it considers sufficiently integrated to stave off an antitrust challenge.

In GRIPA, the FTC found that joint contracting was ancillary to the efficiency enhancing purpose of the program.³⁵¹ In reviewing the program, the FTC noted certain key program provisions. Although one of the goals of the program was to increase physician reimbursement, it did so not through market power, but rather through improved quality and more cost-effective utilization. Also, the FTC noted with approval the investment of both time and money that the physicians would be required to undertake in the clinical integration program, including: collaborative development of practice guidelines, coordinated delivery of medical care, and sharing of treatment information through a clinical information system.³⁵² At the end of the day, the FTC concluded that the proposed program was unlikely to have anticompetitive effects or allow GRIPA to exercise market power.³⁵³

Clinical integration continues to be on the FTC's radar screen and will continue to raise antitrust issues. It is becoming clear that multi-specialty programs with strong clinical management, robust outcomes measurement, and significant physician interdependence can generate sufficient efficiencies to overcome the risk of antitrust challenge. Look for the FTC to continue to refine its guidance on clinical integration in the foreseeable future.³⁵⁴

349. FED. TRADE COMM'N, GREATER ROCHESTER INDEP. PRACTICE ASS'N, INC., ADVISORY OPINION 1 (Sept. 17, 2007), available at <http://www.ftc.gov/bc/adops/gripa.pdf> [hereinafter GRIPA].

350. U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE (1996), available at <http://www.usdoj.gov/atr/public/guidelines/1791.htm>.

351. GRIPA, *supra* note 355, at 1.

352. *Id.*

353. *Id.*

354. See FED. TRADE COMM'N TRISTATE HEALTH PARTNERS, INC., ADVISORY OPINION 1 (Apr.

B. Cascade Health Solutions v. PeaceHealth

In *Cascade Health Solutions v. PeaceHealth*³⁵⁵ the Ninth Circuit found that the exclusionary conduct element of a claim, arising under section 2 of the Sherman Act, against a defendant with monopoly power, over one or more of the bundled products, cannot be satisfied by reference to bundled discounts unless the discounts result in prices that are below an appropriate measure of the defendant's costs.³⁵⁶

PeaceHealth and McKenzie-Williamette Hospital (Cascade)³⁵⁷ were the only two hospital care providers in Lane County, Oregon. PeaceHealth operated three hospitals with a total of 464 beds, offering primary, secondary, and tertiary care. Cascade operated one hospital with 114 beds, which provided only primary and secondary care.³⁵⁸ In what Cascade alleged as unlawful monopolization, attempted monopolization, conspiracy to monopolize, tying, exclusive dealing, and violations of state law, PeaceHealth offered insurers discounts of thirty-five to forty percent on tertiary services if the insurers made PeaceHealth their sole preferred provider for *all* services—primary, secondary, and tertiary.³⁵⁹ In essence, PeaceHealth bundled its services, including its tertiary services, which Cascade did not provide to offer bigger discounts across the board in order to obtain an exclusive contract. Because Cascade did not provide tertiary services, it could not match the aggregate savings payors enjoyed under an exclusive contract with PeaceHealth. Thus, the issue became whether the bundled discount amounted to predatory conduct because Cascade was effectively foreclosed from at least one key payor contract.

Consumers are faced with bundled discounts on a daily basis.³⁶⁰ Sometimes bundled discounts are good for consumers because they offer products at lower prices. But sometimes bundled discounts can lead to anti-competitive behavior—offering lower prices to monopolize the market leading to higher

13, 2009), available at <http://www.ftc.gov/os/closings/staff/090413tristatealetter.pdf>.

355. 515 F.3d 883 (9th Cir. 2008).

356. *Id.* at 903; *cf.* *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 222, 224 (1993) (requiring that a plaintiff prove that defendant's price was below cost and that defendant had a reasonable probability of recouping its investment in below cost prices); *LePage's, Inc. v. 3M*, 324 F.3d 141, 154 (3d Cir. 2003) (en banc) (foregoing cost analysis with respect to defendants with monopoly power, and concluding that all bundled discounts offered by a monopolist are anticompetitive with respect to sellers that do not offer an equally diverse product line), *cert. denied*, 542 U.S. 953 (2004).

357. As a result of a merger with Triad Hospital, Inc., McKenzie's name changed to Cascade Health Solutions. *Cascade*, 515 F.3d at 891.

358. *Id.* "Primary and secondary acute care hospital services are common medical services like setting a broken bone and performing a tonsillectomy '[T]ertiary care' . . . includes more complex services like invasive cardiovascular surgery and intensive neonatal care." *Id.*

359. *Id.* at 892.

360. *See id.* at 894.

prices in the future.³⁶¹ In *Cascade* the Ninth Circuit tried to determine when bundled discounts are “good” and when they are “bad.”

The Ninth Circuit adopted a discount allocation standard that allocates the full amount of the discounts given by the defendant on the bundle to the competitive product or products.³⁶² In other words, the court reallocated the discount amount offered by PeaceHealth for tertiary services to PeaceHealth’s primary and secondary services as if payors paid full charges on tertiary services and discounted amount on primary and secondary services. The court concluded that if the resulting price of the competitive product, or products, is below the defendant’s incremental cost to produce them, the trier of fact may find that the bundled discount is exclusionary for the purpose of section 2.³⁶³ This standard allows a defendant to offer bundled discounts unless the discounts would exclude an equally efficient producer of the product. The Ninth Circuit championed that the discount attribution standard provides clear guidance for sellers that engage in bundled discounting, because a seller can easily ascertain its own price and costs of production and calculate whether its discounting practices run afoul of the standard.³⁶⁴

In adopting the discount allocation standard, the Ninth Circuit rejected the standard set forth in *LePage’s Inc. v. 3M*, thereby creating a split among the circuits over the appropriate legal standard for evaluating bundled discounting practices.³⁶⁵ Because the *LePage’s* standard could insulate a less efficient rival from legitimate competition at the expense of consumer welfare, a discount reallocation methodology should be favored. However, in the health care industry and other industries where seller list prices have little relevance to negotiated rates, a methodology that reallocates the *incremental* discount offered for the bundled products or services should be adopted.

IX. LABOR & EMPLOYMENT

A. *Indiana Case Law Update: Enforceability of Physician Noncompetes*

On March 11, 2008, the Indiana Supreme Court ruled on its first physician covenant not to compete case in nearly twenty-five years.³⁶⁶ The decision will likely impact the enforceability of many existing noncompetition agreements.

From 1996 through 2005, Dr. Kenneth Krueger, a podiatrist, worked with

361. As noted in *Cascade*, “it is possible, at least in theory, for a firm to use a bundled discount to exclude an equally or more efficient competitor and thereby reduce consumer welfare in the long run.” *Id.* at 896 (citing RICHARD A. POSNER, *ANTITRUST LAW* 236 (2d ed. 2001)).

362. *Id.* at 906.

363. *Id.*

364. *Id.* at 907.

365. *Id.* at 903.

366. *Cent. Ind. Podiatry, P.C. v. Krueger*, 882 N.E.2d 723 (Ind. 2008). Prior to *Central Indiana Podiatry*, the last physician noncompete case the court ruled on was *Raymundo v. Hammond Clinic Ass’n*, 449 N.E.2d 276 (Ind. 1983).

Central Indiana Podiatry, P.C. (CIP), which maintains offices in counties throughout central Indiana.³⁶⁷ Krueger had worked at CIP offices in Clinton, Marion, Howard, Tippecanoe, and Hamilton counties.³⁶⁸ But, in the last two years of his employment he only split his time at offices in Marion, Tippecanoe, and Howard counties.³⁶⁹ CIP and Krueger had an employment agreement including a noncompete that prohibited Krueger from practicing podiatry for two years in an area defined as fourteen listed central Indiana counties where CIP maintained offices and all counties adjacent thereto, essentially the middle half of the state of Indiana.³⁷⁰ On July 25, 2005, CIP terminated Krueger and in September 2005, Krueger entered into an agreement with Meridian Health Group, P.C. (Meridian) and began practicing podiatry in Hamilton County, Indiana, about ten minutes away from the Indianapolis office at which he had been working with CIP.³⁷¹ Krueger provided Meridian with a copy of the CIP patient list and created a letter to be mailed to patients which stated his new employment was within ten minutes of his previous office.³⁷²

When CIP learned of the letter, it sought injunctive relief against Krueger and damages from Krueger and Meridian on the basis that Krueger's employment violated the geographic restriction of the noncompete.³⁷³ The trial court found that the geographic restriction was unenforceable and denied CIP's request for injunctive relief.³⁷⁴ The court of appeals disagreed and reversed the trial court.³⁷⁵ The Indiana Supreme Court addressed the issue and ultimately ruled the covenant was only enforceable in Marion, Tippecanoe, and Howard counties, affirming the trial court's decision that it was unenforceable elsewhere, particularly as to Hamilton County where Krueger was competing.³⁷⁶

The court began its opinion by reconsidering whether physicians should be able to enter into noncompetition agreements at all, given the nature of the physician-patient relationship.³⁷⁷ The court first addressed this argument in 1983 in *Raymundo v. Hammond Clinic Ass'n*,³⁷⁸ holding that physician noncompetes were not void because of such concerns.³⁷⁹ This conclusion is consistent with the vast majority of other U.S. jurisdictions allowing noncompetes with reasonable

367. *Cent. Ind. Podiatry*, 882 N.E.2d at 725-26.

368. *Id.* at 726.

369. *Id.*

370. *Id.* at 725-26.

371. *Id.* at 726.

372. *Id.*

373. *Id.*

374. *Id.*

375. *Id.* (citing *Cent. Ind. Podiatry, P.C. v. Krueger*, 859 N.E.2d 686, 689 (Ind. Ct. App. 2007), *trans. granted*, 882 N.E.2d 723 (Ind. 2008)).

376. *Id.* at 731.

377. *Id.* at 727-28.

378. 449 N.E.2d 276 (Ind. 1983).

379. *Cent. Ind. Podiatry*, 882 N.E.2d at 728 (citing *Raymundo*, 449 N.E.2d at 280-81).

restrictions.³⁸⁰ The court observed that noncompetes with physicians are different from noncompetes in other business settings where typically only the employer and employee are impacted by enforcement of the noncompete.³⁸¹ Patients are impacted more by physician noncompetes than the average business consumer.³⁸² Patients often seek out particular physicians, and noncompetes may impair patient choice and confidence.³⁸³ The court determined that those concerns require physician noncompetes to be given “particularly careful scrutiny,” even beyond the disfavor with which all noncompetes are viewed.³⁸⁴ But, the court upheld its earlier ruling that physician noncompetes are not void due to those public policy concerns, noting that any contrary decision is better left to the state legislature.³⁸⁵

The court then examined the reasonableness of Krueger’s noncompete covenant.³⁸⁶ In order for a noncompete to be enforceable, it must be reasonable.³⁸⁷ An employer seeking to enforce a noncompete “must first show that it has a legitimate interest to be protected by the agreement.”³⁸⁸ Then, the employer also must show the noncompete is reasonable in its scope “as to time, activity and geographic area restricted.”³⁸⁹ The court found that CIP demonstrated a legitimate interest in preserving patient relationships developed with CIP resources.³⁹⁰ However, it found the geographic scope of the noncompete to be unreasonable because Krueger had not actually used CIP resources to develop patient relationships outside of the areas served by the particular locations at which he had worked in the last two years of his employment.³⁹¹ The Court refused to enforce the noncompete outside areas in which Krueger himself developed patient relationships, even though the CIP had other offices throughout the area covered by the noncompete.³⁹²

As a result of finding the covenant unreasonable, the court then looked to whether any of it could be saved by striking the unreasonable portions from the agreement under what is known as the “blue-pencil” doctrine.³⁹³ Since the

380. *Id.* (citing Ferdinand S. Tinio, Annotation, *Validity and Construction of Contractual Restrictions on Right of Medical Practitioner to Practice, Incident to Employment Agreement*, 62 A.L.R. 3d 1014 §§ 6-25 (1975)).

381. *Id.* at 727.

382. *Id.*

383. *Id.*

384. *Id.* at 729.

385. *Id.* at 728.

386. *Id.* at 728-31.

387. *Id.* at 729 (citing *Raymundo v. Hammond Clinic Ass’n*, 449 N.E.2d 276, 280 (Ind. 1983)).

388. *Id.* (citing *Sharvelle v. Magnante*, 836 N.E.2d 432, 436-37 (Ind. Ct. App. 2005)).

389. *Id.* (citing *Sharvelle*, 836 N.E.2d at 436).

390. *Id.*

391. *Id.* at 730-31.

392. *Id.* at 730.

393. *Id.* (citing *Dicen v. New SESCO, Inc.*, 839 N.E.2d 684, 687 (Ind. 2005)).

Agreement specifically listed particular counties by name, the court was able to strike all of them, except for Marion, Tippecanoe, and Howard counties to create a reasonable and enforceable restriction.³⁹⁴ The court also found it necessary to strike the language extending the noncompete to adjacent, or contiguous, counties.³⁹⁵ The court reasoned that even though Krueger may have developed patient relationships that crossed county lines, there was no evidence to suggest that there was a substantial number of patients developed in all contiguous counties or at their furthest reaches.³⁹⁶ As the non-compete used entire counties as its measure of the restriction, the court deleted entire contiguous counties from its scope, thereby permitting Krueger to compete in Hamilton county, a mere ten minutes away from his former practice.³⁹⁷

B. Federal Statutory Changes

1. *FMLA Update.*—The National Defense Authorization Act for Fiscal Year 2008 was signed on January 28, 2008.³⁹⁸ This Act includes amendments to the Family and Medical Leave Act (FMLA),³⁹⁹ which provide additional leave benefits to eligible relatives of military service members under two circumstances, “Servicemember Family Leave” and “Qualifying Exigency.”⁴⁰⁰

The first amendment to the FMLA provides an eligible employee a total of twelve weeks of leave during a twelve month period because of any qualifying exigency arising out of the fact that the spouse, son, daughter, or parent of the employee is on active duty or has been notified of an impending call or order to active duty.⁴⁰¹ If foreseeable, an employee requesting leave due to a qualifying exigency must provide reasonable notice.⁴⁰² Under the second amendment, an eligible employee who is the spouse, son, daughter, parent, or next of kin of a covered servicemember is entitled to a total of twenty-six weeks of unpaid leave to care for that servicemember.⁴⁰³ Covered servicemembers include those undergoing medical treatment, recuperation, or therapy, are otherwise in outpatient status, or are on the temporary disability retired list for a serious injury

394. *Id.* at 731.

395. *Id.*

396. *Id.* at 730-31.

397. *Id.* at 731.

398. National Defense Authorization Act for Fiscal Year 2008, Pub. L. No. 110-181, 122 Stat. 3 (2008).

399. 29 U.S.C. §§ 2601-2654 (2006).

400. On February 11, 2008, the U.S. Department of Labor published additional proposed regulations to significantly modify the FMLA. *See* 29 C.F.R. § 825 (2008). The final regulations became effective January 16, 2009 and included substantive changes and clarifications to the FMLA which are outside the timeframe of this article.

401. 29 U.S.C. § 2611.

402. *Id.*

403. *Id.*

or illness.⁴⁰⁴ This leave is available during a single twelve month period.⁴⁰⁵ Employers may require that eligible employees substitute paid leave for leave taken pursuant to either of the amended FMLA provisions.⁴⁰⁶

2. *Genetic Information Nondiscrimination Act.*—On May 21, 2008, President Bush signed into law the Genetic Information Nondiscrimination Act (GINA) of 2008.⁴⁰⁷ GINA bars health insurers and employers from discriminating against individuals or individual's family members based on their genetic information.⁴⁰⁸ Under GINA, genetic information is broadly defined as an individual's genetic tests, the genetic tests of family members, or the manifestation of a disease or disorder in the individual's family members.⁴⁰⁹ The expectation is that GINA will enable individuals to take advantage of genetic testing, technology, research, and new therapies without fear of retaliation from health insurers or employers.

As it relates to health insurers, GINA amends several federal laws, including the Employee Retirement Income Security Act of 1974 (ERISA), the Public Health Service Act, the Internal Revenue Code of 1986, the Social Security Act, and the Health Insurance Portability and Accountability Act (HIPAA) to include anti-discrimination provisions.⁴¹⁰ GINA prohibits health insurers from adjusting premium amounts or establishing distinct eligibility rules based on genetic information. It also prohibits requesting or requiring genetic tests, or requesting, requiring, or purchasing genetic information for underwriting or enrollment purposes.⁴¹¹ These restrictions apply to insurers of group health plans, individual market plans, government plans, and Medicare supplemental policies.⁴¹²

As it relates to employment, GINA covers employers, employment agencies, labor organizations, and joint-labor management committees.⁴¹³ GINA carves out the actions employers may take with an applicant or employee's genetic information, as well as how employers should maintain this sensitive information. Unlawful employment actions under GINA include: (1) using genetic information such as family history of a hereditary disease, to make hiring, firing, or other employment decisions that affect the compensation, terms, conditions, or privileges of employment;⁴¹⁴ (2) limiting, segregating, or classifying employees because of genetic information in any way that would deprive employees of employment opportunities or otherwise adversely affect

404. *Id.*

405. *Id.*

406. *Id.*

407. 42 U.S.C. § 2000ff (2006).

408. *Id.* § 2000ff-1(a).

409. *Id.* § 2000ff-4.

410. *Id.* § 2000ff-5.

411. *Id.*

412. *Id.*

413. *Id.* §§ 2000ff-1 to -3.

414. *Id.* § 2000ff-1.

employment status;⁴¹⁵ (3) requesting, requiring or purchasing an employee's or an employee's family member's genetic information, absent one of the prescribed exceptions;⁴¹⁶ or (4) except under certain conditions,⁴¹⁷ disclosing an applicant's or an employee's genetic information.⁴¹⁸ Regarding employment discrimination, GINA is effective November 21, 2009 and will be enforced by the Equal Opportunity Commission (EEOC).⁴¹⁹ The EEOC proposed regulations on March 2, 2009 to carry out GINA's employment-related provisions.⁴²⁰ The final regulations must be enacted by May 21, 2009.

3. *ADA Amendments Act.*—On September 25, 2008, the ADA Amendments Act of 2008 (Act) was passed and became effective January 1, 2009.⁴²¹ Most significantly, this Act amended the Americans with Disabilities Act of 1990 (ADA).⁴²² An individual is disabled under the ADA if the individual has “a physical or mental impairment that substantially limits one or more major life activities,” has a record of such impairment, or is regarded as having such an impairment.⁴²³ The Act was primarily aimed at reversing some significant U.S. Supreme Court interpretations of the ADA within the last decade, specifically regarding who is “disabled,” and therefore, protected under the ADA.⁴²⁴ Despite

415. *Id.*

416. *Id.* There are several exceptions to this prohibition, including where: (1) an employee provides prior written authorization; (2) genetic services are offered by the employer; (3) the information is inadvertently acquired; (4) the information is obtained for compliance with certification requirements of Family and Medical Leave laws; (5) the information is used for genetic monitoring of the biological effects of toxic substances in the workplace under limited conditions; or (6) the information is required for an employer's forensic laboratory's DNA analysis for law enforcement or human remains identification purposes. *Id.* Also, an employer's acquisition of genetic information through the purchase of public materials such as newspapers or magazines is not unlawful. *Id.*

417. *Id.* § 2000ff-5. Disclosing information is allowed under certain conditions. For example: (1) to an employee upon written request; (2) to an occupational or other health researcher; (3) by court order; (4) to a government official investigating compliance with GINA if the information is relevant to the investigation; (5) in connection with an employee's compliance with FMLA certification provisions; (6) or to a public health agency where the manifestation of a disease or disorder concerns a contagious disease that presents an imminent hazard of death or life-threatening illness. *Id.*

418. *Id.* § 2000ff(2)(A)(i).

419. *Id.* § 2000ff-6.

420. Regulations Under the Genetic Information Nondiscrimination Act of 2008, 74 Fed. Reg. 9056 (proposed Mar. 2, 2009) (to be codified at 29 C.F.R. pt. 1635).

421. ADA Amendments Act of 2008, Pub. L. No. 110-325, 122 Stat. 3553 (2008).

422. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (1990).

423. 42 U.S.C. § 12102 (2006).

424. *Id.* § 12101. The holding of the Supreme Court in *Sutton v. United Air Lines, Inc.*, 527 U.S. 471 (1999), *superseded by statute*, ADA Amendments Act of 2008, Pub. L. No. 110-325, 122 Stat. 3553, and its companion cases narrowed the broad scope of protection intended to be afforded by the ADA, thus eliminating from ADA protection many individuals whom Congress intended to

the intended broad coverage of the ADA, Congress found that courts incorrectly narrowed the definition of disability and scope of protection under the ADA.⁴²⁵

As a result, the Act made several changes. Highlights of the Act include: (1) construing disability in favor of broad coverage;⁴²⁶ (2) setting forth specific major life activities and the types of bodily functions that are covered under the law;⁴²⁷ (3) broadening protection afforded to individuals who are not actually disabled, but are “regarded as” being disabled, by clarifying that individuals who are “regarded as” having an impairment are protected under the Act regardless of whether the impairment limits, or is perceived to limit, a major life activity;⁴²⁸ (4) declaring that the ameliorative effects of mitigating measures, except for ordinary eyeglasses and contact lenses, should not be considered in determining if individuals are disabled;⁴²⁹ (5) indicating that impairments which are episodic or in remission are still covered under the ADA if, when active, the impairment would substantially limit a major life activity;⁴³⁰ (6) clarifying that reasonable accommodation is not required for individuals who are only regarded as being disabled;⁴³¹ and (7) stating that individuals cannot be regarded as disabled for only having an impairment that is minor and lasts for six months or less, unless impairments that are episodic or in remission.⁴³²

X. INDIANA LEGISLATIVE UPDATE

A. *House Enrolled Act 1001: State Assumption of HCI Levy*

Property tax reform was one of the primary issues of concern during the 2008 Indiana legislative session after many Indiana residents saw significant increases in their property taxes months before the session began.⁴³³ To relieve local property tax burdens, the Indiana State government elected to assume responsibility for the hospital care for the indigent fund, which was traditionally funded by a local hospital care for the indigent tax. The State also decided to provide a certain level of funding to the Health & Hospital Corporation of

protect. The scope of the ADA was further narrowed by the Supreme Court in *Toyota Motor Manufacturing Kentucky, Inc. v. Williams*, 534 U.S. 184 (2002), *superseded by statute*, ADA Amendments Act of 2008, Pub. L. No. 110-325, 122 Stat. 3553. As a result, lower courts incorrectly found in individual cases that people with a range of substantially limiting impairments were not disabled under the ADA.

425. 42 U.S.C. § 12101.

426. *Id.* § 12102.

427. *Id.*

428. *Id.*

429. *Id.*

430. *Id.*

431. *Id.* § 12201.

432. *Id.* § 12102.

433. Larry DaBoer, *The Impact of Property Tax Legislation on Indiana Households*, 83 IND. BUS. REV., Spring 2008, at 1, 5.

Marion County, which had also historically been funded by local taxes. These changes provided local tax relief while preserving funding for health care to the indigent.

Since 1986, each county has levied a local tax on its residents to fund the county hospital care for the indigent fund. Proceeds from the taxes and the fund were used to reimburse certain qualified hospitals for uncompensated care they provided to a county's indigent residents. House Bill 1001, which was subsequently enacted in House Enrolled Act 1001 (HEA 1001), implemented comprehensive property tax reform and provides that the state government is responsible for adequate funding for the new state hospital care for the indigent fund.⁴³⁴ The legislation effectively eliminates the local tax that had, since 1986, funded indigent health care and shifts the burden of paying these costs to the state. Further, HEA 1001 amends the Indiana Code to require the State of Indiana to provide \$40 million to fund the Health & Hospital Corporation of Marion County, which operates Wishard Memorial Hospital and provides a substantial amount of indigent care.⁴³⁵ The changes set forth in HEA 1001, while alleviating local tax burdens, also preserve important funding streams to hospitals so that they may continue to provide care to the indigent population of Indiana.

B. Senate Enrolled Act 42: Holding Medicaid Payors Accountable

The Indiana State Legislature took steps towards holding managed care organizations participating in the Indiana Medicaid program (Program) accountable for complying with their contracts with the Program. Senate Bill 42, enacted as Senate Enrolled Act 42 (SEA 42), requires the Select Joint Commission on Medicaid Oversight⁴³⁶ (Commission) "to [d]etermine whether a managed care organization that has contracted with the office to provide Medicaid services has properly performed the terms of the managed care organization's contract with the state."⁴³⁷ SEA 42 also requires certain managed care organizations participating in the Program to: (1) be accredited by the National Committee for Quality Assurance within certain timeframes and (2) accept electronic claims for payment.⁴³⁸ Finally, SEA 42 repeals a provision under which the Commission would have expired as of December 31, 2008.⁴³⁹ This legislation increases the oversight duties of the Commission so that it may scrutinize managed care organizations participating in the Program and ensure

434. H.B. 1001, 115th Gen. Assem., Reg. Sess. (Ind. 2008) (amending IND. CODE § 12-16-7.5-4.5 (2006 & Supp. 2008)).

435. *Id.*

436. The Commission had been created by the Indiana State Legislature before passage of S.B. 42 to oversee general Medicaid matters involving claims, errors, reimbursement and other issues involving the state Medicaid program. IND. CODE § 2-5-26-8 (2006 & Supp. 2008).

437. S.B. 42, 115th Gen. Assem., Reg. Sess. (Ind. 2008) (amending IND. CODE § 2-5-26-8 (2006 & Supp. 2008)).

438. *Id.*

439. *Id.*

that these organizations are complying with the terms of their contracts with the Program, preventing future abuses of the Program, and increasing Program efficiency.

C. Senate Enrolled Act 350: Community Mental Health Centers

The Indiana Legislature committed to establish and fund community health centers in 2008 by enacting Senate Bill 350 into law.⁴⁴⁰ Community health centers are federally funded “community-based and patient-directed organizations that serve populations with limited access to health care . . . [including] . . . low income populations, the uninsured, those with limited English proficiency, migrant and seasonal farm workers, individuals and families experiencing homelessness, and those living in public housing.”⁴⁴¹ Community health centers qualify for federal funding if they meet certain federal requirements, but federal funding may not always provide a sufficient level of resources to keep community health centers operational.⁴⁴² S.B. 350 helps to resolve this problem.

Senate Enrolled Act 350 (SEA 350) requires a county (other than Marion County) to transfer money within a specified time frame to the Division of Mental Health and Addiction (Division) to satisfy the non-federal share of medical assistance payments to community mental health centers for (1) certain administrative services and (2) community mental health rehabilitation services.⁴⁴³ It also permits the Health & Hospital Corporation of Marion County to make payments to the Division for the operation of a community mental health center.⁴⁴⁴ SEA 350 also requires the Division to ensure that the non-federal share of funding received from a county is applied only for a county’s designated community mental health center and specifies the manner in which the Division may distribute certain excess state funds.⁴⁴⁵ Finally, it provides that the county tax levy for community mental health services is allocated for operational expenses of community mental health centers and that provisions of the bill are applicable only to the extent that the congressional moratorium on the implementation of certain rules by the U.S. Secretary of Health and Human Services is not extended and other restricted rules are implemented.⁴⁴⁶ The enactment of SEA 350 shows the Indiana State Legislature’s dedication to indigent care by funding community health centers that offer significant health care solutions to this population.

440. S.B. 350, 115th Gen. Assem., Reg. Sess. (Ind. 2008).

441. Health Resources and Services Administration, *The Health Center Program: What Is a Health Center?*, <http://bphc.hrsa.gov/about/> (last visited July 3, 2009).

442. 42 C.F.R. § 51c.101 (2008).

443. S.B. 350, 115th Gen. Assem., Reg. Sess. (Ind. 2008).

444. *Id.*

445. *Id.*

446. *Id.*

