

SURVEY OF RECENT DEVELOPMENTS IN HEALTH CARE LAW

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INTRODUCTION

As in most other recent years, the 2002 survey year was marked by several significant and instructive developments in the ever-expanding field of health care law. The emphasis of this Survey is upon those issues of most immediate import to the health care law practitioner. This Survey is neither comprehensive nor exhaustive in detail, but instead focuses on important additions or modifications to law and regulation. In the discussion below, this article will address developments respecting: i) reimbursement under the Medicare and Medicaid programs; ii) fraud and abuse and the Stark law and regulations; iii) federal income taxation; iv) provider malpractice liability; v) labor and employment law; vi) Indiana health care legislation; vii) the federal HIPAA Regulations; and, viii) federal case law respecting the constitutionality of certain health care-related business and the reach of the ERISA preemption.

I. REIMBURSEMENT

A. Medicare: Regulations

1. *Medicare Provider-Based Rule Changes.*—On August 1, 2002, CMS¹ published changes to the provider-based rules in the annual update to Medicare hospital inpatient prospective payment systems.² In general, the status of an entity as either provider-based or freestanding determines the Medicare reimbursement amount it may receive for providing services. If an entity is considered provider-based, it may bill for services as though the services were provided in a hospital. Overall, these changes to the provider-based rules are positive for health care providers in that they broaden what were rather narrow requirements that an entity had to meet in order to obtain provider-based status.

The effective date of the rule changes depends on the facility's original status. For a facility treated as provider-based as of October 1, 2000, the new rules are effective for the facility's first cost reporting period beginning on or after July 1, 2003.³ The effective date for every other entity was October 1, 2002. Both procedural and substantive changes were made, including the recognition of a distinction between on-campus and off-campus provider-based entities.

The final rule eliminates the need for an entity to seek CMS's conferral of

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1. Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services.

2. 42 C.F.R. § 413.65(b)(2) (2002).

3. *Id.*

provider-based status. Rather, an entity now has the option voluntarily to self-attest to CMS that it qualifies as a provider-based entity. Moreover, an entity may begin billing as a provider-based entity even before CMS issues a ruling on an entity's provider-based status.⁴ However, if an entity fails to submit a self-attestation statement to CMS, the entity may face serious adverse consequences. If no statement is submitted and CMS subsequently determines the entity does not qualify as a provider-based entity, the entity will be subject to overpayment recovery for provider-based services for all prior cost reporting periods.⁵

Although CMS has not yet issued a uniform request or attestation form, the final rule did provide general guidelines an entity should follow in self-attesting. Regardless of whether an entity is an on-campus or off-campus entity, it should⁶:

- 1) provide the identity of the main provider and the facility or organization for which provider-based status is being sought;
- 2) identify each facility and state its exact location (that is, its street address and whether it is on-campus or off-campus);
- 3) list the date on which the facility became provider-based; and
- 4) provide "supporting documentation."

The regulations state that an on-campus entity only has to "maintain documentation [supporting] the basis for its attestations and to make [it] available to CMS . . . upon request."⁷ However, an off-campus entity must submit documentation in support of the attestation.⁸ The reason for this requirement is that the additional difficulty exists in determining whether an off-campus entity "is truly integrated with a main provider."⁹

The final rule also makes significant substantive changes that offer relief to providers desiring to utilize management contracts or to operate as partners in joint ventures. As seen in the procedural modifications, these changes also treat on and off-campus entities differently. The provider-based rules formerly required an entity to operate under the main provider's ownership and control in order to qualify for favorable reimbursement status. As a result, all non-management employees had to be employed by the provider, essentially defeating the purpose of a management contract. However, the final rule eliminates this requirement and now permits a provider to operate through a management contract.¹⁰ In addition, the final rule contains changes allowing an on-campus entity to be provider-based and to operate as a participant in a joint venture.¹¹

4. *Id.* § 413.65.

5. 42 C.F.R. § 413.65(l).

6. *See* 67 Fed. Reg. 49,982, 50,085 (Aug. 1, 2002) (to be codified at 42 C.F.R. pt. 405, 412, 413, 485).

7. 42 C.F.R. § 413.65(b)(3)(i) (2002).

8. *Id.* § 413.65(b)(3)(ii).

9. 67 Fed. Reg. 49,982, 50,087 (Aug. 1, 2002) (to be codified at 42 C.F.R. pt. 405, 412, 413, 485).

10. 42 C.F.R. § 413.65 (2002).

11. *Id.* § 413.65(f).

Off-campus entities have not been afforded the same substantive relief and are still subject to the same provider-based requirements as in the original regulations. However, off-campus entities have been granted some flexibility in utilizing management contracts since CMS clarified that a management company can hire or lease employees who provide patient care services “of a type that would be paid for by Medicare under a fee schedule.”¹²

Health care providers have generally welcomed these changes to the provider-based rules, particularly on-campus provider-based entities. Counsel for providers need to consider these changes in advising a client how to proceed in self-attesting and entering into a joint venture or management contract.

2. *Prospective Payment System for Long-Term Care Hospitals.*—Prior to the recent publication of CMS’s August 30, 2002 final rule implementing a prospective payment system for long-term care hospitals (individually, a “LTCH”, and collectively, “LTCHs”), Medicare reimbursed these facilities through a reasonable cost-based payment system.¹³ However, with the new prospective payment system (the “PPS”), LTCHs must now be more cost-effective in providing care. The PPS will develop diagnostic-related groups (“DRGs”) into which patients will be categorized based on the expected treatment and resources each will need. Medicare reimbursement will be based on the DRGs.

The new PPS took effect October 1, 2002, with a five-year phase-in period being adopted. Over the course of this period, the percentage of payments based on the PPS will increase while cost-based reimbursement payments will decrease.¹⁴ A LTCH is defined as a facility characterized by having an average inpatient length of stay greater than twenty-five days. Initially there was some debate whether CMS should count only the days in which Medicare covered a patient’s cost of care in determining whether a facility qualified as a LTCH. However, CMS clarified in the final rule that it will “count *all* the days in a Medicare patient’s stay (covered and noncovered days) that is, total days, in the LTCH in calculating whether a LTCH meets the average 25-day length of stay requirement.”¹⁵

In charging Medicare beneficiaries, a LTCH may not bill a beneficiary for any amount greater than the deductible and coinsurance for which Medicare has made a full DRG payment. This rule applies even if the LTCH’s cost of furnishing services to that beneficiary is greater than the PPS payment it received.¹⁶ However, CMS created an exception to this rule for a Medicare payment for a short-stay outlier case that is less than the pertinent full LTCH-

12. *Id.* § 413.65(h)(1).

13. Medicare providers have been paid reasonable costs, as determined by CMS, necessary to the care and treatment of Medicare beneficiaries.

14. 42 C.F.R. § 412.533 (2002).

15. 67 Fed. Reg. 44,954, 55,971 (Aug. 30, 2002) (to be codified at 42 C.F.R. pt. 412, 413, 476).

16. 42 C.F.R. § 412.507 (2002).

DRG payment amount.¹⁷ In addition, the final rule requires a LTCH to furnish covered services to Medicare beneficiaries either directly or under an approved arrangement.¹⁸ Moreover, CMS will not pay any provider or supplier, but instead only the LTCH, for services provided to a Medicare beneficiary who is an inpatient of the LTCH.¹⁹ Certain services not included as inpatient hospital services, however, may be excluded.

The new regulation also requires that a LTCH establish a Quality Improvement Organization (a "QIO") to review and monitor the quality of the care provided by the LTCH. The LTCH's performance in the following areas is to be reviewed: the medical necessity, reasonableness, and appropriateness of the LTCH's admissions and discharges; the validity of the LTCH's diagnostic and procedural information; the completeness, adequacy and quality of the LTCH's furnished services; and the caliber of other medical services furnished by the LTCH to beneficiaries and the quality of LTCH's billing for such services.²⁰ In addition, physicians are now required to complete a statement acknowledging the beneficiary's principal and secondary diagnoses and any major procedures performed. If, after reviewing the information submitted by the QIO, CMS determines that the LTCH has made any misrepresentations, CMS may deny payment or require the LTCH to take necessary actions to prevent or correct the inappropriate practice.²¹ Finally, CMS must refer any determination of a pattern of such inappropriate practice that it makes to the Health and Human Services Office of Inspector General for review.²²

3. *Changes to the "Incident to" Billing Requirements.*—For a service to be considered "incident to" the services a physician provides in an office and, therefore, to be covered by Medicare, a service had to be furnished either by the physician or by an individual who qualified as an employee of the physician. CMS issued a final rule on November 1, 2001, changing the regulations by eliminating this requirement.²³

This final rule only addresses coverage of "incident to" services that are provided in noninstitutional settings, which the regulation defines as "all settings other than a hospital or skilled nursing facility."²⁴ Therefore, "incident to" services provided in a physician's office by a non-employee may be covered by

17. *Id.*

18. *Id.* § 412.509(c).

19. *Id.* § 412.509(b).

20. *Id.* § 412.508.

21. *Id.* § 412.508(c).

22. *Id.*

23. *Id.* § 410.26. There are additional requirements that must be met in order for a service or supply item to be covered and that were not modified. These additional requirements prescribe that the service or supply item must be: 1) an integral part of the physician's professional service; 2) commonly rendered without charge or included in the physician's bill; 3) of a type that are commonly furnished in physicians' offices or clinics; and 4) furnished under the physician's direct personal supervision.

24. *Id.* § 410.26(a)(5).

Medicare Part B, provided that the other pertinent requirements are still satisfied. The regulation specifically states that Medicare Part B will pay for services and supplies incident to the service of a physician (or other practitioner) if “furnished by the physician, practitioner with an incident to benefit, or auxiliary personnel.”²⁵ The term “auxiliary personnel” is defined as any individual who acts under the supervision of the physician, regardless of whether that individual is an employee of the physician, a leased employee, or an independent contractor.²⁶

Although the final rule did not repeal or alter the other requirements, including requiring the physician directly to supervise the auxiliary personnel in furnishing the “incident to” service, this modification is still significant. Providers now have more flexibility in structuring their arrangements and will have a greater likelihood of meeting the requirements and obtaining coverage for services performed.

B. Medicaid

1. Regulations.—

*a. Medicaid managed care and patients’ rights.*²⁷—On June 14, 2002, CMS issued a final rule that provides to Medicaid beneficiaries enrolled in managed care plans protections and rights similar to those provided beneficiaries who are in private plans.²⁸ These regulations took effect on August 13, 2002. Considering that in the year 2000 approximately fifty-six percent of Medicaid beneficiaries received some service through a managed care plan, this final rule will positively affect the coverage of millions of people.²⁹

Emergency room care is one of the more significant additional rights Medicaid beneficiaries in managed care plans will receive. In general terms, managed care plans of Medicaid beneficiaries must pay for emergency room services: 1) though no prior authorization is granted; 2) regardless of whether the medical facility has an existing contract with the managed care plan; 3) though the beneficiary turns out not to have a condition that required immediate care; or, 4) if the beneficiary obtained emergency services based on the instructions of a practitioner or other representative of the managed care plan.³⁰ In addition, the regulations prohibit a managed care plan from limiting what constitutes an emergency medical condition by listing or defining symptoms or diagnoses.

The regulation also outlines the general rule prohibiting a managed care plan

25. *Id.* § 410.26(b)(6).

26. *Id.* § 410.26(a)(1).

27. Please note that the regulations categorize the various types of managed care plans (i.e. MCO, PIHP, PAHP and PCCM), and sometimes create niche exceptions applicable to certain plans and not others.

28. 67 Fed. Reg. 40,989 (June 14, 2002) (to be codified at 42 C.F.R. pt. 400, 430, 431, 434, 435, 438, 440, 447).

29. *Id.* at 40,992.

30. 42 C.F.R. § 438.114 (2002).

from restricting communications and medical advice between a provider and a beneficiary.³¹ This is significant in that it protects the beneficiary's interest by ensuring that a provider will not refrain from dispensing medical advice because the advised treatment plan is not covered by the managed care plan.

Finally, the regulations have placed some procedural restrictions on managed care organizations. These restrictions include significantly limiting the marketing activities of managed care organizations, including prohibiting them from: 1) distributing marketing materials without State approval; and, 2) engaging in door-to-door, telephone or other cold-call marketing activities.³² In addition, Medicaid managed care organizations are now required to have an internal grievance process that meets state-specified timeframes.³³

b. Transferring income prior to medicaid eligibility.—On May 1, 2002, 405 Indiana Administrative Code title 405 rule 2-3-1.1 was amended by final rule of the Indiana Office of the Secretary of Family and Social Services to specify the methodology for calculating the Medicaid Eligibility Penalty for Transferring Income. The rule states that when the right to a stream of income is transferred at less than fair market value, the penalty on the transferor is calculated based on the projected total income expected to be transferred during the individual's lifetime. It further provides that transferred "income" includes, but is not limited to: 1) transferring income producing real property; and 2) accepting less than fair market rental value on properties rented.

The rule further provides that for purposes of the Medicaid eligibility penalty for transferring assets for less than fair market value, "assets" include any income or resources which the applicant or recipient or the applicant's or recipient's spouse is entitled to receive, but does not receive, because of a failure to take action to receive those assets.

The rule also defines "net income" to mean income produced by real property after deducting allowable expenses of ownership.³⁴ Additionally, the rule permits transfers of assets without affecting subsequent Medicaid eligibility if the transferor has purchased a "qualified long-term care insurance policy"³⁵ pursuant to Indiana Code section 12-15-39-6. If an asset is disregarded because it is used to purchase a qualified long-term care insurance policy, that asset and any income it otherwise would have generated are disregarded for purposes of Medicaid eligibility.

The rule further specifies that a transfer of assets includes a transfer of the

31. *Id.* § 438.102.

32. *Id.* § 438.104.

33. *Id.* § 438.400-24.

34. Allowable expenses of ownership if the owner is responsible for the expenses include property taxes, interest payments, repairs and maintenance, advertising expenses, lawn care, property insurance, trash removal expenses, snow removal expenses, utilities, or any other expenses of ownership allowed by the Supplemental Security Income program, 42 U.S.C. § 1381 (2000). Non-allowable expenses of ownership include depreciation, payments on mortgage principal, personal expenses of the owner, and capital expenditures.

35. This term has the meaning set out in IND. ADMIN. CODE tit. 760, r. 2-20-30 (2002).

right to receive income or a stream of income, the renting or leasing of real property, or the waiving of the right to receive a distribution from a decedent's estate, or the failure to take action to receive a distribution that the person is entitled to as a matter of law. A new subsection specifically addresses transfers of streams of income. The value of such income is determined by calculating the greater of the fair market value or the actual amount of total net income that property or another income source is expected to produce during the lifetime of the transferor based on life expectancy tables. Other new subsections of the rule set out the methods to calculate value of income related to less than fair market rental arrangements and to calculate the value of income declined by a beneficiary, entitled to receive a benefit under law who fails to act to effectuate receipt of the benefit. The amended rule eliminated some uncertainty regarding types of income that can be retained or transferred by potential Medicaid beneficiaries or their spouses.

2. *Statutes: Various Medicaid Program Modifications and Additions.*—Effective March 26, 2002, Senate Enrolled Act 228 made various changes in the Medicaid program including provision for deposit of rebates obtained by the Medicaid program either as required under 42 U.S.C. § 1396r-8(a) (2000) or voluntarily negotiated under a prescription drug program that is established or implemented to provide access to prescription drugs for low income senior citizens. The Act also provides that any money remaining at the end of the State's fiscal year in the Indiana Prescription Drug Account³⁶ or the Indiana Tobacco Master Settlement Agreement Fund³⁷ shall be available for a prescription drug program established or implemented to provide access to prescription drugs for low income senior citizens.³⁸ In addition, money in either account may be used to match federal funds available under a Medicaid waiver under which a prescription drug program is established or implemented to provide access to prescription drugs for low income senior citizens. The Act also provides for the establishment of a Therapeutics Committee as a sub-committee of the Drug Utilization Review Board.³⁹ The Therapeutics Committee is composed of five physicians licensed under Indiana Code section 25-22-5, with one physician with expertise in each of the areas of family practice, pediatrics, geriatrics, psychiatric medicine, and internal medicine with a specialty in the treatment of diabetes. Two members of the Therapeutics Committee shall be pharmacists who are licensed under Indiana Code section 25-26 and who have a Doctor of Pharmacy degree or an equivalent degree.

The purpose of the Committee is to identify pharmacological agents primarily characterized by a significant similarity of the bio-chemical or physiological mechanism by which these agents result in an intended clinical outcome. This allows the Committee to identify agents which are generically available and therapeutically equivalent to brand name drugs, thus assuring that

36. IND. CODE § 4-12-8-2 (2002).

37. *See id.* § 4-12-1-14.3(b)(1)-(3).

38. *See id.* § 4-12-8-2(b).

39. *See id.* § 12-15-35-20.5.

the most cost-effective and clinically-appropriate drug is utilized. The Act also prohibits the use of any prior authorization mechanism for the dispensing of anti-anxiety, anti-psychotic, or anti-depressant drugs under the Medicaid program, except for specific formularies or prior authorization programs operated by managed care organizations.

The Act also establishes a procedure for prior authorization for other types and classes of drugs and permits the Office of Medicaid Planning and Policy to limit quantities of drugs dispensed to beneficiaries.

The purpose of Senate Enrolled Act 228 is to address the significantly increasing costs of pharmaceutical supplies for Medicaid beneficiaries.

3. *Cases.*—

a. *Wisconsin Department of Health and Family Services v. Blumer*.⁴⁰—In *Blumer*, the United States Supreme Court overturned the court of appeals and held that the income-first method, used by a majority of states to determine the Medicaid eligibility of institutionalized married individuals, is valid and may continue to be utilized.⁴¹

In 1988, Congress enacted the Medicare Catastrophic Coverage Act (“MCCA”), which outlined certain requirements with which states had to comply in determining a couple’s income and Medicaid eligibility.⁴² Because spouses often have joint assets and income, the purpose of MCCA was to prevent the non-institutionalized spouse (“community spouse”) from intentionally impoverishing himself or herself just so that the institutionalized spouse would qualify for Medicaid.⁴³ Therefore, the MCCA requires states to set a “minimum monthly maintenance needs allowance” (“MMMNA”) for the community spouse. It also provides that a portion of the couple’s resources, known as the “community spouse resource allowance” (“CSRA”), be reserved for the benefit of the community spouse. A state is prohibited from including this allowance in the institutionalized spouse’s income in determining Medicaid eligibility. The MCCA grants a couple the right to a hearing to petition for a higher CSRA amount, which would often have the effect of increasing the institutionalized spouse’s chances of qualifying for Medicaid sooner. Most states utilize the income-first method to determine whether a higher CSRA is necessary. The income-first method considers whether potential income transfers from the institutionalized spouse to the community spouse negate the need for an increase in the CSRA.

Irene Blumer (the institutionalized spouse) applied for Medicaid coverage in 1996 through her husband and asked for an increase in their CSRA amount. In applying the income-first method, the county’s hearing officer found that an increase was not permissible. Therefore, Blumer did not qualify for Medicaid at that time.⁴⁴ The Blumers appealed, arguing that the MCCA precluded the use

40. 534 U.S. 473 (2002).

41. *Id.*

42. 42 U.S.C. § 1396r-5 (2000).

43. *Blumer*, 534 U.S. at 480.

44. *Id.* at 487.

of the income-first method in making such determinations.⁴⁵

The Court stated that the decision turned on whether “the words ‘community spouse’s income’ may be interpreted to include potential, post-eligibility transfers of income from the institutionalized spouse” as permitted by the statute.⁴⁶ The Court found that the MCCA supported such interpretation, and in turn supported the use of the income-first method in implementing the MCCA.

b. *Indiana Family and Social Services Administration v. Culley*.⁴⁷—In *Culley*, the Indiana Court of Appeals held that the transfer of assets to a funeral trust was not subject to a Medicaid transfer penalty.⁴⁸ Shortly after moving into a nursing home, Irene Culley purchased funeral trusts that were to provide burial funds for her two adult children.⁴⁹ Two days after making this purchase, Ms. Culley applied for Medicaid.⁵⁰ Through the Family and Social Services Administration (“FSSA”), the State of Indiana delayed her eligibility for seven months, claiming that she made the funeral trust purchases in order to decrease her net worth and become Medicaid-eligible.⁵¹

The court rejected this argument, noting, “[a] Medicaid applicant may, in some circumstances, use her assets as did Culley to purchase burial spaces for her family members without being subject to a transfer penalty.”⁵² If, on the other hand, the Medicaid applicant transfers cash to a family member who then purchases a burial space, such a cash transfer is not exempt from the transfer penalty.⁵³ The court found no evidence to support the FSSA’s conclusion that the transfers made were in cash rather than in the form of funeral trusts, as claimed by Ms. Culley. The court “accordingly [found] that the agency abused its discretion in determining that Culley’s purchase of funeral trusts for her children and their spouses subjected her to a transfer penalty.”⁵⁴

45. *Id.* at 490.

46. *Id.* at 489.

47. 769 N.E.2d 680 (Ind. Ct. App. 2002).

48. *Id.*

49. *Id.* at 682.

50. *Id.*

51. *Id.* The Indiana Administrative Code provides that “if a Medicaid applicant who is an inpatient at a nursing facility disposes of assets for less than fair market value during a period of thirty-six months before she is institutionalized and has applied for medical assistance (the ‘look back date’), the applicant is ineligible for Medicaid for a certain period that is determined based on the value of the transferred assets.” *Id.* at 683 (quoting IND. ADMIN. CODE tit. 405, r. 2-3-1.1 (2002)).

52. *Id.*

53. *Id.* at 684.

54. *Id.*

II. FRAUD AND ABUSE

A. Cases

In *Healthscript, Inc. v. State*,⁵⁵ the Indiana Supreme Court reviewed the Indiana Medicaid Fraud statute, Indiana Code section 35-43-5-7.1 (a)(1), and found that it was “too vague to meet the requirements of due process.”⁵⁶ Healthscript, Inc. (“Healthscript”) provided pharmaceutical supplies to a long-term care facility and billed Medicaid for many of these supplies.⁵⁷ The government alleged that Healthscript grossly overcharged Medicaid, when compared to charges made for the same supplies to private payors.⁵⁸ Based upon this over-billing, Healthscript was charged with violating the Medicaid Fraud statute, which provides in relevant part, “A person who knowingly or intentionally . . . files a Medicaid claim, including an electronic claim, in violation of Indiana Code § 12-15 . . . commits Medicaid fraud, a Class D felony.”⁵⁹

The Indiana Supreme Court framed the case around the following question: Was the criminal statute “sufficiently definite to put Defendant on notice that its alleged conduct was proscribed?”⁶⁰ The court found that the statute failed the requirements of due process because “[t]he effect of the statute, then, is to say that a provider is prohibited from filing a Medicaid claim ‘in violation of’ nothing more specific than this vast expanse of the Indiana Code.”⁶¹ Due process requires that the law give “fair warning . . . in language that the common world will understand, of what the law intends to do if a certain line is passed.”⁶² In so holding, the Indiana Supreme Court placed the burden on the Indiana legislature to proscribe fraudulent conduct in a manner that is sufficiently precise to place the “common world” on notice. It remains to be seen how the Indiana legislature will respond.

B. *Stark II, Phase I, Final Regulations*

Section 6204 of the Omnibus Budget Reconciliation Act of 1989,⁶³ commonly known as the Stark Law,⁶⁴ originally applied only to physician self-

55. 770 N.E.2d 810 (Ind. 2002).

56. *Id.* at 812.

57. *Id.*

58. *Id.* at 813.

59. *Id.* (quoting IND. CODE § 35-43-5-7.1(a)(1) (2002)).

60. *Id.*

61. *Id.* at 816.

62. *Id.* (quoting *United States v. Bass*, 404 U.S. 336, 348 (1971), where the United States Supreme Court described the rule of lenity as a component of due process).

63. Pub. L. 101-239, 103 Stat. 2106 (1989) (codified as amended at 42 U.S.C. § 1395nn (2000)).

64. So named for its progenitor, California Representative Fortney Pete Stark.

referrals to clinical laboratories. The Stark Law was amended in 1993⁶⁵ to extend to physician self-referrals encompassing a wide array of designated health services (“DHS”),⁶⁶ after which the law was commonly known as Stark II. Stark II enabled the Health Care Financing Administration (“HCFA”), now known as the Centers for Medicare and Medicaid Services (“CMS”),⁶⁷ to issue regulations implementing the statutory prohibitions against physician self-referrals. Stark II proposed regulations were issued in 1998,⁶⁸ and in 2001 the long-awaited Stark II final regulations (the “Phase I” regulations)⁶⁹ were promulgated. CMS has been promising Phase II final regulations under the Stark Law since it published the Phase I regulations.

This portion of the article will focus on the Phase I regulations and will identify the substantive changes introduced into the Stark Law in that final rule. The bulk of the Phase I regulations became effective on January 4, 2003.

1. *The General Statutory Prohibition.*—In bold strokes, the Stark Law provides that if a physician or a member of a physician’s immediate family has a financial relationship with a health care entity, the physician may not make referrals to that entity for the furnishing of DHS under the Medicare program, and the entity may not bill for the services, unless a statutory or regulatory exception exists.⁷⁰ The Social Security Act, which contains the Medicare and Medicaid laws, further extends the prohibitions of the Stark Law to patients covered by other federally funded health plans such as Medicaid. The Stark Law’s numerous exceptions and special rules necessitate rather detailed regulations to implement the statutory prohibitions.

2. *Key Provisions in the Phase I Regulations.*—Source of the important provisions of the Phase I Regulations are noted below.

a. *“Financial Relationship” between physician and entity.*—Financial relationships under the Stark Law include two varieties: ownership or investment interests, and compensation arrangements.⁷¹ The Phase I regulations

65. Pub. L. 103-66, 107 Stat. 312 (1993) (codified as amended at 42 U.S.C. § 1395nn (2000)).

66. DHS include the following: clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. 42 C.F.R. § 1395nn(h) (2002).

67. Effective July 1, 2001, HCFA changed its name to the Centers for Medicare and Medicaid Services. For consistency, this article continues to refer to the agency as CMS throughout.

68. 63 Fed. Reg. 1659 (Jan. 9, 1998) (to be codified at 42 C.F.R. pt. 411, 424, 435, 455).

69. Physicians Referrals to Health Care Entities with Which They Have Financial Relationships, 66 Fed. Reg. 856 (Jan. 4, 2001) (to be codified at 42 C.F.R. pt. 411, 424).

70. 42 U.S.C. § 1395nn(a)(1) (2000).

71. Physician Ownership of, and Referral of Patients or Laboratory Specimens to, Entities Furnishing Clinical Laboratory or Other Health Services, 42 C.F.R. § 411.354(a) (2002).

provide a definition of “financial relationship,” and distinguish between direct and indirect financial relationships.⁷² The indirect financial relationship concept is of particular interest, as the Phase I regulations introduced a “knowledge” element into the equation, regardless of how remote the financial relationship may be. Entities are not under an “affirmative obligation to inquire as to indirect financial relationships,” but have a duty of reasonable inquiry in the circumstances if there is reason to suspect an indirect financial relationship between the entity and a referring physician.⁷³ Entities and physicians are subject to the Stark Law prohibitions where the indirect financial relationship is deliberately ignored or recklessly disregarded.⁷⁴ The relevant test is whether some information that is available to the entity would put a reasonable person on alert that an indirect financial relationship may exist.⁷⁵

On its face, the indirect compensation arrangement definition excludes most compensation arrangements, such as square footage space leases, hourly or fixed medical director contracts, and any arrangement where the physician is paying the money.⁷⁶ Further, commentary to the Phase I regulations states that this definition encompasses the “universe” of financial relationships that may be subject to the Stark Law prohibitions.⁷⁷ While it may not be CMS’ intent to exclude such arrangements from the purview of the Stark Law, this issue must be addressed in Phase II, and most likely will be. Since the purpose for the knowledge requirement is clearly to give some protection to the entity paying money ultimately received by a physician, clarification of the Phase I regulations is needed so that many of the compensation arrangements excluded from the definition of indirect compensation arrangements may be protected.

b. Remuneration.—In the Phase I regulations, CMS modified the definition of the term “remuneration” to exclude the furnishing of items, devices, or supplies that are used solely to collect, transport, process, or store specimens for the entity furnishing the items, devices, or supplies or that are used solely to order or communicate the results of tests or procedures for the entity.⁷⁸ If an item can be used for anything other than these purposes, the item thus constitutes remuneration and thereby gives rise to a prohibition under the Stark Law.

c. Referrals.—The term “referral” is worded broadly to include most requests by a physician for a DHS or a service that includes a DHS, including certifying or recertifying the need for such a service as well as services furnished by or under the supervision of a consultative physician, and including written, oral, or electronic referrals. This term also includes the establishment of a plan of care by a physician that includes the provision of a DHS.

Under the Phase I regulations, an exception to the definition of “referral”

72. *Id.*

73. *Id.* § 411.354(b)-(c).

74. *Id.* § 411.354(b)(5)(I)(B).

75. 66 Fed. Reg. 856, 865 (Jan. 4, 2001) (to be codified at 42 C.F.R. pt. 411, 424).

76. 42 C.F.R. § 411.354(c)(2) (2002).

77. *Id.*

78. *Id.* § 411.351.

provides that self-referrals personally performed are not referrals for purposes of the Stark Law prohibitions.⁷⁹ Further, a request by a pathologist for clinical diagnostic laboratory tests and pathological examination services, by a radiologist for diagnostic radiology services, or by a radiation oncologist for radiation therapy, is not deemed to be a referral if such request results from a consultation initiated by another physician and such tests or services are furnished by or under the supervision of such pathologist, radiologist, or radiation oncologist.⁸⁰

“Consultation” is defined in the Phase I regulations as a professional service furnished to a patient by a physician that meets three conditions. First, the physician’s opinion or advice regarding evaluation and/or management of the specific medical problem must be requested by another physician. Second, the request and need for the consultation must be documented in the patient’s medical record. Third, after the consultation is provided, the physician must prepare a written report of his or her findings and the report must be provided to the physician who requested the consultation. In addition, for radiation therapy services provided by a radiation oncologist, a course of radiation treatments over a period of time will be considered to be pursuant to a consultation, provided the radiation oncologist communicates with the referring physician on a regular basis about the patient’s course of treatment and progress.⁸¹

d. Volume or value of referrals and other business generated standards.— Compensation (including time-based or per unit of service-based compensation) will be deemed not to take into account “the volume or value of referrals” if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation agreement in any manner that takes into account referrals of DHS.⁸² Similarly, compensation (including time-based or per unit of service-based compensation) will be deemed to not take into account “other business generated between the parties” so long as the compensation is fair market value and does not vary during the term of the agreement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business.⁸³

Under the Phase I regulations, CMS made it clear that compensation paid under a per-click lease arrangement will be considered “set in advance” if a time-based or per unit of service-based amount is stated in the initial agreement between the parties in sufficient detail so it can be objectively verified.⁸⁴ Where a per-click payment is set at fair market value and does not change during the term of the lease, the compensation under the lease will be considered “set in advance.” Consequently, such an arrangement may satisfy an exception to the

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.* § 411.354(d)(2).

83. *Id.* § 411.354(d)(3).

84. *Id.* § 411.354(d)(1); *see* 66 Fed. Reg. 855, 866-67, 876-78 (Jan. 4, 2001) (to be codified at 42 C.F.R. pt. 411, 412).

Stark Law, such as the rental of equipment or fair market value exception, so long as the other elements of the exception are satisfied.

e. General requirement of fair market value.—Fair market value is discussed at length in the Phase I regulations. The burden of proving “fairness” is on the parties to the arrangement. Although no single approach is appropriate for each situation and the amount of documentation that will be sufficient to confirm fair market value will vary with the facts of each arrangement, CMS made the following suggestions in its preamble to the Phase I regulations:

- obtain good faith, written assurances as to fair market value from the party paying or receiving the compensation (not a determinative assurance);
- obtain a list of comparable and contemporaneous lease arrangements;
- obtain an appraisal from a qualified independent valuation expert;
- obtain documentation of similar public transactions, where available, or similar public transactions involving comparable parties in similar areas, where local comparable transactions are unavailable;
- obtain documentation of cost plus a reasonable rate of return on investment on leases of comparable medical equipment from disinterested lessors;
- obtain pricing lists for similar equipment;
- local comparable transactions between parties in a position to refer business between them are less compelling than where no referral relationship exists; and
- internally-generated fair market value surveys or comparisons are less compelling than external independent information.⁸⁵

The term “fair market value” means “the value in arm’s length transactions, consistent with the general market value.”⁸⁶ “General market value” means “the price that an asset would bring, as the result of bona fide bargaining between well-informed buyers and sellers” who are not otherwise in a position to generate business for the other party, or, “the compensation that would be included in a service agreement,” as a result of *bona fide* bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.⁸⁷

Usually, the fair market value price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement.⁸⁸

85. 66 Fed. Reg. 856, 944-45 (Jan. 4, 2001) (to be codified at 42 C.F.R. pt. 411, 424).

86. 42 C.F.R. § 411.351 (2002).

87. See 66 Fed. Reg. 856, 944 (Jan. 4, 2001) (to be codified at 42 C.F.R. pt. 411, 424).

88. *Id.*

With respect to rentals and leases, “fair market value” means the value of rental property for general commercial purposes (not taking into account its intended use).⁸⁹ In the case of a lease of space, this value may not be adjusted to reflect the additional value a prospective lessee or lessor would attribute to the proximity or convenience to the lessor when the lessor is a potential source of patient referrals to the lessee.⁹⁰ For purposes of this definition, a rental payment does not take into “intended use” if it includes costs incurred by the lessor in developing or upgrading the property or its improvements.⁹¹

f. Physician services exception.—The exception for physician services applies to “incident to” services that are physician services under 42 C.F.R. § 410.20(a) and not to other services.⁹² Such services must be furnished by or under the supervision of another physician who is a member of the referring physician’s group practice or is a physician in the same group practice as the referring physician.⁹³ A “physician in the same group practice” is defined in the Phase I regulations to include employees and independent contractors, thus expanding the scope of the special treatment afforded to group practices.⁹⁴

g. The in-office ancillary services exception.—The in-office ancillary services exception applies to services and a narrowly-tailored list of durable medical equipment (“DME”) items that are furnished personally by the referring physician, a physician who is a member of the same group practice as the referring physician, or an individual who is supervised by the referring physician or by another physician in the group practice.⁹⁵ For purposes of this exception, the supervision must comply with all other applicable Medicare payment and coverage rules for the services.⁹⁶ The supervision requirement was modified in the Phase I regulations to reflect Medicare requirements.

The in-office ancillary service exception requires that services be furnished in the “same building” in which the referring physician furnishes substantial physician services that are unrelated to the furnishing of DHS or in a “centralized building” from which the group practice provides DHS.⁹⁷ The “same building” is defined as one or more structures sharing a common street address.⁹⁸ Exterior spaces, interior parking garages, and mobile units are not part of the “same

89. *Id.*

90. *Id.*

91. *Id.*

92. 42 C.F.R. § 411.355(a) (2002).

93. *Id.*

94. *Id.* § 411.351.

95. *Id.* § 411.355(b).

96. *Id.*

97. *Id.* § 411.355(b)(2). A designated health service is “furnished” for purposes of this exception in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

98. *Id.* § 411.351; *see* 66 Fed. Reg. 856, 952 (Jan. 4, 2001) (to be codified at 42 C.F.R. pt. 411, 424).

building.”⁹⁹ This definition allows for sharing arrangements for groups working at the same street address. Further, according to CMS commentary in the preamble to the Phase I regulations, if a group practice uses an independent contractor to furnish or supervise services, the service must be in the “same building” as opposed to a “centralized building.”¹⁰⁰ In the case of a referring physician whose principal medical practice consists of treating patients in their private homes, the “same building” requirements of the exception are met if the referring physician (or a qualified person accompanying the physician, such as a nurse or technician) provides the DHS contemporaneously with a physician service that is not a DHS provided by the referring physician to the patient in the patient’s private home.¹⁰¹ A “private home” does not include a nursing, long-term care, or other facility or institution.¹⁰²

The term “centralized building” is defined in the Phase I regulations as all or part of a building, including a mobile unit, that is owned or leased on a full-time basis, and is used exclusively by the group practice.¹⁰³ Shared facilities are not centralized buildings, though a group may provide services to other providers (e.g., purchased diagnostic tests) from within its centralized building.¹⁰⁴ Further, a group may have more than one centralized building.¹⁰⁵

In-office ancillary services must be billed by the physician performing or supervising the service, the performing or supervising physician’s group practice, an entity that is wholly owned by the performing or supervising physician (or by that physician’s group practice), or an independent third party billing company acting on behalf of one of the foregoing.¹⁰⁶ For purposes of this requirement, a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.¹⁰⁷

h. Group practice definition.—The physician services and in-office ancillary service exceptions contemplate a physician group practice situation, although it is wrong to say that there exists a “group practice” exception under Stark II. A physician group must first qualify as a “group practice” as defined under the law, and then it may be eligible to meet the above exceptions.

Under Stark II, the term “group practice” means a physician practice organized as a single legal entity with at least two physicians who are “members of the group” (whether employees or direct or indirect owners).¹⁰⁸ Non-physicians may own an interest in the group practice, provided that at least two physicians also own an interest in the group. Each member of a group practice

99. 42 C.F.R. 411.351 (2002).

100. 66 Fed. Reg. 866, 887 (Jan. 4, 2001) (to be codified at 42 C.F.R. pt. 411, 424).

101. 42 C.F.R. § 411.355(b)(6) (2002).

102. *Id.*

103. *Id.* § 411.351.

104. *Id.*

105. *Id.*

106. *Id.* § 411.355(b)(3).

107. *Id.*

108. *Id.* § 411.352(a), (b).

“must furnish substantially the full range of patient care services that the physician routinely furnishes, including medical care, consultation, diagnosis, and treatment, through the joint use of the group’s shared office space, facilities, equipment, and personnel.”¹⁰⁹

Members of the group must also furnish at least seventy-five percent of their total patient care services through the group, and these services must be billed as receipts of the group under a billing number assigned to the group.¹¹⁰ In addition, “members of the group must personally conduct no less than [seventy-five] percent of the physician-patient encounters of the group practice.”¹¹¹ This requirement effectively limits the extent to which independent contractors may participate in a group practice.

To qualify as a group practice, the practice’s overhead expenses and income must be distributed according to predetermined methods, though the distribution mechanism may be modified prospectively from time to time.¹¹² A group practice must also be a “unified business,” with a “centralized decision-making body”; “consolidated billing, accounting, and financial reporting”; and “centralized utilization review.”¹¹³ This requirement is intended to set some “general parameters of integration.”¹¹⁴ As such, some type of “board” and financial integration are necessary.

In addition, no member of the group practice may be compensated in a manner that reflects the volume or value of referrals by the group member except through certain productivity bonuses and profit shares.¹¹⁵ A group practice member may receive a share of the group’s overall profits, or a productivity bonus based on that physician’s personally performed services, provided that the calculation of such payment does not reflect in any manner the volume or value of referrals of DHS by the physician.¹¹⁶ Supporting documentation verifying the method used to calculate the profit shares or productivity bonus and the resulting amount of compensation must be made available to the secretary upon request.¹¹⁷

A group practice must select an appropriate allocation mechanism for purposes of DHS profit distribution. Several such allocation options are presented in the Phase I regulations.¹¹⁸ Methods other than those presented in the regulations, such as ownership or seniority, are acceptable. Regardless, such other methods must be reasonable, objectively verifiable, and indirectly related to referrals, and a group should maintain objective documentation of

109. *Id.* § 411.352(c).

110. *Id.* § 411.352(d).

111. *Id.* § 411.352(h).

112. *Id.* § 411.352(e).

113. *Id.* § 411.352(f)(1).

114. 66 Fed. Reg. 856, 906 (Jan. 4, 2001) (to be codified at 42 C.F.R. pt. 411, 424).

115. 42 C.F.R. § 411.352(h) (2002).

116. *Id.* § 411.352(i).

117. *See id.* § 411.352(i)(4).

118. *See id.* § 411.352(i)(3).

compliance.¹¹⁹

A potentially problematic issue is found in commentary to the final rule wherein CMS states that it believes that “a compensation structure does not directly take into account the volume or value of referrals if there is no direct correlation between the total amount of a physician’s compensation and the volume or value of the physician’s DHS referrals (regardless of whether the services are personally performed).”¹²⁰ If the services are personally performed, however, there is no referral within the meaning of the Stark Law.¹²¹ CMS should clarify this commentary to reflect that there be no direct correlation between volume or value of referrals.

i. Prepaid plans.—Phase I provides a new exception for services furnished by a specified federally qualified HMO or prepaid health plan that has a contract with Medicare.¹²² This exception does not include “services provided to enrollees in any other plan or line of business offered or administered by the same organization.”¹²³ An additional regulation that would extend this protection to Medicaid prepaid plans is not yet final.¹²⁴

j. Academic medical centers.—CMS was persuaded that the peculiarities of the academic setting warranted a special exception for DHS furnished by academic medical centers. Thus, an exception to the Stark Law for any financial relationship applies where a referring physician is a bona fide employee of an academic medical center on a full-time or substantial part-time basis.¹²⁵ The physician may also be employed by or under contract with a component of an academic medical center, including an affiliated medical school, faculty practice plan, hospital, teaching facility, institution of higher education, or departmental professional corporation.¹²⁶

In addition, this exception requires that the physician be licensed to practice medicine in the State, have a bona fide faculty appointment at the affiliated medical school, and provide substantial academic or clinical teaching services, compensated as part of the employment relationship.¹²⁷ This exception also includes requirements that the physician’s compensation be set in advance in an amount not greater than the fair market value of the services provided and be determined in a manner that does not reflect the volume or value of any referrals or other business generated by the referring physician within the academic medical center.¹²⁸

119. *See id.* § 411.352(i)(2)(iv).

120. *See* 66 Fed. Reg. 856, 908 (Jan. 4, 2001).

121. *See supra* note 70 and accompanying text.

122. *See* 42 C.F.R. § 411.355(c) (2002).

123. *See id.*

124. *See* 66 Fed. Reg. at 911 (referring to a proposed regulation to be codified at 42 C.F.R. § 435.1012).

125. *See* 42 C.F.R. § 411.355(e).

126. *See id.*

127. *See id.*

128. *See id.*

k. Fair market value compensation arrangements.—Another new exception created by the Phase I regulations provides that certain fair market value compensation arrangements are not proscribed financial relationships under the Stark Law.¹²⁹ This exception applies to an arrangement between an entity and a physician or any group of physicians (whether or not a “group practice” within the meaning of the Stark Law) for the provision of items or services by the physician or group practice to the entity, if the arrangement is set forth in an agreement that meets the following conditions:

(1) It is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.

(2) It specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

(3) It specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or any other business generated by the referring physician.

(4) It involves a transaction that is commercially reasonable (taking into account the nature and scope of the transaction) and furthers the legitimate business purposes of the parties.

(5) It meets a safe harbor under the anti-kickback statute in [42 C.F.R.] §1001.952, has been approved by the OIG under a favorable advisory opinion issued in accordance with [42 C.F.R. part] 1008, or does not violate the anti-kickback provisions in section 1128B(b) of the Act.

(6) The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a State or Federal law.¹³⁰

CMS has stated that this exception may be used even if another exception potentially applies. Thus, as this exception has no term requirement, it has advantages over several other similar exceptions that are otherwise burdened with a term limitation (e.g., the personal services arrangement exception¹³¹).

l. Non-monetary compensation up to \$300.—Compensation from an entity in the form of items or services (not including cash or cash equivalents) that does not exceed an aggregate of \$300 per year “is not a financial relationship within the meaning of the Stark Law” if all of the following conditions are satisfied:

129. See 42 C.F.R. § 411.357(l) (2002).

130. *Id.*

131. See 42 C.F.R. § 411.357(d).

- (1) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.
- (2) The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).
- (3) The compensation arrangement does not violate the Federal anti-kickback statute, section 1128B(b) of the Act.¹³²

m. Definitions of the designated health services.—In the Phase I regulations, CMS defined the first four categories of DHS by using CPT and HCPCS codes attached to the regulations with updates posted on the CMS web site. These categories include: (1) clinical laboratory services; (2) physical therapy services, occupational therapy services, and speech-language pathology services; (3) radiology and certain other imaging services; and (4) radiation therapy services and supplies. Modifications to the list occurred on November 1, 2001,¹³³ and April 26, 2002.¹³⁴ In commentary to the Phase I regulations, CMS stated that it has included the professional component in each case in which a professional component is included in the code representing a DHS.¹³⁵ However, it further stated that “[a]s a practical matter the professional component of many services will be excluded from the definition of a referral as services personally performed by the referring physician.”¹³⁶

The Phase I regulations clarified that DHS “means only DHS payable, in whole or in part, by Medicare.”¹³⁷ (The Medicaid aspect will be addressed in Phase II.) Further, DHS do not include services that are reimbursed by Medicare as part of a composite rate (e.g., ambulatory surgical center services or skilled nursing facility Part A payments) unless the DHS themselves reflect a composite rate (e.g., inpatient hospital services).¹³⁸ However, entities that perform consolidated billing (e.g., SNF Part B) will be deemed to provide DHS.¹³⁹

n. Remuneration and the exceptions in section 1877(h)(1)(C) of the Act.—On November 22, 2002, CMS published a final rule extending the effective date of the last sentence of section 411.354(d)(1).¹⁴⁰ Consequently, the rule reflected

132. *Id.* § 411.357(k).

133. Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002, 66 Fed. Reg. 55426, 55311 (Nov. 1, 2001).

134. Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002; Correction, 67 Fed. Reg. 20681-87 (Apr. 26, 2002).

135. *See* 66 Fed. Reg. 856, 924 (Jan. 4, 2001).

136. *Id.*

137. *See* 42 C.F.R. § 411.351 (2002).

138. *Id.*

139. *See* 66 Fed. Reg. 856, 923 (Jan. 4, 2001).

140. Extension of Partial Delay of Effective Date, 67 Fed. Reg. 70322 (Nov. 22, 2002). The last sentence of Sec. 411.354(d)(1) reads as follows:

in the last sentence of section 411.354(d)(1), which would have become effective January 6, 2003, will not become effective until July 7, 2003.¹⁴¹ Section 411.354(d)(1) of the Stark Law relates to percentage compensation arrangements for physicians. This extension of the one-year delay in the effective date of that sentence will give CMS additional time to reconsider the definition of compensation that is “set in advance” as it relates to percentage compensation methodologies in order to avoid unnecessarily disrupting existing contractual arrangements for physician services.¹⁴² CMS expects a future final rule with comment period, entitled “Medicare Program: Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships” (Phase II), to further address this issue prior to the July 7, 2003 effective date.¹⁴³

CMS received numerous comments regarding the Phase I regulations indicating that hospitals, academic medical centers, medical foundations and other health care entities commonly pay physicians for their professional services using a formula that takes into account a percentage of a fluctuating or indeterminate measure (for example, revenues billed or collected for physician services).¹⁴⁴

Several commentators pointed out that this aspect of the [Phase I regulations], which is applicable to academic medical centers and medical foundations (among others), is inconsistent with the compensation methods permitted under the statute for many physician group practices and employed physicians (that is, neither section 1877(h)(4)(B)(i) of the Act nor section 1877(e)(2) of the Act contains the “set in advance” requirement).¹⁴⁵

Recognizing that hospitals, academic medical centers, medical foundations and other health care entities would have to restructure or renegotiate thousands of physician contracts to comply with the language in section 411.354(d)(1) regarding percentage compensation arrangements, CMS has prescribed this one-year delay of the effective date in order to reconsider the definition of compensation that is “set in advance” as it relates to percentage compensation

Percentage compensation arrangements do not constitute compensation that is “set in advance” in which the percentage compensation is based on fluctuating or indeterminate measures or in which the arrangement results in the seller receiving different payment amounts for the same service from the same purchaser.

141. Section 411.354(d)(1) was promulgated in the final rule entitled “Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships,” published in the Federal Register on January 4, 2001 (66 Fed. Reg. 856). A one-year delay of the effective date of the last sentence in § 411.354(d)(1) was published in the Federal Register on December 3, 2001 (66 Fed. Reg. 60154). This final rule further delays the effective date until July 7, 2003.

142. 67 Fed. Reg. at 70323.

143. *Id.*

144. *See id.*

145. *Id.*

methodologies.¹⁴⁶

C. Federal Fraud and Abuse Anti-Kickback Statute: Ambulance Replenishing Safe Harbor

On December 4, 2001, the Department of Health and Human Services Office of Inspector General (“OIG”) issued a final rule¹⁴⁷ establishing a safe harbor exception to the Fraud and Abuse Anti-Kickback Statute¹⁴⁸ for ambulance restocking arrangements (“Safe Harbor”). The Safe Harbor, which became effective January 3, 2002, protects certain arrangements involving hospitals or other receiving facilities¹⁴⁹ that replenish drugs and medical supplies (including linens) used by ambulance providers¹⁵⁰ (and first responders) when transporting patients to such hospitals or receiving facilities. The Safe Harbor does not protect arrangements for the general stocking of the ambulance inventories, but only the gifting or transfer of drugs and supplies that replace comparable drugs and supplies that are administered by the ambulance provider to a patient before the patient is delivered to the receiving facility. The OIG’s stated goal is to provide “safe harbor protection for the vast majority of ambulance restocking arrangements that further the important mission of ensuring that pre-hospital emergency medical services are timely, effective and efficient.”¹⁵¹

Ambulance restocking arrangements implicate the Anti-Kickback Statute because the receiving facility provides something of value to the ambulance provider, who is a potential referral source of federal healthcare business.¹⁵² However, properly structured restocking arrangements can be lawful and allow for ambulances to be ready for emergency use at all times.¹⁵³

146. *Id.*

147. Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute, 66 Fed. Reg. 62979 (Dec. 4, 2001) (codified at 42 C.F.R. §1001.952(v)).

148. 42 U.S.C. §§1320a-7b(b) (1994 & Supp. II 1996).

149. References to “receiving facilities” in the Safe Harbor include hospitals, urgent care clinics or community health clinics that provide emergency services. *See* 42 C.F.R. § 1001.952(v).

150. Unless otherwise specified, the term “ambulance providers” as used in this article and the Safe Harbor refers to independent ambulance suppliers and hospital-based providers, including under-arrangements providers. *See id.*

151. Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute, 66 Fed. Reg. at 62980.

152. *See id.*

153. *Id.* While the OIG issued a non-favorable advisory opinion regarding an ambulance restocking arrangement in 1997 (OIG Advisory Opinion No. 97-6 (October 8, 1997)), it explained that the particular arrangement that was the subject of that advisory opinion presented an “unusual set of facts.” *Id.* The OIG has since issued several favorable opinions approving restocking arrangements that it believed were more representative of typical restocking arrangements. *Id.*; *see* OIG Advisory Opinions Nos. 98-7 (1998); 98-13 (1998); 98-14 (1998); and 00-09 (2000). In the comments to the final rule, the OIG indicated that some hospitals have used the unfavorable 97-6 opinion as a pretext for the hospitals’ decisions to terminate, or decline to participate in, restocking

The Safe Harbor protects three categories of replenishing: general restocking, fair market value restocking, and government-mandated restocking.¹⁵⁴ An arrangement needs only to satisfy the conditions of one of these categories to be protected by the Safe Harbor.¹⁵⁵ In furtherance of the goal to enhance emergency services, the ambulance that is replenished must be used to provide an average of three emergency ambulance services per week, as measured over a reasonable period of time, to qualify for Safe Harbor protection.¹⁵⁶ In addition, the regulation includes two sets of conditions: one set that is generally applicable to all three restocking categories,¹⁵⁷ and another set that includes conditions that are specific to each of these categories.¹⁵⁸ Therefore, to qualify for the Safe Harbor protection, a restocking arrangement must meet all of the conditions set forth in the first set of conditions and all of the conditions applying to any one category in the second set of conditions.¹⁵⁹

The general conditions that are applicable to all restocking arrangements include the following: appropriate billing of federal health care programs (e.g., no duplicate billing and billing must be consistent with all applicable program payment and coverage rules and regulations); documentation of the restocking, which is maintained for a period of five years (the pre-hospital trip sheet or patient encounter form may be sufficient to satisfy this requirement); the restocking arrangement must not be conditioned on, or otherwise take into account, the volume or value of any referrals or other business generated between the parties for which payment may be made in whole or in part by a federal health care program; and such replenishing arrangement must otherwise comply with all other applicable laws.¹⁶⁰

1. *General Replenishing.*—The Safe Harbor for general replenishing requires the receiving facility to replenish medical supplies or drugs on an equal basis for all ambulance providers that bring patients to the receiving facility in any one of the following categories: 1) all ambulance providers; 2) all non-profit and governmental providers; or 3) all non-charging providers, which are typically

arrangements in order to avoid the negative publicity related to such decisions. Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute, 66 Fed. Reg. at 62982.

154. *Id.* at 62981 (codified at C.F.R. §1001.952(v)(3)).

155. *Id.*

156. *See id.* at 62983. Although replenishing ambulance providers that do not provide emergency services of this frequency is outside the scope of this Safe Harbor, it does not mean that such arrangements are per se illegal. Rather, such arrangements must be analyzed for compliance with the Anti-Kickback Statute on a case-by-case basis. *Id.*

157. 42 C.F.R. §1001.952(v)(2).

158. *Id.* §1001.952(v)(3).

159. *See* Ambulance Replenishing Safe Harbor Under the Anti-Kickback Statute, 66 Fed. Reg. at 62981.

160. *Id.* at 62981. Other applicable laws include, for example, the Prescription Drug Marketing Act of 1987 (“PDMA”), Pub. L. No. 100-293, 102 Stat. 95 (1988), which governs the resale of prescription drugs. Therefore, the resale of drugs does not fall within the scope of this Safe Harbor.

volunteers and municipal providers.¹⁶¹ A receiving facility may offer replenishing to one or more of the categories and may offer different replenishing arrangements to different categories, so long as the replenishing is conducted uniformly within each category.¹⁶² Further, the replenishing arrangement must be conducted in an open and public manner.¹⁶³

2. *Fair Market Value Replenishing*.—In addition to the general conditions, this category requires the ambulance provider to pay the receiving facility fair market value, based on an arms-length transaction, for replenished medical supplies, and, if payment is not made at the same time as the replenishing of the medical supplies, the receiving facility and the ambulance provider must make commercially reasonable payment arrangements in advance.¹⁶⁴

3. *Government Mandated Replenishing*.—This category protects replenishing arrangements that are undertaken in accordance with a state or local statute, ordinance, regulation or binding protocol that requires hospitals or receiving facilities in the area subject to such requirement to replenish ambulances that deliver patients to the hospital with drugs or medical supplies (including linens) that are used during the transport of that patient.¹⁶⁵

Since the Safe Harbor became effective, the OIG has issued two favorable advisory opinions interpreting the applicability of the Safe Harbor to replenishing arrangements, finding that both arrangements satisfied the criteria for “general replenishing” under the Safe Harbor.¹⁶⁶

III. TAXATION

1. *St. David's Health Care System, Inc. v. United States*.—Tax-exempt hospitals gained some potential flexibility in the area of joint ventures with for-profit entities with *St. David's Health Care System, Inc. v. United States*.¹⁶⁷ In that case, St. David's Health Care System (“St. David's”), an entity exempt from federal income taxation under Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the “Code”),¹⁶⁸ sued the Internal Revenue Service (“IRS”) for a refund of federal income taxes paid after the IRS revoked its tax-exempt status.¹⁶⁹ The IRS had made the revocation alleging that St. David's had failed the operational test for Section 501(c)(3) status, after it had entered into a joint venture limited partnership with a for-profit subsidiary of HCA (“HCA”), a

161. 42 C.F.R. §1001.952(v)(3)(i).

162. *Id.*

163. *See id.* §1001.952(v)(3)(i)(A)(3)(B)(1)(i) and (ii) for the conditions that must be satisfied to qualify as conducting the replenishing arrangement in an “open and public manner.”

164. *Id.* §1001.952(v)(3)(ii)(B).

165. *Id.* §1001.952(v)(3)(iii).

166. OIG Advisory Opinion Nos. 02-2 & 02-3 (Apr. 4, 2002).

167. 2002 WL 1335230 (W.D. Tex. June 7, 2002).

168. I.R.C. § 501(c)(3) (2002).

169. *St. David's Health Care Sys.*, 2002 WL 1335230 at *1.

national for-profit health care system.¹⁷⁰ Pursuant to the terms of the partnership, St. David's had ownership interests in the partnership totaling 45.9% at the time of the court's decision.¹⁷¹ The partnership was governed by a Board of Governors, in which representation was evenly split between St. David's and HCA.¹⁷² Decisions by the Board of Governors were implemented by a management entity, which was obligated to ensure that the partnership was operated consistent with the community benefit standard of Section 501(c)(3) of the Code.¹⁷³

On summary judgment, the court reversed the determination by the Internal Revenue Service to revoke St. David's tax-exempt status and ordered the refunding of taxes paid by St. David's since the revocation.¹⁷⁴ The court agreed with the IRS that the operational test was at issue,¹⁷⁵ but disagreed with the IRS' contentions that St. David's was not controlled by a community board and that HCA received an impermissible private benefit.¹⁷⁶

The court found, "[A]s a matter of law, the presence of a community board is a point in favor of exemption, but is not an absolute requirement for exemption."¹⁷⁷ The court went on to say that, even if a community board was a requirement for exemption, St. David's met that requirement with the structure of its Board of Governors.¹⁷⁸ The court offered a broader definition of the community board standard than that urged by the IRS, stating, "The purpose of the community board is to ensure that the community's interests are given precedence over any private interests. Thus, if a board is structured to ensure such protection, it is clearly a community board."¹⁷⁹

The court also found that there was no impermissible private benefit that accrued to HCA. Citing the recent *Redlands* case, the court emphasized that private benefit hinges on whether the joint venture has an "*obligation to put*

170. *Id.*

171. *Id.*

172. *Id.* at *5.

173. See Linda S. Moroney & Joseph C. Mandarino, *The St. David's Decision: Breathing Life into Joint Ventures?*, HEALTH LAW. NEWS, at 9 (Oct. 2002) (citing facts not referenced by the court's decision, but by a Technical Advice Memorandum issued by the Internal Revenue Service).

174. *St. David's Health Care System*, 2002 WL 1335230 at *8.

175. *Id.* at *5.

176. *Id.* at *8.

177. *Id.* at *5.

178. *Id.* at *7. The court noted that four factors favored a finding that the partnership Board is a community board: (1) the partnership contract requires that all hospitals owned by the partnership operate in accord with the community benefit standard; (2) St. David's has the unilateral right to dissolve the partnership should the hospital fail to meet that standard; (3) the chairman of the Board is appointed by St. David's, giving St. David's control over the agenda of the Board; and (4) the day-to-day operations of the partnership are disproportionately impacted by St. David's because of its power to unilaterally remove the partnership's Chief Executive Officer. *Id.*

179. *Id.* at *6.

charitable purposes ahead of profit-making objectives."¹⁸⁰ In the partnership at issue, St. David's maintained enough controls to ensure that its charitable purposes were placed ahead of the profit-making objectives of the partnership.¹⁸¹ In spite of the fact that Board representation was fifty-fifty between St. David's and HCA, and in spite of the fact that St. David's had less than a fifty percent interest in the partnership, the court concluded that "it is difficult to imagine a corporate structure more protective of an organization's charitable purpose than the one at issue in this case."¹⁸²

The *St. David's* decision appears to allow for tax-exempt health care entities to have increased freedom as they structure joint ventures with for-profit entities, with less incidents of control, so long as certain incidents of control are maintained and the commitment to charity care supercedes the joint venture's profit-making objectives. Because this is a district court case, however, it should be noted that its ultimate impact will depend on whether its reasoning is more widely adopted by other courts.

2. *Caracci v. Commissioner of Internal Revenue*.—The United States Tax Court in May of 2002 decided *Caracci*, the first case to interpret substantively the intermediate sanctions provisions of Section 4958 of the Code.¹⁸³ The *Caracci* case offers guidance as to the appropriate role of intermediate sanctions as an enforcement tool for the IRS against activities that are inconsistent with an entity's tax-exempt purposes. In that case, the Caracci family owned three different home health care agencies, each of which was exempt from federal income taxation under Section 501(c)(3) of the Code.¹⁸⁴ In 1995, the Caracci family effected the transfer of substantially all of the assets of each of these tax-exempt entities, subject to liabilities, to three newly formed S-corporations, which were thereafter operated as for-profit entities.¹⁸⁵ The only consideration for these transfers was the corresponding assumption of liabilities by each of the S-corporation transferees.¹⁸⁶ The Caracci family determined, based upon appraisals performed on the tax-exempt entities, that the liabilities assumed exceeded the value of the assets transferred, and that, therefore, the transfer was made at or above fair market value.¹⁸⁷

The IRS disagreed, finding that the assets of the tax-exempt entities far exceeded the value of the corresponding liabilities and that the transactions were therefore inconsistent with fair market value.¹⁸⁸ This resulted in an "excess benefits transaction," where a "disqualified person" under Section 4958 of the

180. *Id.* at *8 (quoting *Redlands Surgical Servs. v. Comm'r*, 113 T.C. 47, 78 (1999)).

181. *Id.*

182. *Id.*

183. *Caracci v. Comm'r of Internal Revenue*, 118 T.C. 379 (2002).

184. *Id.* at 379.

185. *Id.*

186. *Id.* at 379-80.

187. *Id.*

188. *Id.* at 380.

Code received an “excess benefit” from a tax-exempt entity.¹⁸⁹ The IRS imposed an excise penalty tax respecting the transaction as an intermediate sanction.¹⁹⁰ In addition, the IRS revoked the tax-exempt status of each of the former home health care agencies.¹⁹¹

The court upheld the imposition of intermediate sanctions by the IRS.¹⁹² After a lengthy discussion, the court found that the value of the assets transferred did exceed the value of the liabilities assumed, rendering the transaction inconsistent with fair market value.¹⁹³ The court declined, however, to revoke the tax-exempt status of the former home health care agencies, finding that the intermediate sanctions penalty was sufficient.¹⁹⁴ It was here that the court gave interpretive guidance to the intermediate sanctions provisions. Quoting the legislative history of Section 4958, the court stated, “In general, the intermediate sanctions are the sole sanction imposed in those cases in which the excess benefit does not rise to a level where it calls into question whether, on the whole, the organization functions as a charitable or other tax-exempt organization.”¹⁹⁵ The court reasoned that the intermediate sanctions provisions were designed as an independent penalty and should only be accompanied by revocation of tax-exempt status in the most egregious of cases.¹⁹⁶ Because the tax-exempt entities at issue had been dormant since the transaction, the court was unable to determine whether they were functioning inconsistently with their charitable or other tax-exempt purposes, and on that basis refused to revoke their tax-exempt statuses.¹⁹⁷

3. *Griffin v. Department of Local Government Finance*.—The Hospital Care for the Indigent (“HCI”) tax survived scrutiny as a possibly unconstitutional taxation of property under article 10, section 1 of the Indiana Constitution.¹⁹⁸ The HCI tax is assessed by each Indiana county on property located within it, and is used to provide cost-free emergency medical care to indigent patients who do

189. *Id.* Section 4958 provides for a tax equal to twenty-five percent of the excess benefit on the disqualified person. I.R.C. § 4958(a)(1) (2003). The Code defines an “excess benefit transaction” as “any transaction in which an economic benefit is provided by an applicable tax-exempt organization directly or indirectly to or for the use of any disqualified person if the value of the economic benefit provided exceeds the value of the consideration (including the performance of services) received for providing such benefit.” *Id.* § 4958(c)(1)(A). The Code defines a “disqualified person” as a person “in a position to exercise substantial influence over the affairs of the organization” or such person’s family member. *Id.* § 4958(f)(1).

190. *Caracci*, 118 T.C. at 380.

191. *Id.*

192. *Id.*

193. *Id.* at 415.

194. *Id.* at 416-18.

195. *Id.* at 417 (quoting H.R. REP. NO. 104-506, at 59 n.15 (1996), 1996-3 C.B. at 107).

196. *Id.*

197. *Id.* at 417-18.

198. *Griffin v. Dep’t Local Gov’t Fin.*, 765 N.E.2d 716 (Ind. Tax Ct. 2002), *overruled by* *Dep’t of Local Gov’t Fin. v. Griffin*, 784 N.E.2d 448 (Ind. 2003).

not qualify for Medicaid.¹⁹⁹ The HCI fund is used to pay millions of dollars to providers in Indiana that provide indigent care.²⁰⁰ For the last ten years, the HCI program has been part of a federal Medicare matching program that is designed to bring up to \$45 million of additional funds into the HCI program.²⁰¹ The HCI tax rate, however, is not uniform across the state, but instead varies from county to county.²⁰²

In *Griffin*, the Indiana Tax Court addressed the constitutionality of the HCI tax. In spite of the government's argument to the contrary, the Indiana Tax Court ruled that the HCI tax is not a local tax, but is instead a state tax.²⁰³ In doing so, the court subjected the tax to the strictures of the Indiana constitutional requirement in article 10, section 1, which mandates that state taxes be applied in a uniform and equal manner.²⁰⁴ The court found that the HCI tax fails this requirement, and is therefore unconstitutional.²⁰⁵ In a subsequent hearing, however, the court declined to enjoin collection of the tax while the appeal is being pursued.²⁰⁶ On September 19, 2002, the government's appeal was transferred to the Indiana Supreme Court and the Indiana Tax Court's opinion was vacated.²⁰⁷ On March 5, 2003, the Indiana Supreme Court reversed the Tax Court's decision, finding the HCI tax constitutional.²⁰⁸ Chief Justice Shepard, speaking for a majority of four justices, stated that taxation is a matter in which the courts should give deference to the legislature.²⁰⁹ In upholding the constitutionality of the HCI tax, he stated that article 10 requires uniformity within a particular taxing district, and not necessarily across the entire state.²¹⁰ "In light of the historic rule of local finance for local service in this field," stated Chief Justice Shepard, "we are not persuaded that the Constitution prohibits the legislature from matching burden with benefit."²¹¹

IV. PROVIDER LIABILITY

1. *St. Anthony Hospital v. United State Department of Health and Human Services*.—In *St. Anthony Hospital v. DHHS*, the United States Court of Appeals for the Tenth Circuit imposed a civil monetary penalty upon a hospital for

199. *Id.* at 719-20.

200. *Id.* at 721.

201. *Id.*

202. *Id.* at 720.

203. *Id.* at 722.

204. *Id.* at 722-23.

205. *Id.* at 723-24.

206. *Griffin v. Dep't Local Gov't Fin.*, 770 N.E.2d 957 (Ind. Tax Ct. 2002).

207. *Griffin v. Dep't Local Gov't Fin.*, 783 N.E.2d 696 (Ind. 2002). Transfer granted to Indiana Supreme Court September 19, 2002.

208. *Dep't of Local Gov't Fin. v. Griffin*, 784 N.E.2d 448 (Ind. 2003).

209. *Id.* at 452.

210. *Id.* at 455-56.

211. *Id.* at 457.

violation of the Emergency Medical Treatment and Labor Act's ("EMTALA") reverse dumping provision.²¹² In that case, a victim of an automobile accident was brought to a small rural hospital ("Shawnee").²¹³ When it was determined that Shawnee was unable to treat the victim, an attempt was made to transfer him to a larger urban hospital.²¹⁴ When that hospital refused to accept the transfer, an attempt was made to transfer him to St. Anthony Hospital ("St. Anthony").²¹⁵ St. Anthony refused the transfer, arguing that the victim should be cared for by the initial transferee hospital.²¹⁶

Allegations of EMTALA violations were initially brought against Shawnee, and the case was referred to a peer review organization.²¹⁷ Although Shawnee was afforded the opportunity to participate in the peer review process, no such opportunity was given to St. Anthony.²¹⁸ A civil monetary penalty was imposed upon St. Anthony for "reverse dumping," a term used to describe an impermissible refusal by a hospital to accept an EMTALA patient transfer.²¹⁹ The penalty was upheld throughout the administrative process, and St. Anthony appealed to the Tenth Circuit.²²⁰

The court held that, under 42 U.S.C. § 1395dd(d)(3), St. Anthony's was entitled to participate in the peer review process, acknowledging that peer review provides expert medical opinion "regarding whether the individual involved had an emergency medical condition, whether the individual's emergency medical condition was stabilized, whether the individual was transferred appropriately, and whether there were any medical utilization or quality of care issues involved in the case."²²¹ In spite of this error, the court found that St. Anthony was not prejudiced by its lack of participation in the peer review process. The court rejected St. Anthony's argument that its due process rights were violated, noting that "[t]he duty of establishing prejudice rests upon St. Anthony; . . . it falls far short of meeting its burden, arguing merely that its request for PRO review was denied and that its statutory and due process rights were violated."²²²

The *St. Anthony* case emphasizes the burden that rests upon the defendant hospital in administrative actions arising under EMTALA. Although the administrative process includes a number of safeguards that are intended to ensure the presence of Fifth Amendment Due Process, the failure of one of those safeguards does not necessarily prejudice the government's claim. The defendant hospital bears the burden of proving that such error was prejudicial

212. 309 F.3d 680, 686 (10th Cir. 2002).

213. *Id.* at 687.

214. *Id.*

215. *Id.* at 688.

216. *Id.*

217. *Id.*

218. *Id.* at 689.

219. *Id.*

220. *Id.* at 690.

221. *Id.* at 697.

222. *Id.* at 698-99 (citation omitted).

upon the outcome of the action.

2. *Jacobs v. Manhart*.—The Indiana Court of Appeals ruled twice on the constitutionality of occurrence-based statutes of limitations in the area of medical malpractice. The Indiana medical malpractice statute of limitations requires the plaintiff to file her claim within two years of the date of the alleged malpractice.²²³ The Indiana statute is “occurrence-based,” triggering the running of the period with the act by the physician, rather than “discovery-based,” as in some states, where the period begins to run with the discovery of the alleged malpractice by the plaintiff.²²⁴ In *Jacobs v. Manhart*, the court found the statute unconstitutional as applied to medical malpractice claims that were not reasonably discoverable until after the two-year period had expired.²²⁵ In *Jacobs*, the plaintiff filed a malpractice claim twenty-seven months after the alleged malpractice act.²²⁶ This, claimed the defendants, barred the plaintiff’s action.²²⁷

The court acknowledged that the plaintiff discovered her condition prior to the statute’s expiration and that plaintiff’s claim was made after the statute of limitations expired.²²⁸ Nonetheless, the court held that “looking at the totality of the circumstances giving rise to this claim, . . . it was a practical impossibility for Mrs. Manhart to assert her claim before expiration of the limitation period and . . . rigid application of the occurrence-based statute would deny her the meaningful opportunity to pursue her claim.”²²⁹ The court found that the plaintiff’s discovery of the malpractice did not take place until the plaintiff knew “facts that, in the exercise of reasonable diligence, should lead to the discovery of the alleged malpractice and the resulting injury.”²³⁰ In this case, that discovery did not occur with the plaintiff’s initial suspicions; rather, it occurred when a physician confirmed those suspicions.²³¹

3. *Johnson v. Gupta*.—The Indiana Court of Appeals upheld the constitutionality of the occurrence-based statute as applied to a defendant whose alleged malpractice was reasonably discoverable within the two-year period.²³² In that case, the defendant physician performed a surgical procedure on the plaintiff in September 1990.²³³ Following the surgical procedure, the plaintiff experienced medical problems which the physician assured her would subside.²³⁴ The plaintiff claimed that she did not discover the defendant’s malpractice until four years after her operation, when a different physician diagnosed her ailment

223. IND. CODE § 34-18-7-1 (2002).

224. See *Martin v. Richey*, 711 N.E.2d 1273, 1278 (Ind. 1999).

225. 770 N.E.2d 344, 355 (Ind. App. 2002).

226. *Id.* at 347-48.

227. *Id.* at 348.

228. *Id.* at 353.

229. *Id.* at 355.

230. *Id.* at 350.

231. *Id.* at 354.

232. *Johnson v. Gupta*, 762 N.E.2d 1280 (Ind. App. 2002).

233. *Id.*

234. *Id.*

as relating back to that operation, and failed to pursue a malpractice claim until the subsequent physician established a causal link between her symptoms and the alleged act of malpractice.²³⁵ The court refused to allow for a tolling of the statute until the establishment of such a causal link, noting that any judicial exception to the statute is intended to allow for a plaintiff who, with reasonable diligence, would be unable to discover the malpractice.²³⁶ In this case, the court reasoned that the plaintiff's knowledge of her immediate medical problems made the alleged malpractice reasonably discoverable immediately after the surgical procedure.²³⁷

The *Johnson* and *Jacobs* cases illustrate a continued tension between the existing occurrence-based statute of limitations and the judicially imposed discovery-based period. While *Johnson* seems to make clear that the occurrence-based statute is still the law, cases like *Jacobs* remind us that courts are willing to impose a discovery-based standard when justice so requires.

V. LABOR AND EMPLOYMENT CASES

In *Clackamas Gastroenterology Associates v. Wells*, the United States Supreme Court granted Clackamas Gastroenterology Associates, P.C. petition for writ of certiorari and ruled that the common-law element of control is the principal guidepost that should be used to determine whether physician-shareholders in a medical practice constitute employees for purposes of the Americans With Disabilities Act of 1990 ("ADA").²³⁸

Wells, an employee of Clackamas, brought an action against Clackamas alleging unlawful discrimination in violation of the ADA. Clackamas moved for summary judgment, arguing that it did not have fifteen or more employees for the twenty weeks required by the statute and therefore was not a covered entity as defined by the ADA.²³⁹ Wells argued that the physician-shareholders were employees of the professional corporation and that, therefore, the corporation met the minimum employee requirement necessary to be subject to the ADA. The court of appeals found in favor of Wells, holding that the physician-shareholders "actively participated in the management and operation of the medical practice and literally were employees of the corporation under employment agreements."²⁴⁰ As a result of the court's counting the physician-shareholders as employees, Clackamas had enough employees to qualify as a covered entity.

The circuits were split on whether shareholders in a professional corporation constitute employees for purposes of federal employment discrimination laws. In *EEOC v. Dowd & Dowd*, the Seventh Circuit applied an "economic realities"

235. *Id.* at 1282-83.

236. *Id.* at 1283.

237. *Id.*

238. *Clackamas Gastroenterology Assocs. v. Wells*, 123 S. Ct. 1673 (2003).

239. *Wells v. Clackamas Gastroenterology Assocs.*, 271 F.3d 903, 904 (9th Cir. 2001).

240. *Id.* at 906.

test in making its determination and held that shareholders do not constitute employees for purposes of discrimination laws.²⁴¹ The court stated, “[t]he role of a shareholder in a professional corporation is far more analogous to a partner in a partnership than it is to the shareholder of a general corporation.”²⁴² The Ninth Circuit in *Wells*, however, was more persuaded by the Second Circuit’s rejection of the “economic realities” test in *Hyland v. New Haven Radiology Associates*.²⁴³ The Second Circuit held that using the professional corporate form “precludes any examination designed to determine whether the entity is in fact a partnership.”²⁴⁴ Both the Second and Ninth Circuits reasoned that it was unfair to allow a professional corporation simultaneously to reap the tax and civil liability benefits of having corporate status and yet avoid being covered by the employment anti-discrimination laws by arguing it was a partnership.²⁴⁵

The Supreme Court resolved the split among the circuit courts by citing guidance published by the EEOC that outlines six factors that should be considered in determining whether shareholders-directors (or physician-shareholders, as in the *Clackamas* case) constitute employees. The six factors include:²⁴⁶

1. Whether the organization can hire or fire the individual or set the rules and regulations of the individual’s work;
2. Whether and, if so, to what extent the organization supervised the individual’s work;
3. Whether the individual reports to someone higher in the organization;
4. Whether and, if so, to what extent the individual is able to influence the organization;
5. Whether the parties intended that the individual be an employee, as expressed in written agreements and contracts; and
6. Whether the individual shares in the profits, losses, and liabilities of the organization.

The Supreme Court ultimately reversed the Ninth Circuit’s decision and remanded the case back to the lower court so a judgment could be rendered consistent with its ruling.

241. *EEOC v. Dowd & Dowd*, 736 F.2d 1177, 1178 (7th Cir. 1984).

242. *Id.*

243. *Wells*, 271 F.3d at 905.

244. *Id.* (quoting *Hyland v. New Haven Radiology Assoc., P.C.*, 794 F.2d 793, 798 (2d Cir. 1986)).

245. *Id.* at 905.

246. *Clackamas*, 123 S. Ct. at 1680.

VI. HEALTH CARE LEGISLATION

A. Modifications of County Hospital Statutes

Effective March 21, 2002, several significant legislative changes were adopted regarding hospitals established under Indiana Code title 16, articles 22 and 12.1. These changes affecting the organization and operation of county-owned hospitals and some instances amends statutes that have been in place for several decades. The newly revised statute eliminates the requirement that county hospital boards be composed of an equal balance of members from each major political party.²⁴⁷ In the case of boards composed of odd numbers of members, the previous requirement was that no more than a simple majority of members could be of the same political party. This statutory change reflects the culmination of nearly three decades of modifications to the county hospital statutes, which have minimized the direct influence of partisan politics in the management and organization of these hospitals. The statute also eliminates the requirement that some county hospital boards be composed in a manner to reflect representation on the board by residents from a certain city or town or from a particular trade or occupation.²⁴⁸ Both of these changes were enacted to provide the appointing authorities of county hospital boards greater flexibility in the selection of suitable board members. To further minimize the influence of partisan politics, the statute was also amended to preclude the appointing authority of the county hospital governing board from serving on that hospital's governing board, except for those hospitals organized under Indiana Code section 16-22-8 wherein the statute mandates service by the appointing authority on the hospital board.²⁴⁹

The statute also permits county hospitals to elect to have audits performed by an independent certified public accounting firm that is experienced in hospital matters.²⁵⁰ If performed, such an independent audit report must be kept on file at the hospital and a copy must be provided to the Indiana State Board of Accounts.²⁵¹ Further, the hospital electing to have an independent audit is required to provide written notice to the State Board of Accounts not less than 180 days prior to the beginning of the hospital's fiscal year in which the hospital elects to be audited by an independent certified public accounting firm.²⁵² For any fiscal year in which a county hospital does not use an independent certified public accounting firm, the State Board of Accounts must audit the hospital.²⁵³ This provision permits county hospitals to function like their not-for-profit and for-profit counterparts with regard to financial affairs.

247. IND. CODE § 16-22-2-2, 3.1 & 5-8 (2002).

248. *See id.*

249. *See id.* § 16-22-2-13.

250. *See id.* § 16-22-3-12(c).

251. *See id.*

252. *See id.* § 16-22-3-12(d).

253. *Id.* § 16-22-3-12(d).

Governing boards of county hospitals are also now permitted to enter into group purchasing agreements to purchase medical malpractice insurance with one or more county hospitals or city hospitals organized and operated under Indiana Code section 16-23-3-21.²⁵⁴

B. Establishment of Interstate Nurse Licensure Compact

Effective July 1, 2002, the General Assembly authorized the Interstate Nurse Licensure Compact for Indiana.²⁵⁵ This Act permits qualified nurses who are licensed in a state that has enacted the compact to practice nursing in any compact state. The Act reduces redundant licensing requirements of nurses who practice in multiple states.²⁵⁶ Compact states will recognize a nurse's license to practice registered nursing which has been issued by his or her home state, as authorizing him or her to practice as a registered nurse in any other compact state.²⁵⁷ This provision is applicable to a registered nurse or a licensed practical nurse.²⁵⁸ Licensure for either category of nurse is dependent upon meeting the home state's requirements for licensure and licensure renewal as well as satisfying all other applicable state laws and regulations.²⁵⁹ Any compact state may, in accordance with that state's due process laws, limit or revoke the multi-state licensure privilege of any nurse to practice in their state and may take any other actions under their applicable state laws necessary to protect the health and safety of their citizens.²⁶⁰ Actions taken by any state shall be reported to the administrator of the Coordinated Licensure Information System, which is a part of the Interstate Nurse Licensure Compact.²⁶¹ The administrator of the Coordinated Licensure Information System shall promptly notify the home state of any actions by any other states in the compact.²⁶² A nurse in a compact state may have licensure in only one compact state at a time issued by the home state.²⁶³ If a nurse changes his or her primary state of residence by moving from one compact state to another and if the nurse obtains a license from the new home state, the license from the former home state is no longer valid.²⁶⁴ However, if a nurse changes his or her primary state of residence by moving from a non-compact state to a compact state, and obtains a license from the new home state, the individual state license issued by the non-compact state is not affected

254. *See id.* § 16-22-3-21.

255. *See id.* § 25-23.2.

256. *See id.* § 25-23.2-1-0.5.

257. *See id.* § 25-23.2-2-1.

258. *Id.*

259. *Id.* § 25-23.2-2-1.

260. *Id.*

261. *Id.*

262. *Id.*

263. *Id.* § 25-23.2-3-2.

264. *Id.* § 25-23.2-3-4(a).

and remains in force.²⁶⁵ In addition, if a nurse changes his or her primary state of residence by moving from a compact state to a non-compact state, the license issued by the prior home state converts to an individual state license valid only in the former host home state without any companion licensure privilege to practice in other compact states as authorized by the statute.²⁶⁶

Either the licensing board of the home state or remote state will promptly report to the administrator of the Coordinated Licensure Information System any adverse actions against the licensee.²⁶⁷ A remote state may take adverse action affecting the multi-state licensure privilege to practice within that state.²⁶⁸ The home state has the authority to impose adverse action against the licensee based upon adverse action taken in a remote state or based upon a factual and legal basis for such action in the home state.²⁶⁹

In furtherance of the Interstate Compact, all party states will participate in a cooperative effort to coordinate data regarding all licensed registered nurses and licensed practical/vocational nurses in the system including information on the licensure and disciplinary history of each nurse as contributed by compact states.²⁷⁰ This will assist in multi-state coordination of nurse license and enforcement efforts.

C. Patient Reports and Records

House Enrolled Act 1200, effective July 1, 2002, modifies an existing statute compelling hospitals licensed under Indiana Code section 16-21 to file data reports with the Indiana State Department of Health. Now such reports will be filed not more than 120 days from the end of each calendar year with the Department or its designated contractor.²⁷¹ The report must contain inpatient and outpatient discharge information at the patient level in a format specified by the State Health Commissioner including length of stay, diagnosis and surgical procedures, date of admission, discharge or birth.²⁷² It also requires reporting of types of admission, admission source, gender, race, discharge disposition, type of payor, total charge for the patient's stay and the zip code of the patient's residence.²⁷³

By amending the statute, the State seeks to obtain more detailed information with regard to patient stays for the aggregation and accumulation of specific data for purposes of public health information. The information reported to the designated contractor is confidential as it relates to data personal to an individual

265. *Id.* § 25-23.2-3-4(b).

266. *Id.* § 25-23.2-3-4(c).

267. *Id.* § 25-23.2-4-2; *see also id.* § 25-23.2-6-2.

268. *Id.* § 25-23.2-4-4.

269. *Id.* § 25-23.2-4-6.

270. *Id.* § 25-23.2-6-1.

271. *Id.* § 16-21-6-6.

272. *Id.*

273. *Id.*

patient.²⁷⁴ The Department may not provide information or analysis that contains any information that personally identifies or may be used to identify a patient or consumer of health care services unless the Department determines such information is necessary for a public health activity.²⁷⁵ The information provided to the Department, except for personal identification data, must be open to public inspection and must be provided to the public by the Department upon request at the Department's actual cost.²⁷⁶

D. Expansion of Practice of Emergency Medical Technician and Advanced Emergency Medical Technicians

Effective July 1, 2002, Senate Enrolled Act 213 modified the existing practice parameters of emergency medical technicians and advanced emergency medical technicians who are certified under Indiana Code section 16-18 by permitting such individuals to administer epinephrine through an auto-injector to an individual who is experiencing symptoms of an allergic reaction or anaphylaxis.²⁷⁷ The Indiana Emergency Medical Services Commission under Indiana Code section 16-31-2-9 will establish the training and certification standards for the administration of epinephrine through an auto-injector.

VII. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT
PRIVACY REGULATIONS

In 1996, Congress passed the Health Insurance Portability and Accountability Act ("HIPAA") which addressed Insurance Portability, Fraud and Abuse and Medical Liability Reform, Administrative Simplification, Tax Related Health Provisions, and Group Health Plan Requirements.²⁷⁸ The Administrative Simplification provisions were further subdivided to reflect three concepts: (i) Electronic Transactions (Standards for Electronic Transactions and Code Sets); (ii) Data Security; and (iii) Privacy.

Congress delegated to the Secretary of Health and Human Services the responsibility of adopting regulations regarding the Electronic Transactions and Data Security, but reserved to Congress the right to adopt privacy legislation. HIPAA, however, did provide that if Congress did not adopt privacy legislation prior to August 21, 1999, the Secretary of Health and Human Services was authorized to adopt regulations governing the privacy of individually identifiable health information. Congress did not adopt privacy legislation by August 21, 1999, and the Secretary of Health and Human Services was left the responsibility of promulgating privacy regulations. The following is a discussion of the privacy regulations that have been issued by the Secretary of Health and Human Services

274. *Id.* § 16-21-6-7(c)(1)(A).

275. *Id.* § 16-21-6-7(d)(1).

276. *Id.* § 16-21-6-7(d)(2) & (3).

277. *Id.* § 16-31-3-23.

278. In the discussion of these regulations that follows, capitalized terms will generally have the same meanings as they are given in the privacy regulations promulgated pursuant to HIPAA.

under HIPAA.

A. Application to Covered Entity and Business Associates

The privacy regulations apply only to Covered Entities. Covered Entities include Health Plans, most Health Care Providers, and Health Care Clearinghouses. The regulations generally define a Health Plan as an individual or group plan that provides, or pays the cost of, medical care.²⁷⁹ A Health Care Provider is a provider of services as defined in 42 U.S.C. § 1395x(u), a provider of medical or health services as defined in 42 U.S.C. § 1395x(s), and any other person or organization who furnishes, bills or is paid for Health Care²⁸⁰ in the normal course of business.²⁸¹ However, only Health Care Providers who transmit Health Information (defined below) in electronic form in connection with a Transaction covered by the regulations governing Standards for Electronic Transactions and Code Sets are covered by the privacy regulations. A Health Care Clearinghouse is a public or private entity, including a billing service, repricing company, community health management information system or community Health Information system, and a “value-added” network or switch, that performs either of the following functions: 1) processes or facilitates the processing of Health Information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a Standard Transaction; or 2) receives a Standard Transaction from another entity and processes or facilitates the processing of Health Information into nonstandard format or nonstandard data content for the receiving entity.²⁸²

While the privacy regulations apply directly only to Covered Entities, the privacy regulations also affect the behavior of certain individuals and entities that perform services for Covered Entities. Such individuals and entities are referred to as Business Associates. A Business Associate is a person or entity who, on behalf of a Covered Entity, performs or assists in the performance of: (i) A function or activity involving the use or Disclosure of Individually Identifiable Health Information or a function regulated by the regulations; or (ii) providing legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to or for a Covered Entity,

279. Public Welfare, 45 C.F.R. § 160.103 (updated by Health Insurance Reform: Security Standards, 68 Fed. Reg. 8334 (Feb. 20, 2003)).

280. The privacy regulations define Health Care as

care, services, or supplies related to the health of an individual. Health Care includes, but is not limited to, the following: (1) preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an Individual or that affects the structure or function of the body; and (2) sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.

45 C.F.R. § 160.103.

281. *Id.*

282. *Id.*

where the provision of the service involves the Disclosure of Individually Identifiable Health Information from the Covered Entity, or from another business associate of the Covered Entity.²⁸³ However, members of the Covered Entity's Workforce²⁸⁴ are not Business Associates and Covered Entities that perform services for or on behalf of an organized health care arrangement²⁸⁵ are not Business Associates of the other Covered Entities participating in the Organized Health Care Arrangement.

B. Information Afforded Protection

By regulating Covered Entities and their relationships with Business Associates, the privacy regulations attempt to protect the Use and Disclosure of Protected Health Information. Health Information is "any information, whether

283. *Id.*

284. The regulations define "Workforce" as "employees, volunteers, trainees, and other persons whose conduct, in the performance of work for a Covered Entity, is under the direct control of such entity, whether or not they are paid by the Covered Entity." *Id.*

285. The regulations define an "Organized Health Care Arrangement" as:

(1) A clinically integrated care setting in which Individuals typically receive Health Care from more than one health care provider;

(2) An organized system of Health Care in which more than one Covered Entity participates, and in which the participating Covered Entities: (i) Hold themselves out to the public as participating in a joint arrangement; and (ii) Participate in joint activities that include at least one of the following: (A) Utilization review, in which health care decisions by participating Covered Entities are reviewed by other participating Covered Entities or by a third party on their behalf; (B) Quality assessment and improvement activities, in which Treatment provided by participating Covered Entities is assessed by other participating Covered Entities or by a third party on their behalf; or (C) Payment activities, if the financial risk for delivering Health Care is shared, in part or in whole, by participating Covered Entities through the joint arrangement and if Protected Health Information created or received by a Covered Entity is reviewed by other participating Covered Entities or by a third party on their behalf for the purpose of administering the sharing of financial risk;

(3) A Group Health Plan and a health insurance issuer or HMO with respect to such Group Health Plan, but only with respect to Protected Health Information created or received by such health insurance issuer or HMO that relates to Individuals who are or who have been participants or beneficiaries in such Group Health Plan;

(4) A Group Health Plan and one or more other Group Health Plans each of which are maintained by the same plan sponsor; or

(5) The Group Health Plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such Group Health Plans, but only with respect to Protected Health Information created or received by such health insurance issuers or HMOs that relates to Individuals who are or have been participants or beneficiaries in any of such Group Health Plans.

Id.

oral or recorded in any form or medium, that: 1) is created or received by a Health Care Provider, Health Plan, public health authority, employer, life insurer, school or university, or Health Care Clearinghouse; and 2) [r]elates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.”²⁸⁶ Individually Identifiable Health Information is “a subset of Health Information, including demographic information collected from an individual, and: 1) is created or received by a Health Care Provider, Health Plan, employer, or Health Care Clearinghouse; and 2) relates to the past, present, or future physical or mental health or condition of an individual; the provision of Health Care to an individual; or the past, present, or future payment for the provision of Health Care to an individual; and (i) [t]hat identifies the individual; or (ii) [w]ith respect to which there is a reasonable basis to believe the information can be used to identify the individual.”²⁸⁷ It is important to note that the definition of “Individually Identifiable Health Information,” while indicating it is a subset of Health Information, does specifically include demographic information that is arguably not included within the definition of Health Information.

What the regulations ultimately protect is “Protected Health Information.” Protected Health Information is a subset of Individually Identifiable Health Information.²⁸⁸ While the proposed regulations provided the type media by which information must be transmitted or maintained in order to be Protected Health Information, the definition in the final privacy regulations included the “catch-all” phrase “[t]ransmitted or maintained in any other form or medium.”²⁸⁹ The inclusion of this “catch-all” phrase renders the prior qualifications in the definition of no consequence, thus resulting in the definitions of Protected Health Information and Individually Identifiable Health Information being identical except for certain information regulated by laws protecting educational records and employment records held by a Covered Entity in its role as an employer.²⁹⁰

The privacy regulations contain provisions by which a Covered Entity can remove identifying information from Health Information and thus remove such information from the category of Protected Health Information.²⁹¹ In order to de-identify Health Information, a Covered Entity must remove elements from the information so that there is no reasonable basis by which the information can be used to identify an individual. A Covered Entity must establish that the information is de-identified in one of two ways. The first approach requires that “[a] person with appropriate knowledge of and experience with generally

286. *Id.*

287. *Id.*

288. *Id.* § 164.501.

289. *Id.*

290. *Id.* Section 164.501 specifically excludes from the definition of Protected Health Information: (i) Education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. § 1232g; and (ii) Records described at 20 U.S.C. § 1232g(a)(4)(B)(iv).

291. 45 C.F.R. § 164.514.

accepted statistical and scientific principles and methods for rendering information not individually identifiable: (i) [a]pplying such principles and methods, and determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and (ii) [d]ocuments the methods and results of the analysis that justify such determination."²⁹² The second approach requires that the Covered Entity remove a significant portion of identifying information, including, among many other things, names, all geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, all elements of dates (except year), as well as telephone numbers.²⁹³ Further, the Covered Entity must also not have any actual knowledge that the information could be used alone or in combination with other information to identify the individual who is the subject of the information. The regulations do provide a method by which a Covered Entity may maintain a method to re-identify the information when such information comes back within the control of the Covered Entity; however, the Covered Entity must not disclose the method for re-identification.²⁹⁴

C. Limitation on Use or Disclosure of Protected Information

A Covered Entity may not use or disclose Protected Health Information except as permitted by the regulations. In general, the regulations permit a Covered Entity to use or disclose Protected Health Information for the purposes of treatment, payment and health care operations ("TPO").²⁹⁵ However, the regulations further clarify that a Covered Entity may use or disclose Protected Health Information for treatment activities of another Health Care Provider or to another Covered Entity or Health Care Provider for the payment activities of the entity that receives the information. Additionally, a Covered Entity may use or disclose Protected Health Information for health care operations activities of the entity that receives the information, if each entity has had a relationship with the individual and the Protected Health Information pertains to such relationship. Lastly, where the Covered Entity participates in an Organized Health Care Arrangement ("OHCA"), it may disclose information to another Covered Entity that participates in the OHCA for any health care operation activities of the OHCA.²⁹⁶

Further, a Covered Entity may use or disclose Protected Health Information

292. *Id.* § 164.514(b)(1).

293. *Id.* § 164.514(b)(2).

294. *Id.* § 164.514(c).

295. See Appendix A for a definition of Treatment, Payment, or Health Care Operations.

296. 45 C.F.R. § 164.506(c).

that is incident to a use²⁹⁷ or disclosure²⁹⁸ otherwise permitted or required by the regulations, provided that the Covered Entity has complied with the minimum necessary standards, as well as the safeguard requirements with respect to such otherwise permitted or required use or disclosure.²⁹⁹ If a Covered Entity wants to use and disclose Protected Health Information for reasons other than those stated above, a Covered Entity must either obtain an authorization³⁰⁰ from the Individual or meet one of the several exceptions to the authorization requirements.³⁰¹

The regulations require that when a Covered Entity uses or discloses Protected Health Information or requests Protected Health Information, it must use reasonable efforts to limit such Disclosure, or request to the minimum information necessary to accomplish the intended purpose.³⁰² However, this requirement does not apply in instances where the Protected Health Information is disclosed to or requested by a Health Care Provider for treatment, requested by the Individual to whom the information relates, disclosed based on an authorization, made to the Secretary, or the Disclosure is required by law.³⁰³

In order to comply with the minimum necessary requirement of the privacy regulations, a Covered Entity must identify those persons or classes of persons in its Workforce who need access to Protected Health Information and designate which portions of the Protected Health Information are necessary to carry out their duties.³⁰⁴ Furthermore, reasonable efforts must be made by the Covered Entity to restrict access to Protected Health Information in accordance with these designations.³⁰⁵

If a Covered Entity must obtain an authorization to use or disclose Protected Health Information, the authorization must be in plain language,³⁰⁶ contain a clear and meaningful description of the information to be used or disclosed,³⁰⁷ identify the person or class of persons authorized to request the Use or Disclosure, and to whom the information may be disclosed.³⁰⁸ The authorization must further provide an expiration date or event,³⁰⁹ state that the Individual has the right to

297. The privacy regulations define "use" as "the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information." *Id.* § 164.501.

298. The privacy regulations define "Disclosure" as "the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information." *Id.*

299. *Id.* § 164.502(a)(1)(iii).

300. *Id.* § 164.508.

301. *Id.* § 164.512(a)-(1).

302. *Id.* § 164.514(d)(3)(1).

303. *Id.* § 164.502(b)(2).

304. *Id.* § 164.514(d)(2)(i)(A).

305. *Id.* § 164.514(d)(2)(ii).

306. *Id.* § 164.508(c).

307. *Id.* § 164.508(c)(1)(i).

308. *Id.* § 164.508(c)(1)(ii)-(iii).

309. *Id.* § 164.508(c)(1)(v).

revoke the authorization,³¹⁰ state that information disclosed may be subject to redisclosure by the recipient and no longer be protected,³¹¹ and state that the Covered Entity may not condition Treatment, Payment, enrollment, or eligibility for benefits on the authorization.³¹² Lastly, the authorization must describe the purpose of each requested Use or Disclosure,³¹³ and be signed by the Individual and dated.³¹⁴

Typically, if the Use or Disclosure does not meet one of the exceptions to obtaining an authorization, an authorization must be obtained prior to using or disclosing Protected Health Information. However, the privacy regulations do permit limited Uses and Disclosures in certain circumstances without an authorization. If the individual has been given an opportunity to agree or object, a covered Health Care Provider may use an Individual's name, location in the facility, general description, and religious affiliation for facility directory purposes.³¹⁵ However, the provider can only disclose the name, location, and condition (and not religious affiliation) to persons who ask for the Individual by name. The provider may disclose the religious affiliation of an Individual to a member of the clergy. In addition, a Covered Entity may disclose to a family member or friend Protected Health Information relevant to such person's involvement with the Individual's care or payment related to Health Care.³¹⁶

A Covered Entity may also use demographic information and dates of health care provided for purposes of fundraising for its own benefit (including the benefit of an institutionally related foundation without obtaining an authorization).³¹⁷ However, the fundraising materials must contain information informing the individual how to opt out of future fundraising solicitation efforts.³¹⁸ If a Covered Entity intends to use Protected Health Information for fundraising purposes, a statement that the Protected Health Information will be used for fundraising purposes must be contained in the Covered Entity's Privacy Notice.³¹⁹

A Covered Entity may utilize Protected Health Information to market products and services without an authorization if the marketing is in the form of: (i) a face-to-face encounter with the individual; or (ii) a promotional gift of nominal value.³²⁰ Otherwise, an authorization is required to use or disclose Protected Health Information for marketing. If the marketing involves direct or indirect remuneration to the Covered Entity from a third party, the authorization

310. *Id.* § 164.508(c)(2)(i).

311. *Id.* § 164.508(c)(2)(iii).

312. *Id.* § 164.508(c)(2)(ii).

313. *Id.* § 508(c)(1)(iv).

314. *Id.* § 508(c)(1)(vi).

315. *Id.* § 164.510(a).

316. *Id.* § 164.510(b).

317. *Id.* § 164.514(f).

318. *Id.* § 164.514(f)(2)(ii).

319. *Id.* § 164.514(f)(2)(i).

320. *Id.* § 164.508(a)(3).

must state that such remuneration is involved.

Lastly, “a Covered Entity may use or disclose a limited data set that meets the requirements” set forth in the privacy regulations without obtaining an authorization, if the Covered Entity enters into a data use agreement with the limited data recipient, and the use or disclosure is for Research, public health, or Health Care Operations purposes.³²¹

“A Covered Entity may use Protected Health Information to create a limited data set that meets the requirements” of the regulations, or “disclose Protected Health Information only to a Business Associate for such purpose,” regardless of whether “the limited data set is to be used by the Covered Entity.”³²² Also, “[a] Covered Entity may use or disclose a limited data set . . . only if the Covered Entity obtains satisfactory assurance, in the form of a data use agreement that meets the requirements of [the regulations], that the limited data set recipient will only use or disclose the Protected Health Information for limited purposes.”³²³ “A data use agreement between the Covered Entity and the limited data set recipient must establish the permitted Uses and Disclosures of such information by the limited data set recipient,”³²⁴ consistent with the purposes of Research, public health, or health care operations. Further, “the data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of [the regulations] if done by the Covered Entity,” must “establish who is permitted to use or receive the limited data set,” and must set forth the obligations of the limited data set recipient.³²⁵

Regardless of whether an authorization is necessary for Use or Disclosure of Protected Health Information, a Covered Entity that has a direct treatment relationship with an Individual (other than an inmate) must provide the Individual with a Notice of Privacy Practices that provides notice of how the Covered Entity will use and disclose the individual’s Protected Health Information,³²⁶ the individual’s rights, and the Covered Entity’s legal duties with respect to the Protected Health Information.³²⁷

D. Rights of Individuals Respecting Protected Information

As set forth in the elements of the Notice of Privacy Practices, the privacy regulations give Individuals certain rights with respect to Protected Health Information. First, “a Covered Entity must permit an individual to request that the Covered Entity restrict: uses and disclosures of Protected Health Information about the Individual to carry out” TPO, and Disclosures otherwise permitted

321. *Id.* § 164.514(e).

322. *Id.* § 164.514(2)(3)(ii).

323. *Id.* § 164.514(e)(4)(i).

324. *Id.* § 164.514(e)(4)(ii)(A).

325. *Id.* § 164.514 (e)(4).

326. *Id.* § 164.520(b)(1)(iv).

327. *Id.* § 164.520(b)(1)(v).

under the privacy regulations.³²⁸ However, a Covered Entity is not required to agree to a restriction.³²⁹

Second, an Individual also has the right of access “to inspect and obtain a copy of Protected Health Information about the Individual in a Designated Record Set,³³⁰ for as long as the Protected Health Information is maintained in the Designated Record Set,” except for Psychotherapy Notes, information compiled in anticipation of legal proceedings, and Protected Health Information maintained by a Covered Entity that is subject to the Clinical Laboratory Improvements Amendments of 1988.³³¹

Third, in addition to the right to request a restriction and the right of access, “an individual has the right to have a Covered Entity amend Protected Health Information or a record about the Individual in a Designated Record Set for as long as the Protected Health Information is maintained in the designated record set.”³³² “A Covered Entity may deny an individual’s request for amendment, if it determines that the Protected Health Information or record . . . was not created by the Covered Entity, unless the Individual provides a reasonable basis to believe that the originator of Protected Health Information is no longer available to act on the requested amendment; is not part of the Designated Record Set; would not be available for inspection” under the privacy regulations, or the record is accurate and complete.³³³

Lastly, an individual has the right “to receive an accounting of Disclosures of Protected Health Information made by a Covered Entity in the six years prior to the date on which the accounting is requested”; however, a Covered Entity is not required to include all Disclosures in the accounting.³³⁴ Importantly, a Covered Entity does not need to include disclosures to carry out TPO, to individuals of Protected Health Information about them, pursuant to an authorization, or that were incident to a Use or Disclosure otherwise permitted. Additionally, a Covered Entity can exclude Disclosures that are part of a limited data set.³³⁵

328. *Id.* § 164.522.

329. *Id.* § 164.522(a)(1)(ii).

330. A “Designated Record Set” is a group of records (any item, collection, or grouping of information that includes Protected Health Information and is maintained, collected, used or disseminated by or for a Covered Entity) maintained by the Covered Entity that is: the medical records and billing records about Individuals maintained by or for the provider; the enrollment, Payment, claims adjudication, and case management record systems maintained by or for a Health Plan; or is used, in whole or in part, by the Covered Entity to make decisions about Individuals.

331. 45 C.F.R. § 164.524.

332. *Id.* § 164.526(a).

333. *Id.* § 164.526(a)(2).

334. *Id.* § 164.528(a)(1).

335. *Id.* § 164.528(a)(i)–(iv).

E. Other Provisions

In order to complete the requirements of HIPAA, the privacy regulations state that “a Covered Entity must designate a privacy official who is responsible for the development and implementation of the policies and procedures of the entity” and that “a Covered Entity must designate a contact person or office who is responsible for receiving complaints” and providing information about matters covered by the Privacy Notice.³³⁶ Further, a Covered Entity must train all members, and subsequent members, of its workforce on the policies and procedures required by the privacy regulations with respect to the Protected Health Information.³³⁷ A Covered Entity must also “have in place appropriate administrative, technical, and physical safeguards to protect the privacy of Protected Health Information” from any “intentional or unintentional use or Disclosure that is in violation of the privacy regulations.”³³⁸ “A Covered Entity must provide a process for Individuals to make complaints concerning the Covered Entity’s policies and procedures . . . or its compliance with such policies and procedures,”³³⁹ and “a Covered Entity must have and apply appropriate sanctions against members of its Workforce who fail to comply with the privacy policies and procedures of the Covered Entity or the requirements” of the privacy regulations.³⁴⁰ Lastly, “a Covered Entity must implement policies and procedures with respect to Protected Health Information that are designed to comply” with the privacy regulations, and “change its policies and procedures as necessary and appropriate to comply with changes in the law.”³⁴¹

The transition provisions of the privacy regulations state that a Covered Entity may continue to use or disclose Protected Health Information “pursuant to an authorization or other express legal permission obtained from an Individual,” permitting the Use or Disclosure of Protected Health Information prior to the compliance date for the Covered Entity “provided that the authorization or other express legal permission specifically permits such Use and Disclosure and there is no agreed-to restriction.”³⁴² For contracts in place with Business Associates as of October 15, 2002, and that will not expire or will not be renegotiated before April 14, 2003, the requirement to include Business Associate contract language is extended by one year to April 14, 2004.³⁴³ Note, however, that the Covered Entity must nevertheless ensure that the Business Associate complies with all applicable requirements as of April 14, 2003. If a contract with a business associate is signed or renegotiated after October 15, 2002, the Covered Entity must have the business associate contract language in

336. *Id.* § 164.530(a).

337. *Id.* § 164.530(b).

338. *Id.* § 164.530(c).

339. *Id.* § 164.530(d).

340. *Id.* § 164.530(e).

341. *Id.* § 164.530(i).

342. *Id.* § 164.532.

343. *Id.* § 164.532(e).

place on or before April 14, 2003. "A covered Health Care Provider must comply with the applicable requirements" of the privacy regulations no later than April 14, 2003. Small Health Plans must comply by April 14, 2004.³⁴⁴

VIII. GENERAL HEALTH LAW

A. *Thompson v. Western States Medical Center*

In a case with immediate impact upon the relationship between physicians and pharmacists, the United States Supreme Court ruled that the Food and Drug Administration Modernization Act of 1997 ("FDAMA") which banned compounded drug advertising was a restriction of commercial speech prohibited by the First Amendment.³⁴⁵ Pharmacists challenged a portion of FDAMA that exempted compounded drugs from the FDA's standard drug approval process on the condition that the pharmacists refrain from advertising or promoting such drugs.³⁴⁶ Drug compounding is a process whereby a pharmacist "combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient."³⁴⁷ The government, concerned about the possibility of manufacturing disguised as compounding,³⁴⁸ defended its prohibition on the advertising of such drugs, arguing that such prohibition was supported by three substantial government interests: i) "preserving the effectiveness and integrity of the FDCA's new drug approval process and the protection of the public health that it provides"; ii) "preserving the availability of compounded drugs for those individual patients who, for particularized medical reasons, cannot use commercially available products that have been approved by the FDA"; and iii) "achieving the proper balance between those two independently compelling but competing interests."³⁴⁹

In an opinion authored by Justice O'Connor, the Court rejected these interests as insufficiently substantial to justify regulating this exercise of commercial speech. O'Connor stated that "the Government has failed to demonstrate that the speech restrictions are 'not more extensive than is necessary to serve those interests.'"³⁵⁰ She asserted, "[s]everal non-speech-related means of drawing a line between compounding and large-scale manufacturing might be possible here."³⁵¹ She commented in conclusion that "[i]f the First Amendment means anything, it means that regulating speech must be a last—not

344. *Id.* § 164.534 (as amended).

345. *Thompson v. Western States Med. Ctr.*, 122 S. Ct. 1497 (2002).

346. *Id.* at 1500.

347. *Id.*

348. *Id.* at 1501.

349. *Id.* at 1504.

350. *Id.* at 1506 (quoting *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980), a case that has been since used by the Court as the test for whether a regulation of commercial speech is constitutionally permissible).

351. *Id.*

first—resort.”³⁵² O’Connor stressed that this decision opens the door for increased communication between pharmacists and physicians as to compounding techniques that may help patients with specific pharmaceutical needs.³⁵³

B. Rush Prudential HMO, Inc. v. Moran

In the case of *Rush Prudential HMO, Inc. v. Moran*,³⁵⁴ the Supreme Court attempted to add clarity to the murky boundaries of the scope of the Employee Retirement Income Security Act of 1974 (“ERISA”)³⁵⁵ in preempting state laws. The specific issue before the Court was whether ERISA preempted a state statute, which provided participants in a health maintenance organization (“HMO”) with the right to an independent medical review of benefit denials related to the HMO’s determination that the services were not medically necessary.³⁵⁶ ERISA typically preempts state laws that alter the ERISA civil enforcement scheme, including claims for benefits. Holding that the state statute was not preempted, the Seventh Circuit Court of Appeals noted that although ERISA preempts all state laws that “relate to” employee benefit plans,³⁵⁷ the ERISA savings clause protects from preemption state laws, such as the law at issue, that “regulate insurance.”³⁵⁸ The Supreme Court granted certiorari to settle a conflict in the circuits.³⁵⁹

In this case, an HMO denied coverage for services rendered to a beneficiary on the grounds that such services were not “medically necessary.”³⁶⁰ Following the exhaustion of the internal appeals process, the beneficiary made a written demand for an independent medical review, which was guaranteed under state law.³⁶¹ The HMO failed to provide such independent review and the beneficiary

352. *Id.* at 1507.

353. *Id.* at 1509. O’Connor’s examples of such needs included a pharmacist serving a children’s hospital who could now inform the physicians about alternative ingestion methods for certain drugs and about methods for changing the taste of certain drugs through the addition of flavoring. *Id.* She noted, “The fact that the FDAMA would prohibit such seemingly useful speech even though doing so does not appear to directly further any asserted governmental objective confirms our belief that the prohibition is unconstitutional.” *Id.*

354. 536 U.S. 355 (2002).

355. 29 U.S.C. § 1001 (2000).

356. Illinois’ Health Maintenance Organization Act, 215 ILL. COMP. STAT., ch. 125, § 4-10 (2000).

357. 536 U.S. at 363-64 (citing 29 U.S.C. § 1144(a) (2000)).

358. *Id.* (citing 29 U.S.C. § 1144(b)(2)(A) (2000)).

359. *See Corporate Health Ins., Inc. v. Texas Dep’t of Ins.*, 215 F.3d 526 (5th Cir. 2000).

360. 536 U.S. at 359.

361. 215 ILL. COMP. STAT., ch. 125, § 4-10 (2000) states that each HMO must “provide a mechanism for timely review by a physician,” who holds the same class of license as the primary care physician (PCP) and is unaffiliated with the HMO, “in the event of a dispute between the [PCP] and the [HMO] regarding the medical necessity” of a recommended treatment. If the

sued in state court to compel the HMO's compliance with the state law. The state court ordered an independent review which determined that the services were medically necessary; however, the HMO continued to deny the claim. While the case was pending, the beneficiary proceeded with the treatment, and then amended her complaint to seek reimbursement. The HMO removed the case to federal court arguing that the amended complaint stated a claim under ERISA.³⁶²

The district court denied the beneficiary's claim on the grounds that the state statute was preempted by ERISA. The Seventh Circuit reversed and the Supreme Court affirmed on the grounds that, although the state statute clearly "related to" employee benefits plans for purposes of § 1144(a) of ERISA making it subject to preemption, the state statute also "regulates insurance" under both the "common-sense" test as outlined in *Pilot Life Ins. Co. v. Dedeaux*³⁶³ and the "guidepost" factors set forth in the McCarran-Ferguson Act.³⁶⁴ Specifically, in analyzing the McCarran-Ferguson factors, the Court held that the independent medical review required by the state statute clearly affected the "policy relationship" between the HMO and the beneficiary, and that the statute applied to entities in the insurance industry and did not apply to those entities outside the insurance industry.³⁶⁵ In upholding the Illinois statute allowing beneficiaries to seek an independent medical review of benefit denials that are based on medical necessity, the Court viewed the review of medical necessity determinations as more similar to a "second opinion" than an arbitration, which would be an enlargement of the civil enforcement scheme provided for under ERISA.³⁶⁶

In summing up its rationale for holding that the state statute was not preempted by ERISA, the Court noted that health care is "quintessentially" regulated by state law standards, and therefore, "there is no ERISA preemption without clear manifestation of congressional purpose."³⁶⁷ The Court went on to state that even if federal courts are faced with an increase in benefits litigation

independent physician determines that the treatment is medically necessary, the HMO must provide the covered service. 536 U.S. at 361.

362. 536 U.S. at 362.

363. 481 U.S. 41, 50 (1987).

364. 536 U.S. at 373. The McCarran-Ferguson Act, 15 U.S.C. §§ 1011-1015, prohibits a federal law from preempting a state law that regulates insurance. The Court stated, "[a]lthough this is not the place to plot the exact perimeter of the savings clause, it is generally fair to think of the combined 'common-sense' and McCarran-Ferguson factors as parsing the 'who' and the 'what': when insurers are regulated with respect to their insurance practices, the state law survives ERISA." *Id.* at 366. The three factors include whether the state statute (i) relates to a practice that spreads a policyholder's risk; (ii) regulates "an integral part of the policy relationship between the insurer and the insured"; or (iii) is limited to regulating entities "within the insurance industry." *Id.* at 373 (quoting *Union Labor Life Ins. Co. v. Pireno*, 458 U.S. 119, 129 (1982)).

365. *Id.* at 374.

366. Joel L. Michaels & Robin J. Bowen, *Rush to Judgment? An Analysis of Rush Prudential HMO, Inc. v. Moran*, HEALTH L. DIG., at 27 (Aug. 2002).

367. 536 U.S. at 387 (quoting *Pegram v. Herdrich*, 530 U.S. 211, 237 (2000)).

as a result of the state statute, "it would be an exaggeration to hold that the objectives of [ERISA] are undermined."³⁶⁸

Although a quick read of this decision leads one to believe that the previously blurred boundaries of ERISA preemption have been brought into focus, it has possibly just created another challenge for practitioners with regard to anticipating the permissible breadth of a state independent review and appeal process that will survive ERISA preemption under *Rush*.

CONCLUSION

During the survey period, there were several regulatory efforts aimed at curbing health care expenditures at the state and federal level. These efforts have increasingly been combined with regulatory initiatives either to increase enforcement in the area of fraud and abuse or to narrow or clarify existing regulations. Practitioners would be well advised to confer with their health care clients to structure their business affairs to comport with pervasive and complex regulatory requirements affecting health care.

368. *Id.*

