

SURVEY OF RECENT DEVELOPMENTS IN HEALTH CARE LAW

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INTRODUCTION

Arguably, no other period since the adoption of the Social Security Act in 1965 has seen more developments in health care law than 2009-10. Health care is always an evolving and changing body of law at both the state and federal levels. But 2010 saw President Obama sign the Patient Protection and Affordable Care Act into law—a truly sweeping change in our nation’s health care system. Although not an exhaustive review, this Survey summarizes many of the recent and more significant developments in various areas of health law, including fraud and abuse, labor and employment, tax, health information technology, and privacy rights.

I. HEALTH CARE REFORM

The Patient Protection and Affordable Care Act¹ and the Health Care and Education Reconciliation Act of 2010² are the result of a decade-long effort by various interests to reform the United States health care system (referred to collectively as the “PPACA”). In what began life as a campaign promise of President Obama, then taking on several iterations before being signed into law on March 23, 2010, the PPACA is a true behemoth of federal legislation. Generally speaking, the PPACA was designed to target the areas of access, cost, and quality.³

Although the legislative process for such expansive legislation may have outwardly seemed efficient given the compressed time period in which the PPACA was adopted, it was not without controversy. Namely, there was significant dispute regarding whether there would be a public health insurance option, how health insurance exchanges would be structured, concerns over federal funding for abortion coverage, and the use of circuitous parliamentary

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1. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (to be codified at 42 U.S.C. §1320a-7a).

2. Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029.

3. While the cited policy and legislative bases are numerous, the Obama administration generally touts the laws as giving all Americans “better health security by putting into place comprehensive health insurance reforms that help to hold insurance companies accountable, lower health care costs, guarantee more choice, and enhance the quality of care for all Americans.” U.S. DEP’T. OF HEALTH & HUMAN SERVS., THE AFFORDABLE CARE ACT—WHAT IT MEANS FOR YOU 1 (2010), *available at* http://www.healthcare.gov/center/brochures/for_you.pdf.

procedure. In the end, the PPACA was adopted relying solely on Democrat support.⁴

The PPACA contains significant expansions of health care access and insurance coverage for most Americans and adds numerous provisions that address federal health care program integrity and reimbursement restructuring. While this survey focuses on many developments in health care law (as they may impact providers), many provisions of the law reach beyond providers.⁵ Significant provisions include the following:

- (1) increased access and coverage to health care through various insurance market reforms ranging from a prohibition on lifetime coverage limits, insurance rescission, and preexisting condition exclusion;⁶
- (2) creation of American Health Benefit Exchanges and Small Business Health Options Program Exchanges in each state to facilitate individual and small employers to purchase qualified health plans;⁷
- (3) penalties for individuals who fail to have minimum essential health insurance coverage for themselves or their dependents;⁸
- (4) significant expansion of individuals eligible for coverage under Medicaid;⁹
- (5) accelerated Medicare and Medicaid reimbursement reform;¹⁰
- (6) narrowed definition of the so-called Medicare Part D drug benefit “donut hole”;¹¹
- (7) significant improvements in health care workforce development;¹² and
- (8) enhancement and extension of the federal government’s fraud and abuse capabilities and providers’ program integrity obligations.¹³

As may be expected with legislation that is both far-reaching and controversial, many legal challenges followed the PPACA’s enactment. During the preparation of this Survey, no fewer than twenty seven states sued or joined in litigation

4. See *U.S. Senate Roll Call Votes 111th Congress—1st Session*, U.S. SENATE, http://www.senate.gov/legislative/LIS/roll_call_lists/roll_call_vote_cfm.cfm?congress=111&session=1&vote=00396 (last visited Aug. 2, 2011) (showing voting summary for the PPACA).

5. Given the scope and breadth of the PPACA, this Survey focuses on many of the more significant provisions that impact health care providers of all types and does not discuss many provisions within the PPACA such as insurance market reform, affordability of coverage, Medicare Part D improvements, disease prevention, and wellness, among others.

6. See generally Patient Protection and Affordable Care Act §§ 1101-05.

7. *Id.* §§ 1301-43.

8. *Id.* §§ 1501-15.

9. *Id.* §§ 2001-07.

10. *Id.* §§ 2001-07, 3001-27.

11. *Id.* §§ 2301-04.

12. *Id.* §§ 5001-701.

13. *Id.* §§ 6001-801.

against the federal government challenging the constitutionality of PPACA—with others, including the U.S. Supreme Court, expected to also intervene.¹⁴ Constitutional scholars appear to be evenly split on the merits and likelihood of success of these challenges, which are based substantially on whether the individual mandate to obtain minimum essential health insurance coverage is constitutional.

II. FRAUD & ABUSE

A. *Expansion of the False Claims Act*

2009 ushered in many changes to health care fraud and abuse laws, the most significant of which can be found in the federal False Claims Act (FCA).¹⁵ The FCA is the most widely utilized enforcement tool of the Department of Justice. On May 20, 2009, the strength of the FCA was enhanced by the passage of the Fraud Enforcement and Recovery Act (FERA).¹⁶ Some of the key impacts that FERA had on the FCA include:

1. *Obligation to Repay.*—Before the passage of FERA, there was much debate over what constituted an obligation to repay funds. FERA clarifies that failure to repay any known overpayment constitutes a false claims violation.¹⁷ The PPACA further clarified what constitutes an obligation to repay by defining “obligation” to require the return of all known overpayments within sixty days of the identification of the overpayment.¹⁸

2. *Reverse False Claim.*—One of the most significant changes of FERA is the establishment of the “reverse false claim.” Ignoring or decreasing an obligation to repay monies owed to the government now constitutes a false claim.¹⁹

3. *Request for Payment Does Not Need to Be Submitted Directly to the Government.*—FERA clarifies that a party does not need to submit a claim directly to, or deal directly with, the federal government in order to trigger a violation of the FCA. Rather, the FCA is triggered whenever a person knowingly makes a false claim to obtain money or property—any part of which is provided by the government—without regard to whether the wrongdoer deals directly with the federal government, with an agent acting on the government’s behalf, or with a third-party contractor, grantee or other recipient of such money or property.²⁰ Previously, a claim needed to be presented to an officer or employee of the

14. See Florida *ex rel.* Bondi v. U.S. Dep’t of Health & Human Servs., No. 3:10-CV-91-RV/EMT, 2011 WL 723117 (N.D. Fla. Mar. 3, 2011); see also Virginia *ex rel.* Cuccinelli v. Sebelius, 728 F. Supp. 2d 768 (E.D. Va. 2010).

15. False Claims Act, 31 U.S.C. §§ 3729-31 (West, Westlaw through 2011 legislation).

16. Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-121, 123 Stat. 1617.

17. 31 U.S.C. § 3729(b)(1)-(3) (West, Westlaw through 2011 legislation).

18. Patient Protection and Affordable Care Act § 1128J(d)(2).

19. 31 U.S.C. § 3729(a)(1)(G).

20. *Id.* § 3729(a)(1)(D).

federal government in order for the FCA to be triggered. It remains to be seen how far downstream the government will reach into a financial relationship involving federal funds to allege a violation of the FCA.

4. *Eliminating the Defenses.*—As indicated above, prior to the enactment of FERA, a claim needed to be submitted directly to the federal government in order for the FCA to be triggered. The requirement that the claim be submitted directly to the government served as the basis for the intent requirement in the U.S. Supreme Court decision *Allison Engines Co. v. United States ex rel. Sanders*.²¹ FERA clarifies that a statement only needs to have a “natural tendency to influence, or be capable of influencing,”²² the payment of government funds.

5. *Whistleblower Protections.*—The whistleblower protections under the FCA were greatly expanded to cover not only employees, but also contractors or agents. Specifically, 31 U.S.C. § 3730(h) now provides that

[a]ny employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any manner discriminated against in the terms and conditions of employment because of lawful acts done by the employee, contractor, agent, or associated others in furtherance of an action under this section or other efforts to stop . . . [one] or more violations²³

This revision goes to the underlying purpose of FCA, which is to foster the disclosure of fraud and abuse.²⁴

There are still many open issues with regard to how the FCA will be interpreted. For example, FERA does not establish when a payment becomes a “known” overpayment, prompting the following question: is it the point when the parties discover the potential overpayment? Further, if due to a Stark violation, is it when the potentially noncompliant relationship is discovered, or is it after the parties complete their research and affirmatively conclude that a Stark violation occurred? Additionally, the process for establishing a repayment has not yet been determined.

B. *OIG'S Exclusionary Authority*

Under Section 1128 of the Social Security Act (SSA), the Office of Inspector General (OIG) has the ability to exclude entities and individuals from participating in federal health care programs via mandatory and permissive

21. 553 U.S. 662, 668 (2008) (“Eliminating this element of intent, as the [c]ourt of [a]ppeals did, would expand the FCA well beyond its intended role of combating ‘fraud against the [g]overnment.’”).

22. False Claims Act, 31 U.S.C. § 3729(b)(4) (West, Westlaw through 2011 legislation).

23. 31 U.S.C. § 3730(h)(1) (2010).

24. See, e.g., *Why the False Claims Act?*, FALSE CLAIMS ACT LEGAL CTR., <http://www.taf.org/whyfca.htm> (last visited Aug. 2, 2011).

exclusionary authority.²⁵ The SSA identifies criteria that, if met, are grounds for exclusion from participation in federal health care programs.²⁶ Mandatory criteria generally include convictions of patient abuse or neglect, felonies relating to health care fraud, and criminal offenses related to Medicare or state health care programs.²⁷ The permissive criteria under the SSA give the OIG the ability to exclude individuals and entities for a number of reasons.²⁸ The PPACA expands the list of permissive criteria that may be considered, as outlined below.

First, a new subsection was added to 42 U.S.C. 1320a-7(b), permitting the OIG to exclude

[a]ny individual or entity that knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program . . . and entities that apply to participate as providers of services or suppliers in such managed care organizations and such plans.²⁹

Section 1128(c)(3)(B) of the SSA addresses when an exclusion may go into effect. It also outlines the duration of the exclusion and grants the Secretary of Health and Human Services (the “Secretary”) the ability to grant a waiver exclusion under certain circumstances.³⁰ Prior to the PPACA, this section waived the provider’s exclusion if it could be demonstrated that the exclusion would impose a hardship on beneficiaries under Medicare Parts A or B.³¹ Now, the exception applies if the exclusion would impose hardship on beneficiaries under any federal health care program,³² thus broadening the exclusion exception.

Section 1128(b)(11) of the SSA formerly allowed the Secretary to exclude

[a]ny individual or entity furnishing items or services for which payment may be made under subchapter XVIII of this chapter or a State health care program that fails to provide such information as the Secretary or the appropriate State agency finds necessary to determine whether such payments are or were due and the amounts thereof, or has refused to permit such examination of its records by or on behalf of the Secretary or that agency as may be necessary to verify such information.³³

The PPACA broadens the scope of this statute to apply not only to the entity

25. 42 U.S.C. § 1320a-7 (2010).

26. *Id.* § 1320a-7(a)(1)-(4).

27. *Id.*

28. *Id.* § 1320a-7(b)(1)-(16).

29. *Id.* § 1320a-7(b)(16); *see also* Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 5001-701, 124 Stat. 119 (2010) (to be codified at 42 U.S.C. § 1320).

30. 42 U.S.C. § 1320a-7(c)(3)(B).

31. *See* JOHN T. BRENNAN, JR. & ROBERT G. HOMCHICK, FRAUD AND ABUSE IN HEALTH CARE REFORM 2-3 (2010).

32. Patient Protection and Affordable Care Act § 6402(k).

33. 42 U.S.C. § 1320a-7(b)(11) (2006).

furnishing the service, but to persons “ordering, referring for furnishing, or certifying the need for items or services for which payment may be made” under a federal or state health care program.³⁴ This amendment is effective for any referrals, orders, and certifications made on or after January 1, 2010.³⁵

Section 6408(c) of the PPACA amended 42 U.S.C. § 1320a-7(b)(2) of the SSA, which gives the OIG the ability to exclude an “individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation” into a criminal offense related to health care fraud, or those activities that constitute grounds for mandatory exclusion.³⁶ This provision was revised to apply not only to criminal investigations, but also to investigations regarding the “use of funds received, directly or indirectly, from any Federal health care program.”³⁷

C. Stark Law Update

The federal Stark Law prohibits a physician from making a referral to an entity for the furnishing of certain “designated health services” (DHS)³⁸ for which payment may be made under Medicare if such physician (or the immediate family member of such physician) has a “financial relationship” with the DHS entity, unless an exception applies.³⁹ Further, the DHS entity may not bill Medicare for DHS furnished pursuant to a prohibited referral, unless one of the Stark exceptions applies.⁴⁰

1. *Overview.*—As part of the PPACA, the Centers for Medicare and Medicaid Services (CMS) recently released final regulations implementing several changes to the federal Stark Law. First, the PPACA amended the Stark Law to further restrict the ability of physicians to own an interest in hospitals to which they refer.⁴¹ Second, the PPACA amended the Stark Law’s in-office ancillary services exception by adding new patient disclosure requirements.⁴² The PPACA also established a new “self-referral disclosure protocol” for actual or potential Stark Law violations.⁴³

2. *Changes to Physician-Owned Hospital Exceptions.*—Section 6001(a)(3) of the PPACA recommended a new § 1877(i) to the SSA, imposing a number of

34. Patient Protection and Affordable Care Act § 6406(c).

35. *Id.* § 6406(d).

36. 42 U.S.C. § 1320a-7(b)(2) (2010).

37. Patient Protection and Affordable Care Act § 6408(c).

38. 42 U.S.C. § 1395nn(h)(6) (West, Westlaw current through 2011). The term “designated health services” includes such items as radiology, clinical laboratory services, physical and occupational therapy services, inpatient and outpatient hospital services, and durable medical equipment and supplies. *Id.*

39. *See generally id.*

40. *Id.*

41. Patient Protection and Affordable Care Act § 6001.

42. *Id.* § 6003.

43. *Id.* § 6409(a)(1).

new requirements for a hospital to meet in order to qualify for an exception to the prohibition of physician ownership of rural providers and hospitals.⁴⁴ Most notably, this addition prohibits expansion of physician-owned hospitals that rely on the “whole hospital” or “rural provider” exceptions in order to comply with the law.⁴⁵ CMS recently issued the final regulations implementing these changes to the “whole hospital” and “rural provider” exceptions.⁴⁶ Hospitals must be in compliance with the requirements below no later than September 23, 2011.⁴⁷ Notably, the PPACA provided for requirements to be put into place that would permit expansion of certain applicable hospitals and high-Medicaid facilities to be implemented by August 1, 2011,⁴⁸ but CMS has not yet issued final regulations implementing such requirements.

a. General requirements.—The following general requirements have accompanied the changes to this portion of the law:

(1) The hospital must have been physician-owned as of December 31, 2010 with a valid Medicare provider agreement in effect as of such date.⁴⁹

(2) The hospital is not permitted to increase the number of operating rooms, procedure rooms, and beds beyond the number for which it was licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect after such date but before December 31, 2010, the effective date of such agreement).⁵⁰ “Procedure room means a room in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include an emergency room or department (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).”⁵¹

(3) The hospital cannot have previously operated as an ambulatory surgical center and converted to a hospital on or after March 23, 2010.⁵²

b. Conflicts of interest.—To address conflicts of interest, the following changes were also proposed:

44. *Id.* § 6001(a)(3).

45. *Id.*

46. *See* Regulations Ensuring Bona-Fide Investment, 75 Fed. Reg. 72,249, 72,249-56 (Nov. 24, 2010); Exceptions to the Referral Prohibition Related to Ownership or Investment Interests, 75 Fed. Reg. 72,260, 72,260 (Nov. 24, 2010) (citing 42 C.F.R. § 411.356(3)(iv) (2011)).

47. Exceptions to the Referral Prohibition Related to Ownership or Investment Interests, 75 Fed. Reg. at 72,260.

48. Patient Protection and Affordable Care Act § 6001(a)(3)(A)(iii).

49. Additional Requirements Concerning Physician Ownership and Investment in Hospitals, 75 Fed. Reg. 72,260, 72,260 (citing 42 C.F.R. § 411.362(b)(1)).

50. *Id.* (citing 42 C.F.R. § 411.362(b)(2)).

51. *Id.* (citing 42 C.F.R. § 411.362(a)).

52. *Id.* at 72,261(citing 42 C.F.R. § 411.362(b)(6)).

(1) In order to protect patients from a potential conflict of interest arising from ownership by referring physicians, CMS will require each hospital to submit a report on an annual basis describing the identity of ownership and the nature and extent of all physician ownership in the hospital.

(2) Not later than September 23, 2011, the hospital must require physician-owners to disclose in writing to patients referred to the hospital such ownership or investment interest in the hospital as a condition of medical staff membership. Such disclosure shall also include, if applicable, the ownership or investment interest of any treating physician. The required disclosure must be made at such time as to provide the patient the opportunity “to make a meaningful decision regarding the receipt of care” from such physician and hospital.⁵³

(3) The hospital cannot condition physician ownership or investment directly or indirectly on the physician “making or influencing referrals to the hospital or otherwise generating business for the hospital.”⁵⁴

(4) Not later than September 23, 2011, the hospital must provide disclosure of its physician ownership on the hospital website and in any public advertising.⁵⁵

c. Ensuring bona fide investment.—In order to show that a bona fide investment by physician-owners exists, the following criteria must be met:

(1) There may be no increase in the aggregate percentage of physician ownership or investment in the hospital (or in an entity whose assets include the hospital) from the percentage that existed as of March 23, 2010.⁵⁶

(2) A hospital may not offer ownership or investment in the hospital to a physician on more favorable terms than those which would be offered to non-physicians.⁵⁷

(3) The hospital (or any owner or investor in the hospital) does not provide loans or financing for investment in the hospital by a physician.⁵⁸

(4) The hospital (or any owner or investor in the hospital) does not guarantee a loan or make a payment toward a loan for any individual physician or group of physicians if the loan is geared toward acquiring any ownership or investment interest in the hospital.⁵⁹

(4) Distributions are made to owners or investors in the hospital in an

53. *Id.* (citing 42 C.F.R. § 411.362(b)(3)(ii)(A)).

54. *Id.* (citing 42 C.F.R. § 411.362(b)(3)(ii)(B)).

55. *Id.* (citing 42 C.F.R. § 411.362(b)(3)(ii)(C) (2011)).

56. *Id.* (citing 42 C.F.R. § 411.362(b)(4)(i)).

57. *Id.* (citing 42 C.F.R. § 411.362(b)(4)(ii)).

58. *Id.* (citing 42 C.F.R. § 411.362(b)(4)(iii)).

59. *Id.* (citing 42 C.F.R. § 411.362(b)(4)(iv)).

amount that is “directly proportional to the ownership or investment interest of such owner or investor in the hospital.”⁶⁰

(5) Physician owners or investors do not receive a guaranteed receipt of or right to purchase other business interests related to the hospital, such as real property.⁶¹

(6) “The hospital does not offer a physician owner or investor the opportunity to purchase or lease property . . . on more favorable terms than the terms offered to an individual who is not a physician.”⁶²

*d. Patient safety.*⁶³—With patient safety becoming an ever-increasing concern, the regulations address the issue as follows:

(1) Effective September 23, 2011, if a physician is not available on site at the hospital during all hours in which the hospital is providing patient care services, the hospital must disclose this information to the patient. Such disclosure (and written acknowledgement of the receipt of the disclosure by the patient) must be received prior to providing services to the patient.⁶⁴

(2) Effective September 23, 2011, the hospital must have the capacity to provide initial assessments and treatment for patients, and it must have made arrangements to refer or transfer patients who require other services not provided by that hospital.⁶⁵

3. *Physician Disclosure Requirements for MRI, CT, and PET.*—Section 6003 of the PPACA amended the federal Stark Law statutory exception for in-office ancillary services to require physicians to provide patients with written notice, at the time of the referral for certain imaging services, that such services may be obtained by a person or entity other than the physician or that physician’s group. Such imaging services include magnetic resonance imaging (MRI), computed tomography (CT), and positron emission tomography (PET), as well as other DHS as designated by the Secretary of Health and Human Services.⁶⁶ The PPACA further requires a referring physician to provide a list of alternate suppliers who provide these imaging services in the local area.⁶⁷ CMS recently issued the final regulations implanting these changes to the in-office ancillary services exception, effective January 1, 2011.⁶⁸

60. *Id.* (citing 42 C.F.R. § 411.362(b)(4)(v)).

61. *Id.* (citing 42 C.F.R. § 411.362(b)(4)(vi)).

62. *Id.* (quoting 42 C.F.R. § 411.362(b)(4)(vii)).

63. *Id.* (citing 42 C.F.R. § 411.362(b)(5)).

64. *Id.* (citing 42 C.F.R. § 411.362(b)(5)(i)).

65. *Id.* at 72,260-61 (citing 42 C.F.R. § 411.362(b)(5)(ii)).

66. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 6003(a), 124 Stat. 119 (2010).

67. *Id.*

68. Disclosure Requirements for In-Office Ancillary Services Exception to the Prohibition on Physician Self-Referral for Certain Imaging Services, 75 Fed. Reg. 73,443, 73,443 (Nov. 29,

a. Services triggering disclosure.—As noted above, the PPACA provided that the new disclosure requirements apply to MRI, CT, and PET services as well as such other radiology or imaging services as the Secretary determines appropriate.⁶⁹ CMS declined to expand the list of services in the final regulations and limited the disclosure requirements to MRI, CT, and PET services that are “identified as ‘radiology and certain other imaging services’ on the [l]ist of DHS CPT/HCPCS [c]odes.”⁷⁰

b. Form/timing of notice.—The required notice “should be written in a manner sufficient to be reasonably understood by all patients” and be given to the patient “at the time of the referral.”⁷¹ Importantly, there is no exception to the disclosure requirement for MRI, CT, or PET services furnished on an “emergency or time-sensitive” basis.⁷² Where there are subsequent referrals for advance imaging services by such physician, separate notices must be provided to the patient.⁷³ If the referrals are by phone, the obligation to provide a written disclosure still exists, but it may be mailed or emailed to the patient once the patient has been notified verbally.⁷⁴

The notice must indicate to the patient that the services may be obtained from a person or entity other than the referring physician or physician’s group practice and include a list of other suppliers who provide the service being referred.⁷⁵

c. Types and number of suppliers.—Suppliers must be “located within a 25-mile radius of the physician’s office at the time of the referral” regardless of whether the office is in an urban or rural area, and the list must include no fewer than five alternative suppliers.⁷⁶ If there are not five other suppliers in the 25-mile radius, the physician must supply a list of all alternative imaging services providers within such area.⁷⁷ If there are no qualifying suppliers within this radius, the physician is not required to provide a list, but he must still notify the patient that the services may be provided by another supplier, and he must

2010); Financial Relationships Between Physicians and Entities Furnishing Designated Health Service, 75 Fed. Reg. 73,616, 73,616 (Nov. 29, 2010) (citing 42 C.F.R. § 411.355).

69. Patient Protection and Affordable Care Act § 6003(a).

70. General Exceptions to the Referral Prohibition Related to Both Ownership/Investment and Compensation, 75 Fed. Reg. at 73,616 (citing 42 C.F.R. § 411.355(b)(7)(i)); *see also Code List for Certain Designated Health Services (DHS)*, CTRS. FOR MEDICARE & MEDICAID SERVS., http://www.cms.gov/PhysicianSelfReferral/40_List_of_Codes.asp#TopOfPage (last visited Aug. 3, 2011).

71. Disclosure Requirement for Certain Imaging Services, 75 Fed. Reg. at 73,616 (citing 42 C.F.R. § 411.355(b)(7)(i)).

72. *See id.*

73. General Disclosure Requirements, 75 Fed. Reg. at 73,445.

74. *Id.*

75. Disclosure Requirement for Certain Imaging Services, 75 Fed. Reg. at 73,616 (citing 42 C.F.R. § 411.355(b)(7)(i)).

76. List of Alternate Suppliers, 75 Fed. Reg. at 73,445 (citing 42 C.F.R. § 411.355(b)(7)(i)).

77. *Id.* (citing 42 C.F.R. § 411.355(b)(7)(ii)).

document the disclosure.⁷⁸ The list of suppliers must include the “name, address, [and phone] number” of each supplier at the time of the referral.⁷⁹

*d. Documentation.*⁸⁰—No patient signature is required to document that the disclosure requirements have been satisfied.⁸¹ However, CMS advises that “physicians should be able to document or otherwise establish that they have complied with the disclosure requirement.”⁸²

4. *CMS Issues Stark Law Voluntary Disclosure Protocol.*—Section 6409 of the PPACA required the Secretary to develop a protocol, in cooperation with the Office of Inspector General (OIG) of the Department of Health and Human Services, to enable health care providers “to disclose an actual or potential violation of” the federal Stark Law.⁸³ On September 23, 2010, CMS published the Self-Referral Disclosure Protocol (the “Protocol”) online.⁸⁴

Importantly, the PPACA authorized the Secretary to reduce payment and penalty amounts for violations of the Stark Law.⁸⁵ In determining the amount due for a violation, the Secretary was instructed to consider (i) “[t]he nature and extent of the improper or illegal practice”; (ii) “[t]he timeliness of such self-disclosure”; (iii) the provider’s cooperation in supplementing information as needed; and (iv) any “other factors” the Secretary deems appropriate.⁸⁶

The PPACA also established a deadline for reporting and returning overpayments by the later of: (1) “[sixty] days after the date on which the overpayment was identified”⁸⁷ or (2) “the date any corresponding cost report is due, if applicable.”⁸⁸ Importantly, such sixty-day period is tolled at the time the provider receives e-mail confirmation from CMS that the disclosure has been received.

a. In general.—The Protocol is available to all health care providers and suppliers (collectively, “Disclosing Parties”), including Disclosing Parties already subject to government investigation.⁸⁹ Failure to fully cooperate in the self-disclosure process or “to circumvent an ongoing [government] inquiry” will result in removal from the Protocol.⁹⁰

78. *Id.*

79. *Id.* (citing 42 C.F.R. § 411.355(c)).

80. Documentation of Disclosure, 75 Fed. Reg. 73, 447 (Nov. 29, 2010).

81. *Id.*

82. *Id.*

83. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 6409(a)(1), 124 Stat. 119 (2010).

84. CTRS. FOR MEDICARE & MEDICAID SERVS., CMS VOLUNTARY SELF-DISCLOSURE PROTOCOL, (2010), available at http://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf [hereinafter SELF-REFERRAL DISCLOSURE PROTOCOL].

85. Patient Protection and Affordable Care Act § 6409(b).

86. *Id.* § 6409(b)(1)-(4).

87. *Id.* § 1125J(d)(2)(A).

88. *Id.* § 1128J(d)(2)(B).

89. SELF-REFERRAL DISCLOSURE PROTOCOL, *supra* note 84, at 2.

90. *Id.*

The Protocol is not intended as an advisory process by CMS or to determine “whether an actual or potential violation” of the Stark Law exists.⁹¹ Rather, submissions under the Protocol should be made to resolve liability for actual or potential violations.⁹²

CMS will review the circumstances surrounding the disclosed matter but “is not bound by any conclusions made by the [D]isclosing [P]arty under . . . [this protocol] and is not obligated to resolve the matter in any particular manner.”⁹³ Medicare contractors may be responsible for processing any identified overpayment, and Disclosing Parties must acknowledge “that no appeal rights attach to claims relating to the conduct disclosed if resolved through a settlement agreement.”⁹⁴ However, an appeal of any overpayment demand letter is permitted if the Disclosing Party withdraws or is removed from the Protocol.⁹⁵ Further, the reopening rules at 42 C.F.R., sections 405.980 through 405.986, shall apply if the Disclosing Party is denied acceptance into the Protocol, withdraws from the Protocol, or is removed from the Protocol by CMS.⁹⁶

2. *Cooperation with the OIG and the Department of Justice.*—The Protocol is limited to Stark Law violations.⁹⁷ Alternatively, “[t]he OIG’s Self-Disclosure Protocol is available for disclosing conduct that raises potential liabilities under other federal criminal, civil, or administrative laws.”⁹⁸ Conduct that raises liability risks under the Stark Law and under the OIG’s civil monetary penalty authorities, including the federal Anti-Kickback Statute, should be disclosed through the OIG’s self-disclosure protocol.⁹⁹ The same conduct should not be disclosed under both the Protocol and OIG’s self-disclosure protocol.¹⁰⁰ When appropriate, CMS may coordinate with the OIG and the Department of Justice (DOJ) to prepare a recommendation to such entities for the resolution of the False Claims Act, any civil monetary penalty, or other liability.¹⁰¹

If a Disclosing Party has a corporate integrity agreement (CIA) or certification of compliance agreement (CCA) with the OIG, disclosures shall comply with the terms of those agreements.¹⁰² “Effective September 23, 2010, a reportable event solely related to a Stark issue should be disclosed to CMS using the requirements set forth in this self-disclosure protocol with a copy [of the disclosure sent to the] [D]isclosing [P]arty’s OIG monitor.”¹⁰³

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.*

96. *Id.*

97. *See id.*

98. *Id.*; *see also* Provider Self-Disclosure Protocol, 63 Fed. Reg. 58,399 (Oct. 30, 1998).

99. *See* SELF-REFERRAL DISCLOSURE PROTOCOL, *supra* note 84, at 2.

100. *Id.*

101. *Id.* at 3.

102. *Id.*

103. *Id.*

3. *Instructions Regarding the Voluntary Disclosure Submission.*—Disclosures pursuant to the Protocol must be sent to CMS electronically, along with the original disclosure and one additional copy sent by U.S. mail.¹⁰⁴ “After reviewing the submission, CMS will send a letter to the [D]isclosing [P]arty or its representative either accepting or rejecting the disclosure.”¹⁰⁵

The submission shall include a description of the actual or potential violation(s), including: identifying information of the Disclosing Party; a description of the nature of the matter being disclosed; a statement from the Disclosing Party regarding why it believes a violation may have occurred; circumstances under which the matter was discovered and measures taken upon discovery to address the issue; a statement identifying whether there is a history of similar conduct; descriptions of the existence and adequacy of a pre-existing compliance program; description of appropriate notices provided to other government agencies in connection with the disclosed matter; an indication of whether the Disclosing Party has knowledge that the matter is under current inquiry by a government agency or contractor, and a description of any such inquiry.¹⁰⁶

The Disclosing Party must also conduct a financial analysis that “[sets] forth the total amount . . . that is actually or potentially due and owing” based upon the period of time during which the Disclosing Party may not have been in compliance.¹⁰⁷ The Disclosing Party must also “[d]escribe the methodology used to set forth the amount that is actually or potentially due and owing” and “[p]rovide a summary of any auditing activity undertaken and a summary of the documents the [D]isclosing [P]arty . . . relied upon.”¹⁰⁸ Finally, the Disclosing Party must submit “a signed certification stating that, to the best of the individual’s knowledge, the information provided contains truthful information and is based on a good faith effort to bring the matter to CMS’[s] attention for purposes of resolving any potential liabilities”¹⁰⁹

4. *CMS Verification.*—“Upon receipt of a [D]isclosing [P]arty’s submission, CMS will begin its verification of the disclosed information.”¹¹⁰ The quality and thoroughness of the submission will determine CMS’s verification effort.¹¹¹ New issues identified during the verification process, which are outside the scope of the initial disclosure, may be treated as new matters outside the Protocol.¹¹² “CMS is prepared to discuss with a [D]isclosing [P]arty’s counsel ways to gain access to underlying information without waiver of protections provided by an

104. *Id.*

105. *Id.*

106. *Id.* at 3-4.

107. *Id.* at 5.

108. *Id.*

109. *Id.*

110. *Id.*

111. *Id.*

112. *Id.*

appropriately asserted claim of privilege.”¹¹³

5. *Payments*.—“CMS will not accept payments of presumed overpayments determined by the [D]isclosing [P]arty prior to the completion of CMS’[s] inquiry.”¹¹⁴ During the verification process, “the [D]isclosing [P]arty must refrain from making payments relating to the disclosed matter to the Federal health care programs or their contractors without CMS’[s] prior consent.”¹¹⁵

6. *Cooperation and Removal from the Protocol and Timeliness of Disclosures*.—CMS expects to receive documents and information from the Disclosing Party voluntarily.¹¹⁶ Failure to cooperate with CMS during the disclosure process will be assessed during CMS’s consideration of the appropriate resolution of the matter.¹¹⁷ Intentional submission of false information or intentional omission of relevant information will be referred to the DOJ or other federal agencies.¹¹⁸

7. *Factors Considered in Reducing the Amounts Owed*.—In determining the amounts owed, CMS may consider the following factors:

(1) the nature and extent of the improper or illegal practice; (2) the timeliness of the self-disclosure; (3) the cooperation in providing additional information related to the disclosure; (4) the litigation risk associated with the matter disclosed; and (5) the financial position of the [D]isclosing [P]arty. While CMS may consider these factors in determining whether reduction in any amounts owed is appropriate, CMS is not obligated to reduce any amounts due and owing.¹¹⁹

D. *Anti-Kickback Statute*

The Medicare and Medicaid Patient Protection Act of 1987, as amended by 42 U.S.C. Section 1320a-7b (the “Anti-Kickback Statute”), prohibits the knowing and willful solicitation, receipt, offer, or payment of remuneration in exchange for or to induce the provision of items or services that are reimbursable under Medicare, Medicaid, or other government health care programs.¹²⁰ Prohibited remuneration may be direct or indirect, overt or covert, and made in cash or in kind.¹²¹ Violation of the Anti-Kickback Statute can result in both criminal and civil liability. The violation, which is considered a felony, can result in up to five

113. *Id.*

114. *Id.* at 6.

115. *Id.*

116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.*

120. Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142 § 4(b)(1), 91 Stat. 1175, 1181 (1977) (codified as amended at 42 U.S.C. § 1320a-7b (2010)).

121. *See generally id.*

years imprisonment, with fines up to \$25,000 and/or civil monetary penalties.¹²² Offenders may also be excluded from participation in Medicare, Medicaid, or other government health care programs.¹²³

1. *Overview.*—As demonstrated by the PPACA's sweeping impact on the Stark Law, the PPACA also made significant reforms to the Anti-Kickback Statute. First, the PPACA created a direct connection between violations of the Anti-Kickback Statute and a subsequent submission of a false claim.¹²⁴ Second, the PPACA amended the intent requirement under the Anti-Kickback Statute.¹²⁵ The PPACA also created a new statutory exception for prescription discounts for certain government health care beneficiaries.¹²⁶

2. *False Claims Correlation.*—The PPACA clarified that a violation of the Anti-Kickback Statute is considered a false or fraudulent claim.¹²⁷ The new 42 U.S.C. Section 1320(a)-7b(g) provision provides that “a claim that includes items or services resulting from a violation of . . . [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of . . . [the False Claims Act].”¹²⁸ Prior to this new language, violations of the Anti-Kickback Statute were argued to also evidence a false claim under the “implied certification” theory.¹²⁹ However, this theory is not infallible, given the knowledge requirement under the False Claims Act.¹³⁰ The new provision set forth by the PPACA further supports the notion that a violation of the Anti-Kickback Statute results in false claims.

3. *Changes in Intent Requirement.*—In interpreting the Anti-Kickback Statute, the OIG has historically relied on *United States v. Greber*,¹³¹ the landmark case regarding the scope of the Anti-Kickback Statute. In *Greber*, the Third Circuit Court of Appeals established the “one purpose” test.¹³² Under the “one purpose” test, “if one purpose of the payment was to induce future referrals, the [M]edicare statute has been violated.”¹³³ However, in *Hanlester Network v. Shalala*,¹³⁴ the Ninth Circuit Court of Appeals interpreted the Anti-Kickback

122. *Id.*

123. *Id.* § 1320a-7b(a)(6).

124. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 6402(f)(1), 124 Stat. 119 (2010).

125. *See id.*

126. *See id.*

127. *See id.*

128. *Id.*

129. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 18 (D. Mass. 2007) (stating that the “government can state a claim under the FCA for an antecedent violation of the Anti-Kickback Statute for claims submitted through the Medicare program” because the Medicare program requires providers to certify their Anti-Kickback Statute compliance).

130. *See* 31 U.S.C. § 3729 (2006).

131. 760 F.2d 68 (3d Cir. 1985).

132. *Id.* at 69.

133. *Id.*

134. 51 F.3d 1390 (9th Cir. 1995).

Statute to require “specific intent” to violate the law.¹³⁵ In *Hanlester*, the court found that the offender must have knowledge of the specific referral prohibitions contained in the Anti-Kickback Statute and violate the law with specific intent to do so.¹³⁶ The holding in *Hanlester* sharply contrasted the broader interpretation of intent under the Third Circuit’s holding in *Greber*.

The PPACA amended the actual language of the Anti-Kickback Statute, significantly diminishing this intent requirement and providing an additional means to establish a false claim.¹³⁷ Section 6402(f)(2) of the PPACA adds a new subsection, which states, “With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.”¹³⁸ The change to the intent requirement has effectively overruled *Hanlester*, as a party may now be held liable regardless of whether he or she has actual knowledge of the Anti-Kickback Statute or specific intent to violate the law. This amendment lessens the burden on the government to demonstrate a violation of the Anti-Kickback Statute and establish a false claim. Such changes to the intent threshold have the potential to increase both criminal and civil liability exposure with regard to many hospital and physician transactions.

4. *New Exception to the Anti-Kickback Statute.*—The PPACA also added a new exception to the Anti-Kickback Statute to permit prescription discounts for certain beneficiaries participating in Medicare’s coverage gap discount program.¹³⁹ The new exception states that the negotiated price of an applicable drug of a manufacturer that is furnished to an applicable beneficiary under the Medicare coverage gap discount program under section 1860D-14A, regardless of whether part of such costs were paid by a manufacturer under such program, will not be subject to the Anti-Kickback Statute.¹⁴⁰ For purposes of the new exception to the Anti-Kickback Statute, the PPACA also established new definitions, which include:

a. *Applicable beneficiary.*—The term “applicable beneficiary” means an individual who, on the date of dispensing an applicable drug . . . (A) is enrolled in a prescription drug plan or an MA-PD plan; (B) is not enrolled in a qualified retiree prescription drug plan; (C) is not entitled to an income-related subsidy under section 1860D-14(a); (D) is not subject to a reduction in premium subsidy under section 1839(i); and (E) who (i) has reached or exceeded the initial coverage limit under section 1860D-2(b)(3) during the year; and (ii) has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket

135. *Id.* at 1400.

136. *Id.*

137. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 6402(f)(2), 124 Stat. 119 (2010).

138. *Id.*

139. Patient Protection and Affordable Care Act § 3301(c).

140. *Id.*

threshold specified in section 1860D–2(b)(4)(B).¹⁴¹

b. Applicable drug.—The term “applicable drug” means

with respect to an applicable beneficiary, a covered part D drug . . . (A) approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and (B)(i) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; (ii) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or (iii) is provided through an exception or appeal.¹⁴²

E. Civil Monetary Penalties Law

Under the federal Civil Monetary Penalties (CMP) law, monetary sanctions may be imposed against any person who gives “remuneration” to a Medicare or Medicaid participant that the person knows or should know will likely influence the participant’s selection of a particular practitioner, provider, or supplier of a service paid for by Medicare or Medicaid.¹⁴³

1. Overview.—The PPACA made several sweeping changes to the CMP law. More specifically, Section 6402 of the PPACA clarifies the definition of “remuneration” as used in the administration of the CMP law.¹⁴⁴ The PPACA also created new civil monetary penalties and amended existing ones.

2. CMP Definition of Remuneration: New Exceptions.—Under the CMP law, any hospital that “knowingly makes a payment, directly or indirectly, to a physician [and any physician that receives such a payment] as an inducement to reduce or limit” items or services to Medicare or Medicaid beneficiaries under the physician’s direct care may be subject to civil monetary penalties.¹⁴⁵ “Remuneration” includes the provision or transfer of items or services “for other than fair market value.”¹⁴⁶ Nevertheless, the OIG has stated that providing “nominal” gifts is not likely to induce a beneficiary to use a particular provider, practitioner, or supplier.¹⁴⁷ The OIG interprets nominal value to include items

141. *Id.* § 1860D-14A(g)(1).

142. *Id.* § 1860D-14A(g)(1).

143. 42 U.S.C. § 1320a-7a(a) (2006).

144. Patient Protection and Affordable Care Act § 6402(d)(2)(B).

145. 42 U.S.C. § 1320a-7a(b).

146. *Id.* § 1320a-7a(i)(6).

147. See OFFICE OF INSPECTOR GEN., SPECIAL ADVISORY BULLETIN: OFFERING GIFTS AND OTHER INDUCEMENTS TO BENEFICIARIES 4 (2002), available at <http://oig.hhs.gov/fraud/docs/>

of value no greater than \$10 each and \$50 aggregated annually.¹⁴⁸ Given this interpretation, health care providers who provide charitable assistance to patients in excess of these monetary limits (e.g., free transportation, lodging, medication, gift cards for food and gasoline) may risk violation of the CMP law. In addition to this “nominal value” exception, there are several very narrow statutory and regulatory exceptions for: waiving cost-sharing amounts for those with financial need; disclosed health plan copayment differentials; items or services that promote the delivery of preventative care, as determined by CMS; practices authorized under the Anti-Kickback Statute; or waiving hospital outpatient copayments that exceed minimum copayments.¹⁴⁹

Section 6402(d)(2)(B) of the PPACA provides additional options for health care providers to offer certain charitable assistance or other items or services for free or below fair market value.¹⁵⁰ Notably, Section 6402(d)(2)(B) excludes from the definition of remuneration:

(1) items or services that promote access to care and pose a low fraud and abuse risk;

(2) offering items or services for free or less than fair market value, if the items or services consist of coupons, rebates, or other rewards from a retailer;

the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under title XVIII or a State health care program (as defined in section 1128(h))”;¹⁵¹

(3) offering items or services for free or less than fair market value, if the items or services are not offered as part of any advertisement or solicitation;

the items or services are not tied to the provision of other services reimbursed in whole or in part by the program under title XVIII or a State health care program (as so defined);

there is a reasonable connection between the items or services and the medical care of the individual; and

the person provides the items or services after determining in good faith that the individual is in financial need.”¹⁵²

In light of these new exclusions, providers may have greater freedom to design a program aimed at assisting those in financial need or a program that

alertsandbulletins/SABGiftsandInducements.pdf.

148. *Id.* at 2.

149. *Id.*

150. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 6402(d)(2)(B), 124 Stat. 119, 758-59 (2010) (to be codified at 42 U.S.C. §1320a-7a).

151. *Id.*

152. *Id.*

improves access to health care without risk of monetary penalties under the CMP law.

3. *New and Amended Civil Monetary Penalties in Section 6402 of the PPACA.*—Section 6402(d)(2) of the PPACA creates three new CMPs for the purpose of enhancing Medicare and Medicaid program integrity.¹⁵³ The PPACA also amended Section 1128A(a)(1)(D) of the CMP law.¹⁵⁴ As amended, the CMP law now includes the following additional CMPs:

a. *New section 1128A(a)(8).*—This section imposes CMPs on any person who “orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program (as so defined),” when such person knows or should have known that a claim would be made under a Federal health care program.¹⁵⁵ The penalty for violating this new section 1128A(a)(8) is no more than \$10,000 per item or service, plus no more than three times the amount claimed for such item or service.¹⁵⁶

b. *New section 1128A(a)(9).*—This section imposes CMPs on any person who “knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program (as so defined).”¹⁵⁷ Violations of this new CMP can result in penalties of no more than \$50,000 for each instance, plus no more than “[three] times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement or misrepresentation of a material fact.”¹⁵⁸

c. *New section 1128A(a)(10).*—This section imposes CMPs on any person who “knows of an overpayment (as defined in paragraph (4) of section 1128J(d)) and does not report and return the overpayment in accordance with such section.”¹⁵⁹ The penalty for violating new section 1128A(a)(10) is no more than \$10,000 per item or service, plus no more than three times the amount claimed for such item or service.¹⁶⁰

d. *New section 1128J(d).*—Section 6402(a) of the PPACA created new section 1128J(d), which requires a person to “report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor” and provide an explanation to the same entity as to why there was an overpayment.¹⁶¹ An “overpayment” is “any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under

153. Patient Protection and Affordable Care Act § 6402(d)(2)(A).

154. *Id.*

155. Patient Protection and Affordable Care Act § 6402(d)(2)(A)(iii).

156. 42 U.S.C. § 1320a-7a(a) (2006).

157. Patient Protection and Affordable Care Act § 6402(d)(2)(A)(iii).

158. *Id.* § 6402(d)(2)(A)(iv)-(v).

159. *Id.* § 6402(d)(2)(A)(iii).

160. 42 U.S.C. § 1320a-7a(a)(10) (2006).

161. Patient Protection and Affordable Care Act § 6402(a).

such title.”¹⁶² For purposes of this new provision, the term “person” does not include beneficiaries.¹⁶³

The PPACA also amends section 1128A(a)(1)(D) of the CMP law, which imposes CMPs on persons who knowingly present, or cause to be presented, claims for items or services provided “during a period in which the person was excluded” pursuant to a determination by the Secretary under a list of statutory provisions.¹⁶⁴ The PPACA amends this provision by replacing the list of statutes with “from the Federal health care program (as defined in section 1128B(f)) under which the claim was made pursuant to Federal law.”¹⁶⁵ This amendment broadens the application of section 1128A(a)(1)(D) of the CMP law.

4. *New Civil Monetary Penalties in Section 6408 of the PPACA.*—Section 6408(a) of the PPACA creates new CMPs for false statements or delaying OIG inspections.¹⁶⁶ As amended, the CMP law now includes the following additional CMPs:

a. *New section 1128A(a)(8).*—This section imposes CMPs on any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program.”¹⁶⁷

b. *New section 1128A(a)(9).*—This section imposes CMPs on any person who “fails to grant timely access, upon reasonable request . . . to the Inspector General of the Department of Health and Human Services, for the purpose of audits, investigations, evaluations, or other statutory functions of the Inspector General of the Department of Health and Human Services.”¹⁶⁸

c. *Penalties.*—The penalties imposed for violating these new CMPs are \$50,000 for each false record or statement under new section 1128A(a)(8) and \$15,000 for each day the person fails to grant timely access under new section 1128A(a)(9).¹⁶⁹

F. *Office of Inspector General Work Plan for Fiscal Year 2010*

On October 1, 2009, the OIG published its proposed Work Plan for Fiscal Year 2010 (“Work Plan”), which describes new and ongoing audit and enforcement priorities of the OIG.¹⁷⁰ Important focus areas for providers and suppliers include, but are not limited to:

1. *“Hospital Admissions with Conditions Coded Present-on-Admission*

162. *Id.*

163. *Id.*

164. 42 U.S.C. § 1320a-7a(a)(8).

165. Patient Protection and Affordable Care Act § 6402(d)(2)(A)(i).

166. *Id.* § 6408(a).

167. *Id.* § 6408(a)(2).

168. *Id.*

169. *Id.* § 6408(a)(3)(B).

170. OFFICE OF INSPECTOR GEN., FY 2010 OFFICE OF INSPECTOR GEN. WORK PLAN (2010), available at http://oig.hhs.gov/publications/docs/workplan/2010/Work_Plan_FY_2010.pdf.

(*POA*).¹⁷¹—The OIG will review Medicare claims to determine the number of inpatient hospital admissions for which certain diagnoses are coded as *POA* and the conditions that are most frequently coded as *POA*.¹⁷² The OIG will also determine which types of facilities are most frequently transferring patients with a *POA* diagnosis specified by CMS to hospitals and whether specific providers transferred a high number of patients to hospitals with *POA* diagnoses.¹⁷³

2. “*Payments for Services Ordered or Referred by Excluded Providers*.”¹⁷⁴—Entities or providers that are excluded from Medicare or Medicaid may not receive payment for items furnished, ordered, or prescribed by the excluded party.¹⁷⁵ Under the Work Plan, the OIG will review Medicare payments ordered or referred by excluded providers and will examine CMS’s oversight mechanisms for identifying improper payments.¹⁷⁶

3. “*Medicare Incentive Payments for E-Prescribing*.”¹⁷⁷—Under the Work Plan, the OIG “will review Medicare incentive payments made in 2010 to eligible health care professionals for their 2009 electronic prescribing (e-prescribing) activities.”¹⁷⁸ Physicians will be eligible for incentive payments beginning in 2010 if they are “successful electronic prescribers.”¹⁷⁹

4. “*Physician Reassignment of Benefits*.”¹⁸⁰—Unless an exception applies, physicians providing Medicare services may not reassign their right to payment to another entity.¹⁸¹ The OIG will review the extent to which Medicare physicians reassign their benefits to other entities and the extent to which physicians are aware of their reassignments.¹⁸²

III. LABOR AND EMPLOYMENT

A. Racial Preferences of Medical Facility Residents

In *Chaney v. Plainfield Healthcare Center*,¹⁸³ the United States Court of Appeals for the Seventh Circuit held that a nursing home’s policy of not allowing African-American certified nursing assistants (CNAs) to provide care to residents who had requested that they not be treated by African-American CNAs constituted a hostile work environment.

171. *Id.* at 6.

172. *Id.*

173. *Id.*

174. *Id.* at 18.

175. *Id.*

176. *Id.*

177. *Id.* at 14.

178. *Id.*

179. *Id.*

180. *Id.* at 17.

181. *Id.*

182. *Id.* at 18.

183. 612 F.3d 908 (7th Cir. 2010).

Brenda Chaney (“Chaney”) was a CNA at Plainfield Healthcare Center (“Plainfield”).¹⁸⁴ Plainfield had a policy of permitting residents to express their racial preferences and honoring those preferences in assigning health care providers.¹⁸⁵ The residents’ racial preferences, if any, were listed on the assignment sheets of the CNAs, which were provided to the CNAs upon arriving at work. “In the case of Marjorie Latshaw, a resident in Chaney’s unit, the [assignment] sheet instructed nurse aides that Latshaw ‘Prefers No Black CNAs.’”¹⁸⁶ Plainfield acknowledged that the assignment sheet effectively banned Chaney, who was African-American, from assisting Latshaw.¹⁸⁷ “For fear of being fired, Chaney went along with the policy” and “refrained from assisting . . . [Latshaw], even when she was in the best position to respond.”¹⁸⁸

Plainfield argued that its policy of honoring racial preferences of residents was necessary to avoid “violating state and federal laws that grant residents the rights to choose providers, to privacy, and to bodily autonomy.”¹⁸⁹ Specifically, Plainfield stated that its policy was a reasonable and good faith effort to comply with title 410, section 16.2-3.1-3(n)(1) of the Indiana Administrative Code, which provides residents the right to “choose a personal attending physician and other providers of services.”¹⁹⁰ The court, however, disagreed, finding that Plainfield was a racially hostile workplace because it “acted to foster and engender a racially-charged environment through its assignment sheet that unambiguously, and daily, reminded Chaney and her co-workers that certain residents preferred no black CNAs” and stating that the policy was unreasonable and unnecessary to comply with applicable laws.¹⁹¹

The court noted that Plainfield’s reading of the Indiana regulation conflicted with Title VII, and “[w]hen two laws conflict, one state, one federal, the Supremacy Clause dictates that the federal law prevails.”¹⁹² While acceding to a patient’s preference regarding the gender of a health care provider can be legitimate under Title VII, it is never legitimate on the basis of race.¹⁹³ Further, “Indiana’s regulations do not require Plainfield to instruct its employees to accede to the racial preferences of its residents”—they merely require Plainfield “to allow residents access to health-care providers of their choice.”¹⁹⁴ That is, the

184. *Id.* at 910.

185. *Id.*

186. *Id.*

187. *Id.*

188. *Id.*

189. *Id.*

190. *Id.* at 913-14; *see also* 410 IND. ADMIN. CODE 16.2-3.1-3(n)(1)(2010) (“The resident has the right to . . . [c]hoose a personal attending physician and other providers of services.”).

191. *Id.* at 912-13.

192. *Id.* at 914 (citing U.S. CONST. art. VI, cl. 2).

193. *See id.* at 913-14. The court cited *Rucker v. Higher Educational Aids Board*, 669 F.2d 1179 (7th Cir. 1982), to show that Title VII forbids employers from using race as a bona fide occupational qualification or a legitimate criterion for accommodating patients’ privacy interests.

194. *Chaney*, 612 F.3d at 914.

regulations do not require Plainfield to accede to the racial preferences of residents with respect to its own employees. The court stated that

[i]f a racially-biased resident wishes to employ at her own expense a white aide, Indiana law may require Plainfield to allow the resident reasonable access to that aide. But the regulations do not say that a patient's preference for white aides that *Plainfield* employs trumps Plainfield's duty to its employees to abstain from race-based work assignments.¹⁹⁵

Next, Plainfield argued that its policy was legitimate under 42 U.S.C. § 1395i, "which provides that Medicare beneficiaries in long-term care facilities have a right to choose 'a personal attending physician.'"¹⁹⁶ The court rejected this argument, stating that "[t]he law is silent about a beneficiary's right to choose *other* service providers, such as CNAs."¹⁹⁷

Finally, Plainfield attempted to defend its policy by arguing that without the policy, Plainfield risked exposing black employees to racial harassment from the residents, thus "exposing itself to hostile workplace liability."¹⁹⁸ The court rejected this argument as well and offered several alternative ways that Plainfield could have confronted hostile residents. For instance, the court suggested "warn[ing] residents before admitting them of the facility's nondiscrimination policy, securing the resident's consent in writing."¹⁹⁹ In sum, the court held that Plainfield's policy created a racially-charged workplace in contravention of Title VII.

B. TRICARE and Affirmative Action Considerations

Another labor and employment case—this time in the affirmative action arena—that affects the health care industry both in Indiana and across the nation is *In re Office of Federal Contract Compliance Programs, United States Department of Labor v. Florida Hospital of Orlando*.²⁰⁰ There, an administrative law judge (ALJ) considered whether a not-for-profit hospital was a subcontractor to a government contractor and, as a result, was subject to federal affirmative action and nondiscrimination requirements.

TRICARE Management Activity (TMA) is a federal financial assistance

195. *Id.*

196. *Id.*

197. *Id.*; see also 42 U.S.C. § 1395i-3(c)(1)(A)(i) (2010) ("A skilled nursing facility must protect and promote the rights of each resident, including . . . the right to choose a personal attending physician . . .").

198. *Chaney*, 612 F.3d at 914.

199. *Id.* at 915. In addition, the court suggested attempting to reform residents' post-admission behavior, assigning staff "based on race-neutral criteria that minimize the risk of conflict", and advising Plainfield employees "that they could ask for protection from racially harassing residents." *Id.*

200. Fla. Hosp. of Orlando, U.S. Dep't of Labor, No. 2009-OFC-00002 (Oct. 18, 2010).

program that administers health care for active duty and retired military and their families under the TRICARE program.²⁰¹ To assist with the administration of the program, TMA contracts with managed care support contractors, who are responsible for “enrollment, referral management, medical management, claims processing and customer service,” as well as “[underwriting] healthcare costs and establish[ing] networks of providers who agree to follow rules and procedures of the TRICARE program when treating TRICARE patients.”²⁰² Beginning in August 2003, Humana Military Healthcare Services, Inc. (HMHS) contracted with TMA “to provide networks of health care providers” to TRICARE beneficiaries.²⁰³ The TMA-HMHS contract provided that “HMHS shall provide a managed, stable high-quality network or networks of individual and institutional health care providers” and must “establish provider networks through contractual arrangements.”²⁰⁴

The defendant in this case, Florida Hospital of Orlando, is an acute care, not-for-profit hospital with more than fifty employees located in Orlando, Florida.²⁰⁵ This hospital had a hospital agreement with HMHS since April 2005, pursuant to which the hospital agreed to become a participating hospital and “provide health care services for beneficiaries designated as eligible to receive benefits under the agreement between HMHS and TRICARE in accordance with the TRICARE rules, regulations, policies and procedures.”²⁰⁶ Under the TMA-HMHS contract, HMHS paid the hospital \$100,000 or more annually for medical services provided to TRICARE beneficiaries from January 1, 2006 onward.

On August 14, 2007, the Office of Federal Contract Compliance Programs (OFCCP) initiated compliance reviews of the hospital and requested documentation to show that the hospital was complying with the affirmative action and equal employment opportunity obligations set forth in Executive Order 11, 246.²⁰⁷

The hospital refused to provide any information requested by OFCCP and argued that the OFCCP lacked jurisdiction over the hospital. Because Executive Order 11,246 applies only to government contractors and subcontractors, the hospital raised two arguments in support of its position that it is not a covered

201. *Id.* at 2.

202. *Id.*

203. *Id.*

204. *Id.* (internal citation omitted).

205. *Id.*

206. *Id.*

207. *Id.* at 3; *see also* Exec. Order No. 11,246, 3 C.F.R. § 339 (1964-65), *as amended by* Exec. Order No. 11,375, 3 C.F.R. § 684 (1966-70); Exec. Order No. 12,086, 3 C.F.R. § 230. Specifically, the Executive Orders, as codified at 41 C.F.R. §§ 601.3, 60-250.2, and 741.2, require that any government contractors or subcontractors must establish written affirmative action employment programs (AAPs). OFCCP sought information about the hospital’s AAPs and requested “(1) a copy of Defendant’s Executive Order . . . [AAP]; (2) a copy of Defendant’s § 503 (38 U.S.C. § 4212) AAP(s) prepared according to 41 CFR parts 60-741 and 60-250; and (3) support data specified in an enclosed itemized listing.” *Fla. Hosp. of Orlando*, No. No. 2009-OFC-00002, at 3.

subcontractor under the statutes.²⁰⁸ First, the hospital argued that it was not a “covered contractor” because it did not enter into a subcontract as defined in 41 C.F.R. §§ 60-1.3, 60-250.2, and 741.2. Under the regulations, a “subcontract” is defined as:

[a]ny agreement or arrangement between a contractor and any person . . . (1) For the purchase, sale or use of personal property or nonpersonal services which, in whole or in part, is necessary to the performance of any one or more contracts; or (2) Under which any portion of the contractor’s obligation under any one or more contracts is performed, undertaken or assumed.²⁰⁹

But the ALJ, relying on *OFCCP v. UPMC Braddock*,²¹⁰ found that the hospital did perform a portion of the contractor’s obligation under its contract with TRICARE. Specifically, the ALJ stated that under the hospital agreement, the hospital contracted “to provide medical services to TRICARE’s beneficiaries under the agreement between HMHS and . . . [TMA].”²¹¹ Therefore, the hospital was a subcontractor under HMHS’s contract with TRICARE because it performed “‘a portion of the contractor’s obligations’ by providing some of the medical services to TRICARE’s beneficiaries which HMHS has contracted to provide.”²¹²

The second argument raised by the hospital was that its participation in the TRICARE program constituted the receipt of federal financial assistance, and OFCCP did not have jurisdiction over businesses that receive federal financial assistance. In 1993, OFCCP issued a statement that “OFCCP lacks jurisdiction over businesses if their only relationship with the federal government is as a recipient of federal financial assistance, be it from Medicare or other federal programs.”²¹³ As a result, the hospital argued that TRICARE is “essentially indistinguishable” from Medicare, and thus, receipt of federal funding under this program did not constitute a subcontractor relationship.

In response to the hospital’s second argument, the ALJ again disagreed and found that Medicare and TRICARE are substantially different; while “Medicare does not provide medical services to its beneficiaries . . . TRICARE is the uniformed services health care program for active duty service members and their families. . . . That Medicare may be considered federal financial assistance has no relevance to TRICARE. They are totally different programs.”²¹⁴ Ultimately,

208. *Id.* at 4.

209. *Id.*

210. *UPMC Braddock*, No. 08-048 (May 29, 2009) (holding that defendant hospitals were subcontractors to a government contract where the hospital contracted with an HMO to provide services to federal employees pursuant to an agreement between the HMO and the Office of Personnel Management).

211. *Fla. Hosp. of Orlando*, No. 2009-OFC-00002, at 4.

212. *Id.* at 4-5.

213. *Id.* at 5.

214. *Id.* at 5-6 (internal citation omitted). Note that this holding is contrary to the Department

the hospital was ordered to give OFCCP access to its facilities and otherwise permit OFCCP to conduct and complete its compliance audit. The hospital has appealed the ALJ's opinion to the Administrative Review Board.

In light of the *OFCCP* decision, and subject to the outcome of the hospital's appeal to the administrative review board, the number of health care providers that are now subject to affirmative action requirements appears to have been dramatically increased.

C. Amendments to the Fair Labor Standards Act of 1938 in Light of the Patient Protection and Affordable Care Act

While the majority of the provisions in the PPACA are aimed at improving health care access and quality and reducing cost, the PPACA also made amendments to the Fair Labor Standards Act of 1938 (FLSA).²¹⁵ The four amendments concern automatic enrollment of employees for health care benefits with an "opt-out" mechanism,²¹⁶ a requirement that employers inform employees of insurance exchanges,²¹⁷ anti-retaliation and whistleblower protection,²¹⁸ and lactation accommodations for nursing mothers.²¹⁹ With the exception of the provision concerning notice of insurance exchanges (which becomes effective March 1, 2013), none of these provisions have express effective dates and presumably require employers to comply immediately.

PPACA § 1511 adds § 218a to the FLSA.²²⁰ Under this section, an employer with more than 200 full-time employees that offers one or more health benefit plans must automatically enroll newly hired full-time employees in one of the plans offered. However, the employer must provide adequate notice of the enrollment as well as an opportunity for the employee to opt out of the coverage in which he or she was automatically enrolled.²²¹

PPACA § 1512 adds § 218b to the FLSA,²²² which requires an employer to provide written notice of the existence of an insurance exchange to newly hired employees and all current employees.²²³ As stated above, this provision is not

of Defense's position—the ALJ noted that "TRICARE's position . . . is that 'it would be impossible to achieve the TRICARE mission of providing affordable health care for our nation's active duty and retired military members and their families if onerous federal contracting rules were applied to the more than 500,000 TRICARE providers in the United States' and that "it was never the agency's intent to do so." *Id.* at 3 (internal citation omitted).

215. Fair Labor Standards Act of 1938, 29 U.S.C. § 201 (2006).

216. Pub. L. No. 111-148, tit. I, § 1511, 124 Stat. 252 (2010) (amending 29 U.S.C. § 218a).

217. *Id.* § 1512 (amending 29 U.S.C. § 218b).

218. *Id.* § 1558 (amending 29 U.S.C. § 218c).

219. Pub. L. No. 111-148, tit. IV, § 4207, 124 Stat. 577 (2010) (amending 29 U.S.C. § 207(r)(1)(A)).

220. *Id.* § 1511.

221. *Id.*

222. *Id.* § 1512.

223. *Id.*

effective until March 1, 2013.²²⁴

PPACA § 1558, which adds § 218c to the FLSA,²²⁵ prohibits employer discrimination or retaliation against any employee who has received a tax credit or subsidy for a health plan.²²⁶ The employer is also prohibited from discriminating or retaliating against an employee who has provided (or is about to provide) the federal government or state attorney general information concerning the employer's action or inaction that the employee reasonably believes to be a violation of the PPACA.²²⁷ An employee who believes that he or she has been discriminated or retaliated against in violation of this section may seek relief using the procedures outlined in 15 U.S.C. §2087(b).²²⁸

Finally, PPACA § 4207 adds § 207(r)(1)-(4) to the FLSA.²²⁹ Under this provision, an employer must provide "reasonable break time . . . [to allow a mother] to express breast milk for her nursing child" as often as the mother needs to do so for one year after the child's birth.²³⁰ However, the employer is not required to compensate the employee during this time.²³¹ The employer must provide the employee with "a place, other than a bathroom, that is shielded from view and free from intrusion from coworkers and the public" in which to express breast milk.²³² An employer with fewer than fifty employees is not subject to these requirements if the requirements cause undue hardship by imposing significant difficulty or expense in relation to the employer's "size, financial resources, nature, or structure of the employer's business."²³³ This section does not preempt state law that provides greater protection for employees²³⁴ (such as requiring compensation during breaks or requiring breaks past the child's first birthday).

D. Immigration: Impact of Neufeld Memorandum on Physicians

The H-1B program is one of the avenues for non-U.S. citizens coming to the United States to obtain temporary work authorization. The H-1B regulations specifically authorize the use of this program by physicians.²³⁵ H-1B work authorization is employer-specific. To constitute an "employer" for purposes of the H-1B program, a petitioner must establish that a valid employer-employee relationship exists between the U.S. employer and prospective H-1B

224. *Id.*

225. *Id.* § 1558.

226. *Id.*

227. *Id.*

228. *Id.*; see also 15 U.S.C. § 2087(b) (addressing whistleblower protections).

229. Pub. L. No. 111-148, tit. IV, § 4207, 124 Stat. 577 (2010) (adding 29 U.S.C. § 207(r)).

230. *Id.*

231. *Id.*

232. *Id.*

233. *Id.*

234. *Id.*

235. 8 C.F.R. § 214.2(h)(4)(viii)(2010).

beneficiary.²³⁶ In the past, United States Citizenship and Immigration Services (USCIS) examined the employer-employee relationship under the “conventional master-servant relationship as understood by the common-law agency doctrine.”²³⁷

Despite the previously relied upon common law principles of agency, on January 8, 2010, USCIS released a memorandum stating that there is a lack of formal guidance for determining whether the required employer-employee relationship exists between the petitioner and H-1B beneficiary.²³⁸ This lack of guidance causes problems, particularly for certain types of H-1B petitions, such as where the H-1B beneficiary is placed at a third-party worksite.²³⁹ According to the memorandum, while some third-party worksite arrangements are based on valid employer-employee relationships, other relationships do not meet this baseline test.²⁴⁰ To create additional guidance, the memorandum delineated the following eleven factors to be considered in evaluating whether a valid employer-employee relationship exists:

- (1) Does the petitioner supervise the beneficiary and is such supervision off-site or on-site?
- (2) If the supervision is off-site, how does the petitioner maintain such supervision, *i.e.* weekly calls, reporting back to main office routinely, or site visits by the petitioner?
- (3) Does the petitioner have the right to control the work of the beneficiary on a day-to-day basis if such control is required?
- (4) Does the petitioner provide the tools or instrumentalities needed for the beneficiary to perform the duties of employment?
- (5) Does the petitioner hire, pay, and have the ability to fire the beneficiary?
- (6) Does the petitioner evaluate the work-product of the beneficiary, *i.e.* progress/performance reviews?
- (7) Does the petitioner claim the beneficiary for tax purposes?
- (8) Does the petitioner provide the beneficiary any type of employment benefits?
- (9) Does the beneficiary use proprietary information of the petitioner in order to perform the duties of employment?

236. *Id.* § 214.2(h)(4)(ii)(4) (defining employer as “a person, firm, corporation, contractor, or other association or organization in the United States which . . . [e]ngages a person to work within the United States; [h]as an employer-employee relationship with respect to employees”; and has an Internal Revenue Service tax identification number).

237. *See* Memorandum from Donald Neufeld, Associate Director of Service Center Organizations, to Service Center Directors of U.S. Citizen & Immigration Services 3 (Jan. 8, 2010), available at <http://www.uscis.gov/USCIS/Laws/Memoranda/2010/H1B%20Employer-Employee%20Memo010810.pdf> (quoting *Nationwide Mut. Ins. Co. v. Darden*, 503 U.S. 318, 322-23 (1992)).

238. *Id.* at 2.

239. *Id.* at 2.

240. *Id.*

(10) Does the beneficiary produce an end-product that is directly linked to the petitioner's line of business?

(11) Does the petitioner have the ability to control the manner and means in which the work product of the beneficiary is accomplished?²⁴¹

The employer will meet the relationship test if it is able to establish its right to control the H-1B beneficiary, as determined by the totality of circumstances.²⁴²

Contrary to the intent of the memorandum, this eleven-factor test creates a potential conflict where the H-1B beneficiary provides services at a third-party worksite. Physicians fall into this potential conflict arena, as they are often employed by one entity and provide services at a third-party hospital or medical clinic. In these situations, the H-1B process is significantly more document-intensive. To establish a valid employer-employee relationship under the eleven-factor test, the petitioner must submit evidence of the right to control the H-1B beneficiary's work, "including the ability to hire, fire, and supervise the beneficiary", and evidence that the employer maintains responsibility "for the overall direction of the beneficiary's work."²⁴³ This is complicated in the physician setting, where physicians are employed by one entity but perform their duties at a third-party medical facility.

The memorandum lists several types of evidence which may help establish the employer-employee relationship, including a signed employment agreement, position description, contracts between the petitioner and third-party worksite which evidence the petitioner's right to control the H-1B beneficiary, and a copy of the organizational chart, demonstrating the H-1B beneficiary's supervisory chain, among other items.²⁴⁴ Because each H-1B petition involving a physician and third-party worksite is evaluated on a case-by-case basis, no specific combination of evidence will suffice for every petition.

Where the petitioner is unable to establish the right to control the H-1B beneficiary, per the eleven factors outlined in the memorandum, USCIS may issue a request for evidence (RFE)²⁴⁵ in connection with the petition, or the petition may be denied for failure to satisfy these requirements.²⁴⁶

IV. TAX

A. New Requirements for Tax-Exempt Hospitals

The landscape for hospital organizations in Indiana and across the country that are exempt from tax under Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the "Code"), changed significantly with the enactment of the PPACA. Section 9007 of the PPACA adds Section 501(r) to the Code, which

241. *Id.* at 3-4.

242. *Id.* at 4.

243. *Id.* at 8 (citing 8 C.F.R. § 214.2(h)(4)(ii)).

244. *Id.* at 8-9.

245. *Id.* at 10.

246. *Id.* at 8.

contains four new requirements that hospital organizations must satisfy in order to attain or maintain their tax-exempt status. Hospital organizations subject to Code Section 501(r) are now required to do the following: adopt a written financial assistance policy; limit charges for emergency or other necessary care; refrain from engaging in extraordinary collection efforts; and conduct a community health needs assessment once every three years.²⁴⁷ Except for the community health needs assessment requirement, these provisions apply for tax years beginning after the date of enactment of the PPACA (March 23, 2010).

B. Applicability of Code Section 501(r) and Definition of Hospital

The requirements of Code Section 501(r) apply to any organization exempt from tax under Code Section 501(c)(3) that operates a facility which is required by a state to be licensed, registered or similarly recognized as a hospital, or otherwise has hospital care as its principal function or purpose constituting the basis for its exemption under Code Section 501(c)(3). The PPACA does not address or define what “similarly recognized” means, nor does it address what constitutes “hospital care” for purposes of these new requirements. Notably, under Code Section 501(r)(2)(B), if a hospital organization operates more than one hospital facility, then each separate facility must meet the new requirements.²⁴⁸

C. New Requirements

1. Financial Assistance Policy.—Hospital organizations must have a written financial policy in place that establishes:

- (i) eligibility criteria for financial assistance, and whether such assistance includes free or discounted care;
- (ii) the basis for calculating amounts charged to patients;
- (iii) the method for applying for financial assistance;
- (iv) in the case of an organization which does not have a separate billing and collections policy, the actions the organization may take in the event of non-payment, including collections action and reporting to credit agencies; and
- (v) measures to widely publicize the policy within the community to be served by the organization.²⁴⁹

In addition, hospital organizations must have a written policy requiring the organization to provide care for emergency medical conditions to individuals regardless of their eligibility under the aforementioned financial assistance policy.

2. Limitation on Charges.—Hospital organizations must limit the amount

247. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 9007, 124 Stat. 119 (2010).

248. I.R.C. § 502(r)(2)(B) (West, Westlaw through 2011 legislation).

249. *Id.* § 501(r)(4).

they charge for emergency or other medically necessary care to those individuals who are eligible for assistance under a financial assistance policy to “not more than the amounts generally billed to individuals who have insurance covering such care.”²⁵⁰

3. *Billing and Collections.*—Hospital organizations may not engage in “extraordinary” collections efforts unless they have made “reasonable efforts” to determine whether an individual is eligible for their financial assistance policy.²⁵¹

4. *Community Health Needs Assessment.*—Within three taxable years following the PPACA’s date of enactment and no less than every three years thereafter, hospital organizations must conduct a community health needs assessment.²⁵² This assessment must take into account input from persons with a broad range of interests in the communities they serve and include individuals with expertise in public health. The assessments must be made widely available to the public, and hospital organizations must adopt an implementation strategy to address the community health needs identified in the assessments.²⁵³ Failure to comply with this requirement can result in a \$50,000 excise tax to the hospital organization.

Hospital organizations will also be required to file in each taxable year a description of how they are addressing community health needs identified in the assessment, any identified needs not being addressed and the reasons why they are not being addressed, and audited financial statements. This description and the audited financial statements will be reported as part of the organization’s Form 990.²⁵⁴ The PPACA further mandates that the Internal Revenue Service (IRS) review the community benefit activities of each hospital organization at least once every three years.²⁵⁵

D. Impact on Indiana Hospital Organizations

Hospital organizations in Indiana may have a head start on compliance with some of the PPACA’s new requirements. Specifically, the community health needs assessment requirement under the PPACA is similar to a requirement under Indiana law for Indiana nonprofit hospitals to develop and report on a community benefits plan. Indiana law requires nonprofit hospitals²⁵⁶ to develop

250. *Id.* § 501(r)(5).

251. *Id.* § 501(r)(6).

252. *Id.* § 501(r)(3).

253. *Id.* § 501(r)(3)(B).

254. Patient Protection and Affordable Care Act, Pub. L. No. 111-148 § 9007, 124 Stat. 119 (2010).

255. *Id.*

256. The Indiana Code defines a “nonprofit hospital” as “a hospital that is organized as a nonprofit corporation or a charitable trust under Indiana law or the laws of any other state or country and that is: (1) eligible for tax exempt bond financing; or (2) exempt from state or local taxes.” IND. CODE § 16-21-9-3 (2011).

a community benefits plan that these hospitals will use to address the health care needs of the communities they serve.²⁵⁷ When developing this community benefits plan, nonprofit hospitals must consider the health care needs of the communities they serve “as determined by communitywide needs assessments.”²⁵⁸ The community benefits plan must consist of “(1) [m]echanisms to evaluate the plan’s effectiveness, including a method for soliciting the views of the communities served by the hospital[;] (2) measurable objectives to be achieved within a specified time frame[; and] (3) a budget for the plan.”²⁵⁹ Finally, nonprofit hospitals must file an annual report of the community benefits plan with the Indiana State Department of Health and make the report widely available to the public by posting it in prominent places, including the emergency room waiting area and the admissions office waiting area.²⁶⁰

When one compares the requirements of Code Section 501(r)(3) regarding a community health needs assessment to the Indiana state law requirements regarding a community benefits plan, several similarities can be found. The Indiana Code provisions require, as part of the community benefits plan, that nonprofit hospitals conduct communitywide needs assessments, and these communitywide assessments may be similar to what is ultimately required in a community health needs assessment under Code Section 501(r)(3). Further, the Indiana Code requires that the community benefit report, which may include the communitywide assessments, be made widely available to the public, which is similar to the new requirements in Code Section 501(r)(3). Lastly, the Indiana Code requires that nonprofit hospitals file an annual community benefit report, which, depending on further guidance from the Treasury and the IRS, may be similar to the reporting requirements of Code Section 501(r)(3). In sum, the existing Indiana Code requirements, while not identical, are similar to the new requirements of Code Section 501(r)(3) and may make it easier for Indiana hospital organizations to comply with the new requirements under the PPACA for community health needs assessments.

Meanwhile, the applicability of Code Section 501(r) to some Indiana county and community hospitals remains unclear. While Code Section 501(r) will require hospitals exempt from taxation under Section 501(c)(3) of the Code to comply with the new requirements of Code Section 501(r), it does not address whether hospitals exempt from taxation under another section of the Code, including many Indiana county or community hospitals, have the same responsibility.²⁶¹ These hospitals are exempt from taxation under Code Section 115 or via Treasury Regulation Section 1.103-1(b). However, they may have sought and received rulings that they also qualify as exempt organizations under Code Section 501(c)(3) in order to offer certain employee benefit plans. Given that these hospitals do not derive their exempt status from Section 501(c)(3), it

257. *Id.* § 16-21-9-4.

258. *Id.* § 16-21-9-5.

259. *Id.* § 16-21-9-6.

260. *Id.* § 16-21-9-7.

261. *See generally* I.R.C. § 502(r) (West, Westlaw through 2011 legislation).

is unclear whether such hospitals will be subject to the requirements and penalties contained in Code Section 501(r). Additional guidance regarding this aspect of the law will provide welcome clarity for these particular organizations.

E. Guidance on the Horizon

Hospital organizations can expect that the IRS and the Department of the Treasury will issue proposed Treasury Regulations that provide clarification on a number of issues, as evidenced by the issuance of Notice 2010-39 (the “Notice”) in May of this year to solicit comments regarding the application various aspects of the new requirements on Hospital Organizations.²⁶² The Notice specifically requested comments by July 22, 2010, regarding: (1) the appropriate requirements for a community health needs assessment;²⁶³ (2) what constitutes “reasonable efforts” in determining eligibility for assistance under a hospital’s financial assistance policy (for purposes of the new billing and collection rule);²⁶⁴ (3) where a hospital organization operates more than one hospital facility, the consequences of that organization’s failure to comply with the new rules with respect to some, but not all, of its hospital facilities;²⁶⁵ and (4) input for particular areas in need of additional guidance.

With the close of the public comment period in July of 2010, initial guidance from the IRS and the Department of the Treasury should be produced in the coming months.

F. Next Steps

Until guidance is released by the IRS and the Department of the Treasury, hospital organizations need to be evaluating whether their current policies address the basic components of the new requirements. Particular attention should be paid to the requirements for financial assistance policies, limitations on charges, and billing and collections practices because they are effective for tax years starting after the date of enactment of the PPACA (March 23, 2010). Hospital organizations should also begin considering who will perform community health needs assessments and how they will be performed—these are optional now and will become mandatory for tax years beginning after March 23, 2012.

V. HEALTH INFORMATION TECHNOLOGY

When implemented properly and widely adopted, health information technology (HIT) is accepted as a means to increase health care system

262. INTERNAL REVENUE SERV., NOTICE 2010-39: REQUEST FOR COMMENTS REGARDING ADDITIONAL REQUIREMENTS FOR TAX-EXEMPT HOSPITALS (2010), *available at* <http://www.irs.gov/pub/irs-drop/n-10-39.pdf>.

263. *Id.* at 1-2.

264. *Id.* at 3.

265. *Id.* at 4.

efficiency, improve patient care and quality, and bend the cost curve.²⁶⁶ HIT allows health care professionals to manage patient care through integrated data sources like electronic health records (EHRs), decision support systems, and physician order entry at multiple practice sites through synchronized state and national health information exchanges.²⁶⁷ The development and implementation of HIT continues to expand due in large part to the financial incentives unveiled in this past year's statutory and regulatory developments at the federal level.²⁶⁸ The following presents a brief survey of key HIT developments affecting Indiana health professionals from October of 2009 to September of 2010.

A. Federal HIT Statutory & Regulatory Development

Since October of 2009, both the federal legislature and administrative agencies' actions continued to stimulate HIT implementation at the local, regional, and national level. The promulgation of regulations for the Medicare and Medicaid Electronic Health Record Incentive Programs ("EHR Incentive

266. *Health Information Technology: Can HIT Lower Costs and Improve Quality?*, RAND CORP. (2005), http://www.rand.org/pubs/research_briefs/RB9136/index1.html ("If all hospitals had a HIT system including Computerized Physician Order Entry, around 200,000 adverse drug events could be eliminated each year, at an annual savings of about \$1 billion. Most of the savings would be generated by hospitals with more than 100 beds.") (internal citation omitted). *But see* Spencer S. Jones et al. *Electronic Health Record Adoption and Quality Improvement in US Hospitals*, 16 AM. J. MANAGED CARE 64 (2010), available at http://www.ajmc.com/supplement/managed-care/2010/AJMC_10dec_HIT/AJMC_10decHIT_Jones_SP64to71 ("Mixed results suggest that current practices for implementation and use of EHRs have had a limited effect on quality improvement in US hospitals. However, potential 'ceiling effects' limit the ability of existing measures to assess the effects that EHRs have had on hospital quality. In addition to the development of standard criteria for EHR functionality and use, standard measures of the effect of EHRs are needed.").

267. Health information exchanges are organizations that connect health care providers and enable medical information to follow a patient regardless of the treatment location. In Indiana, the Indiana Health Information Exchange, a nonprofit organization, is one of the largest health information exchanges in the United States—with a network of almost seventy hospitals and 19,000 physicians serving over twelve million patients with approximately 2.5 million pieces of data added daily. IND. HEALTH INFO. EXCHANGE, OVERVIEW, available at <http://www.ihie.org/pdfs/IHIE-Overview.pdf> (last visited Aug. 6, 2011); RAND CORP., *supra* note 266.

268. Richard Hillestad et al., *Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs*, 24.5 HEALTH AFFAIRS 1003, 1004 (2005) (discussing benefits and barriers to EHR implementation); *see generally* David Blumenthal & Marilyn Tavenner, *The "Meaningful Use" Regulation for Electronic Health Records*, 363:6 NEW ENG. J. MED. 501-04 (2010) (discussing the EHR Incentive Program); *see also* *Interest-Free Loans Available to Help Physicians Adopt Electronic Health Records*, UNITED HEALTH GROUP (Jan. 11, 2010), <http://www.unitedhealthgroup.com/newsroom/news.aspx?id=219ef4ce-ac1e-4dea-8e6d-aa5c76614a92> (discussing newly available interest-free financing to health care providers to purchase select EHR technology).

Program”) and the comprehensive reform efforts of the PPACA were the prominent catalysts behind HIT advancement and expansion.

B. EHR Incentive Program

The EHR Incentive Program was established in February of 2009 under the American Recovery and Reinvestment Act of 2009 and the Health Information and Technology Act (HITECH).²⁶⁹ This past year, under HITECH’s statutory authority, both the federal Department of Health and Human Services (HHS) and the Office of the National Coordinator for Health Information Technology (ONC) released administrative regulations detailing the EHR Incentive Program.²⁷⁰

In June 2010, ONC issued final rules, standards, and implementation measures for a temporary certification program for EHR Incentive Program technology.²⁷¹ Health professionals must use certified EHR technology to receive the incentive payments.²⁷² In July 2010, HHS released the final rules implementing the EHR Incentive Program, which provide incentive payments totaling up to twenty-seven billion over the next ten years for eligible professionals, eligible hospitals, and critical access hospitals participating in the Medicare and Medicaid programs that adopt, implement, and successfully demonstrate “meaningful use” of certified EHR technology.²⁷³ Successful “meaningful use” requires showing that certified EHR technology can be measured in both quantity and quality by fulfilling two sets of objective measures: the core set and the menu set.²⁷⁴ The core set consists of basic measurements such as patient’s vital signs, demographic information, and active medications.²⁷⁵ The menu set offers professionals the option to choose from a list of applicable tasks such as drug formulary checks or recording advance directives for patients sixty-five years of age or older.²⁷⁶ Practitioners can expect HHS to expand and require additional measures in 2013 and 2015 for both sets in order

269. Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, 123 Stat. 115 (2009).

270. *Registration for the Medicare and Medicare EHR Incentive Program Is Now Open*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/EHRIncentivePrograms/20_RegistrationandAttestation.asp (last modified July 29, 2011).

271. Establishment of the Temporary Certification Program for Health Information Technology, 75 Fed. Reg. 36,158 (June 24, 2010) (to be codified at 42 C.F.R. pt. 170).

272. *Id.* at 36,160.

273. Medicare and Medicaid Programs; Electronic Health Record Incentive Program, 75 Fed. Reg. 44,314 (July 28, 2010) (to be codified at 42 C.F.R. pts. 412, 413, 422, and 495).

274. *CMS EHR Meaningful Use Overview*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/EHRIncentivePrograms/30_Meaningful_Use.asp (last modified Apr. 20, 2011) (discussing meaningful use requirements).

275. Blumenthal & Tavenner, *supra* note 268, at 502.

276. *Id.* at 503.

to continuously improve quality care metrics.²⁷⁷

C. Patient Protection and Affordable Care Act of 2010

The passage of the PPACA in March of 2010 further encouraged the deployment and adaptation of HIT by healthcare professionals.²⁷⁸ The PPACA's impact on and advancement of HIT is threefold: (1) quality of health care; (2) operating rules and standards; and (3) HIT availability and workforce.²⁷⁹ Professionals can expect administrative regulations to expand upon these areas in the coming years.

1. *Quality of Health Care.*—The PPACA emphasizes HIT as a principal component to improve the quality of reporting, accuracy, and efficiency of data collection and management.²⁸⁰ Under the PPACA, HHS and ONC will develop national standards for data collection, interoperability, and security measures for data management systems.²⁸¹ The PPACA will also require collection and public reporting of certain performance information summarizing data on quality measures that are in turn aligned with the HIT expansion and interoperability efforts like the EHR Incentive Program.²⁸² In addition, professionals and entities who receive technical assistance grants under PPACA § 934 (quality improvement technical assistance and implementation) to demonstrate the capability to provide information and technical assistance to healthcare providers are required to coordinate with HIT regional extension centers regarding quality improvement and system delivery reform.²⁸³

2. *Operating Rules and Standards.*—PPACA § 1561 requires HHS and the HIT policy and standards committees to develop interoperable and secure standards for enrolling individuals in federal and state health and human service programs.²⁸⁴ Also, Section 1104 requires establishing a single set of operating

277. *See id.* at 504. Meaningful use measurements and criteria will be implemented in three stages, with each stage adding additional requirements. Currently, Stage 1 is set for 2011-12, Stage 2 will be implemented in 2013, and Stage 3 in 2015. *CMS EHR Meaningful Use Overview, supra* note 274.

278. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); *see also* HEALTHCARE INFO. & MGMT. SYS. SOC'Y, THE PATIENT PROTECTION AND AFFORDABLE CARE ACT: SUMMARY OF KEY HEALTH INFORMATION TECHNOLOGY PROVISIONS (2010), *available at* http://www.himss.org/content/files/PPACA_Summary.pdf (providing a more detailed discussion of HIT utilization under the PPACA).

279. *Id.* at 1.

280. *Id.*

281. Patient Protection and Affordable Care Act § 4302(a)(3).

282. *Id.* §§ 399JJ, 10305.

283. *Id.* § 934.

284. The Health IT Standards Committee is responsible for making recommendations to the National Coordinator for HIT Standards. *Health IT Standards Committee (a Federal Advisory Committee)*, OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., <http://healthit.hhs.gov/portal/server.pt?open=512&objID=1271&parentname=CommunityPage&parentid=6&mode=2> (last

rules to simplify health care administration for actions such as electronic funds transfers, healthcare payments, health claims, and referral authorization.²⁸⁵

3. *HIT Availability & Workforce*.—Similar to HITECH, the PPACA makes available grants for qualifying long-term care facilities to acquire certified EHR technology.²⁸⁶ In addition, HHS is seeking to improve HIT availability under the authority of PPACA § 6114, which authorizes a demonstration project to develop best practices in skilled nursing facilities for the use of HIT to improve resident care.²⁸⁷ As HIT becomes more available, the health care workforce will face new tasks and potentially new employment duties requiring the use of HIT. For example, the PPACA authorized under § 3502 the creation of community-based “health teams” comprised of health care professionals from multiple disciplines and expertise who can competently use HIT in delivery patient care.²⁸⁸

D. Indiana State HIT Developments

This past year, the State of Indiana began to take steps towards implementing federally initiated HIT programs. As required by HITECH in order to be eligible to receive grant awards, Indiana selected Indiana Health Information Technology, Inc as the qualified state-designated entity.²⁸⁹ In March of 2010, ONC announced that Indiana Health Information Technology, Inc. received a \$10,300,000 grant under the HITECH State Health Information Exchange Cooperative Agreement Program (SHIECAP). SHIECAP is designed to further advance both state and regional health information exchanges while continuing to work towards unified nationwide interoperability.²⁹⁰ Also, in 2010, HHS awarded \$16,008,431 to the Indiana Health Information Exchange as one of seventeen HIT Beacon Communities under HITECH.²⁹¹ In addition, the Indiana Medicaid office is in

modified June 30, 2011). The Health Policy Committee is responsible for making recommendations to the National Coordinator for HIT Standards on issues of policy. *Health IT Policy Committee (a Federal Advisory Committee)*, OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., <http://healthit.hhs.gov/portal/server.pt?open=512&objID=1269&parentname=CommunityPage&parentid=5&mode=2> (last modified July 23, 2011).

285. Patient Protection and Affordable Care Act § 1104.

286. *Id.* § 2041.

287. *Id.* § 6114.

288. *Id.* § 3502.

289. *See id.* § 2041.

290. *State Health Information Exchange Cooperative Agreement Program*, OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., <http://healthit.hhs.gov/portal/server.pt?open=512&objID=1336&mode=2&cached=true> (last modified Jan. 19, 2011).

291. The HITECH Beacon Communities primarily “focus on specific and measurable improvement goals in the three vital areas for health systems improvement in the Beacon Community”—quality, cost efficiency, and population health—to demonstrate HIT’s function in transforming the local health care systems. *Beacon Community Program: Improving Health Through Health Information Technology*, OFFICE OF THE NAT'L COORDINATOR FOR HEALTH INFO. TECH., http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov__onc_

the planning phases of readiness for the EHR Incentive Program.²⁹²

E. 2011 Developments and Beyond

From October 2009 to September 2010, as a result of federal efforts (but also key operations at the state and local level), Indiana took significant steps towards making HIT a more central component for health professionals' daily patient care. In the near future, health professionals can expect HIT implementation to continue to expand with additional federal administrative regulations for both the EHR Incentive Program and PPACA programs. As this trend continues, Indiana health professionals can expect increased legislative, administrative, and possible judicial action in regard to HIT both locally and nationally.

VI. HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) AND PRIVACY UPDATES

A. HITECH

Recently, significant developments have occurred within the area of HIPAA enforcement. On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act of 2009 (the "Recovery Act").²⁹³ Title XIII of the Recovery Act is known as the Health Information Technology for Economic and Clinical Health Act (HITECH). Among other provisions, HITECH makes several changes to the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)—more specifically, the privacy and security rules.²⁹⁴ These changes include: extending the applicability of certain of the privacy and security rules' requirements to the business associates of covered entities; requiring HIPAA-covered entities and business associates to provide for notification of breaches of protected health information (PHI) that is unsecured; establishing new

beacon_community_program__improving_health_through_health_it/1805 (last modified May 19, 2011).

292. *Indiana Electronic Health Records (EHR) Incentive Program*, INDIANA MEDICAID FOR PROVIDERS, <http://provider.indianamedicaid.com/general-provider-services/ehr-incentive-program.aspx> (last visited Aug. 6, 2011).

293. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115.

294. The administrative simplification provisions of HIPAA provided for the establishment of national standards for the electronic transmission of certain health information, such as standards for certain health care transactions conducted electronically and code sets and unique health care identifiers for health care providers and employers. These provisions also required the establishment of national standards to protect the privacy and security of personal health information and established civil money and criminal penalties for violations. The provisions apply to three types of entities known as "covered entities": health care providers who conduct covered health care transactions electronically, health plans, and health care clearinghouses. *HIPAA Administrative Simplification Statute and Rules*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/ocr/privacy/hipaa/administrative/index.html> (last visited Aug. 6, 2011).

limitations on the use and disclosure of PHI for marketing and fundraising purposes; prohibiting the sale of PHI; requiring the consideration of a limited data set as the minimum necessary amount of information; and expanding individuals' rights to access and receive an accounting of disclosures of their PHI, and to obtain restrictions on certain disclosures of PHI to health plans.²⁹⁵ In addition, HITECH adopts provisions designed to strengthen and expand HIPAA's enforcement provisions.

Certain HITECH provisions have already been the subject of rulemakings and related actions, as published by HHS as interim final regulations.

1. Breach Notification.—On August 24, 2009, HHS published interim final regulations to implement the breach notification provisions of HITECH.²⁹⁶ This interim final regulation was effective September 23, 2009.

In general, the interim final rule requires covered entities to notify affected individuals and HHS in the event of a breach²⁹⁷ of unsecured PHI²⁹⁸ that compromises the security or privacy of the PHI, unless an exception applies. Accordingly, in order to determine if notice is required under this interim final rule, a covered entity must make the following three determinations: (1) whether a breach of PHI occurred; (2) whether the PHI was unsecured; and (3) whether an exception applies.²⁹⁹ The interim final rule clarified and reasserted the three exceptions contained in HITECH. Those exceptions are as follows:

- (1) Unintentional acquisition, access, or use of PHI by a workforce member acting under the authority of a covered entity or business associate, if done in good faith and the information was not further used or disclosed;
- (2) Inadvertent disclosure of PHI by a person authorized to access PHI at a covered entity or business associate to another person authorized to access PHI at the same covered entity, business associate, or organized health care arrangement, and the PHI was not further used or disclosed; and
- (3) A disclosure of PHI where there is a good-faith belief by the covered entity or business associate that an unauthorized person to whom the disclosure was made would not reasonably have been able to retain such

295. See generally American Recovery and Reinvestment Act of 2009, tit. XIII.

296. Breach Notification for Unsecured Protected Health Information, 74 Fed. Reg. 42,740 (Aug. 24, 2009) (to be codified at 45 C.F.R. pts. 160, 164).

297. The interim final rule defines "breach" as the "acquisition, access, use, or disclosure of protected health information" in a manner not permitted by the HIPAA Privacy Rule, "which compromises the security or privacy of the PHI." *Id.* at 42,743.

298. The interim rule defines "unsecured PHI" as PHI that is not rendered unusable, unreadable or indecipherable to unauthorized individuals through the use of a technology or methodology specified by the Secretary of HHS. Accordingly, if PHI is secured by one of the methods or technologies listed above, notification is not required under the rule, even if the PHI was used or disclosed in violation of the HIPAA privacy rule. *Id.* at 42,748.

299. See generally *id.*

information.³⁰⁰

If any of these exceptions applies, notification is not required under the interim final rule. Otherwise, a covered entity must notify affected individuals and HHS for all breaches under the interim final rule.³⁰¹ Depending on the size of the group affected and the availability of contact information, media notice may also be required.³⁰² All notifications must be given to the affected individual without unreasonable delay, but no later than sixty days after discovery. A breach is considered “discovered” on the first day the breach is known, or by reasonable diligence would have been known, to the covered entity.³⁰³ The interim final rule requires business associates to notify the covered entity under the same standard. Business associates are not required to provide the notifications themselves.

A covered entity must notify an affected individual via first-class mail at his or her last known address or, if the individual has agreed to receive electronic notice, via e-mail.³⁰⁴ The interim final rule specifies that for deceased individuals, the covered entity must provide the notification to the individual’s next of kin or personal representative.³⁰⁵ The notice must contain at least the following elements, in plain language:

- (1) A brief description of what happened, including the date of breach and the date of discovery of the breach;
- (2) A description of the types of unsecured PHI involved in the breach (i.e., whether full name, Social Security number, date of birth, home address, account number, diagnosis, disability code or other types of information were involved);
- (3) Any steps that individuals should take to protect themselves from potential harm resulting from the breach;
- (4) A brief description of what the covered entity is doing to investigate the breach, to mitigate the harm to individuals and to protect against any further breaches; and
- (5) Contact procedures for individuals to ask questions or learn additional information, which must include a toll-free telephone number, an e-mail address, Web site, or postal address.³⁰⁶

Similarly, on August 25, 2009, the Federal Trade Commission (FTC) published final regulations implementing the breach notification provisions for personal

300. *Id.* at 42,746-47.

301. *Id.* at 42,748-49.

302. For breaches involving more than 500 residents, a covered entity must also notify prominent media outlets. In such instances, a covered entity must also notify HHS at the same time, in the manner and form to be prescribed on HHS’s website. *Id.* at 42,751.

303. *Id.* at 42,749.

304. *Id.* at 42,750.

305. *Id.*

306. *Id.* The interim final rule specifies that the requisite information may be given in separate notices, if necessary.

health record vendors and their third party service providers.³⁰⁷ This interim final rule was effective September 24, 2009.

For purposes of determining the information to which the HHS and FTC breach notification regulations apply, HHS also issued—first on April 27, 2009,³⁰⁸ and then later with its interim final rule—the guidance required by the HITECH Act specifying the technologies and methodologies that render PHI unusable, unreadable, or indecipherable to unauthorized individuals.

2. *Increased Civil Monetary Penalties.*—To conform the provisions of the enforcement rule to the new tiered and increased civil money penalty structure made effective by the HITECH Act on the day after enactment (February 18, 2009), HHS published an interim final rule on October 30, 2009 that became effective November 30, 2009.³⁰⁹

3. *2010 Notice of Proposed Rulemaking.*—On July 14, 2010, HHS formally published its proposed regulations implementing changes made to the privacy, security, and enforcement rules by HITECH.³¹⁰ When finalized, the new regulations will implement the statutory amendments made to HIPAA under HITECH. The proposed rules concern the privacy and security standards issued pursuant to HIPAA, as well as the enforcement rules that implement HIPAA's civil money penalty authority.

Although the effective date of February 17, 2010 for many HITECH provisions has passed, the proposed rules and final rule (expected in March of 2011) provide specific information regarding the expected date of compliance and enforcement of the new requirements. HHS has recognized that it would be difficult for covered entities and business associates to comply with the new regulations until after these rules are finalized. Therefore, for most provisions, HHS intends to set the effective date for compliance at 180 days after the final rule is published.

4. *Extending Privacy Requirements to Business Associates.*—Historically, HIPAA applied to business associates only indirectly through business associate agreements with covered entities. HITECH requires business associates to comply not only with the privacy terms required in HIPAA business associate agreements, but also with “additional” privacy requirements.³¹¹ The proposed rules modify the privacy rule in several ways to address the permitted and required uses and disclosures of PHI by business associates.³¹²

307. Health Breach Notification Rule, 74 Fed. Reg. 42,962 (Aug. 25, 2009).

308. Guidance Specifying the Technologies and Methodologies That Render Protected Health Information Unusable, Unreadable, or Indecipherable to Unauthorized Individuals, 74 Fed. Reg. 19,006 (Apr. 27, 2009).

309. HIPAA Administration Simplification: Enforcement, 74 Fed. Reg. 56,123 (Oct. 30, 2009).

310. Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act, 75 Fed. Reg. 40,868 (July 14, 2010) (to be codified at 45 C.F.R. pts. 160, 164).

311. American Recovery and Reinvestment Act of 2009, tit. XIII, § 13404.

312. See 45 C.F.R. § 164.502.

First, HHS proposes to modify the rules to clarify that a business associate, like a covered entity, may only use or disclose PHI as permitted or required by the privacy rule or the enforcement rule.³¹³ The proposed changes also clarify the particular sections of the privacy rule that apply only to covered entities.³¹⁴

Second, HHS proposes that business associates may use or disclose PHI only as permitted or required by the business associate agreement, for the business associate's own management and administration, or for the provision of data aggregation services relating to the health care operations of the covered entity.³¹⁵ If the business associate and covered entity have failed to enter into a business associate agreement or other arrangement, then the business associate may use or disclose the PHI only as necessary to perform its obligations for the covered entity.³¹⁶ The proposed rule continues to place the burden on the covered entity to obtain a business associate agreement.³¹⁷ Notably, however, a person or entity that meets the definition of "business associate" under the regulations would still be required to follow the applicable portions of the privacy rule regardless of whether a business associate agreement is in place. The proposed rule also makes it clear that a business associate would not be permitted to use or disclose PHI in a way that would violate the requirements of the privacy rule.³¹⁸

Third, business associates also would be required to disclose PHI to the Secretary of HHS to investigate or determine the business associate's compliance with the privacy rule.³¹⁹ Business associates also would be required to disclose PHI to the covered entity, individual, or individual's designee, as necessary, to satisfy the covered entity's obligations to respect an individual's request for an electronic copy of PHI.³²⁰

Finally, the proposed rule also would apply the minimum necessary standard directly to business associates.³²¹

5. *Proposed Security Rule Changes Affecting Business Associates.*—HITECH applies the primary requirements of the HIPAA security rule to business associates, including the requirement that business associates implement administrative, physical, and technical safeguards and meet the policies and documentation standards. The proposed rule introduced an expansion of the statutory requirement under HITECH by proposing that a business associate would be required to comply with the entire HIPAA security rule.³²²

313. *Id.*

314. *Id.*

315. *Id.* at 40,919-20.

316. *Id.* at 40,919.

317. *Id.* at 40,919-20.

318. *Id.* at 40,919.

319. *Id.*

320. *Id.*

321. *Id.*

322. Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the Health Information Technology for Economic and Clinical Health Act, 75 Fed. Reg. 40,868, 40,872 (July 14, 2010).

Also, to be consistent with the privacy rule, the proposed security rule revisions also would require business associates to have business associate agreements with their subcontractors, as discussed in more detail below.

6. *New “Subcontractor” Category.*³²³—The regulations propose to expand the definition of “business associate” to include the new category of “subcontractors,” which are individuals or agencies that act on behalf of a business associate in a manner that requires access by the subcontractor to the covered entity’s protected health information. Under the proposed language, a subcontractor need not have entered into a formal business associate agreement to be subject to the same rules and regulations that apply to the business associate.³²⁴ Accordingly, any such individual or agent is included under the proposed definition.

7. *Requirements for Business Associate Agreements.*³²⁵—Under the proposed rules, covered entities will no longer be required to report to HHS when a pattern or practice of a business associate violates the business associate agreement and termination of the arrangement is not feasible. According to commentary contained in the proposed regulations, such a requirement is no longer necessary in light of the breach notification rule and the direct liability of business associates under HITECH.

Business associates will be required to take reasonable steps to cure violations of a business associate subcontractor agreement if the business associate becomes aware of a pattern or practice of a subcontractor that violates the agreement.³²⁶ This provision simply requires business associates to respond to noncompliance by their subcontractors in the same way that covered entities are required to respond to noncompliance by their business associates.

Business associate agreements will be required to include provisions providing that business associates will do the following:

- (1) Comply with the security rule with regard to electronic protected health information;
- (2) Report breaches of unsecured PHI to covered entities in accordance with the breach notification rule;
- (3) Ensure that their subcontractors agree to the same restrictions and conditions as apply to the business associate; and
- (4) Comply with the privacy rule requirements as if it were the covered entity in those instances when the business associate is carrying out the covered entity’s obligation under the privacy rule.³²⁷

The proposed rules also stipulate that business associate subcontractor agreements will be required to meet all of the requirements applicable to business associate agreements.

323. *Id.* at 40,873.

324. *Id.*

325. *See generally id.* at 40,887.

326. *Id.* at 40,888.

327. *Id.* at 40,889.

HHS has acknowledged the anticipated administrative burden and cost to implement the revised business associate agreement provisions of the privacy and security rules. Therefore, the proposed rules introduce transition provisions that allow covered entities and business associates to continue to operate under certain existing contracts for up to one year beyond the compliance date.³²⁸

B. Other Changes to the Privacy Rule

1. *Access to Electronic Protected Health Information.*—Currently, the privacy rule provides individuals with the right to access and request copies of their PHI.³²⁹ The proposed rules state that covered entities must provide access to hard copy or electronic PHI in both the form and format requested by the individual, if such PHI is readily available in that form or format. If it is not, the covered entity must provide access to a legible alternative form and format agreed upon by the individual and the covered entity.³³⁰ Additionally, if the PHI requested is maintained electronically and the individual requests it in electronic form, the covered entity must provide the PHI in the electronic form requested if it is readily producible in that form. If it is not readily producible in that form, the covered entity must provide the PHI in an alternate electronic form. The covered entity may still charge a reasonable cost-based fee for any electronic media it provides.³³¹ The proposed rules also provide that covered entities must honor patients' written requests to transmit PHI to another designated individual, provided that the request contains the patient's signature and clearly identifies the recipient and where to send a copy of the PHI.

2. *Restrictions on PHI Disclosures for Services Paid Out of Pocket in Full.*³³²—HIPAA provides an individual the right to request restrictions on how a covered entity uses and discloses his or her PHI, but covered entities are not required to agree to such requests. HITECH, however, changed this for disclosures relating to services for which the individual paid out of pocket in full.³³³ The proposed rules implement that change and clarify that covered entities are required to comply with a patient's request to restrict disclosure of PHI to a health plan if: the PHI relates exclusively to health care items or services provided; the patient (or an individual on the patient's behalf) paid for the items or services in full; and disclosure is not otherwise legally required. Covered entities are also prohibited from disclosing the restricted PHI to the health plan's business associates.

3. *Additional Provisions in Notices of Privacy Practices.*—The proposed rules require covered entities to ensure that their notices of privacy practices include language stating that:

328. *Id.*

329. *Id.* at 40,901.

330. *Id.*

331. *Id.* at 40,902.

332. *Id.* at 40,905.

333. *Id.*

- (1) Most disclosures of PHI for remuneration will require the individual's authorization;
- (2) Most uses and disclosures of psychotherapy notes will require the individual's authorization;
- (3) Most uses and disclosures for marketing purposes will require the individual's authorization; and
- (4) The individual has the right to request restrictions on PHI disclosures for services paid out-of-pocket in full.³³⁴

Additionally, if a health care provider intends to send communications regarding treatment alternatives or other health-related products or services and the provider will receive financial remuneration in return for making the communication, the provider's notice of privacy practices must inform the individual of that intention as well as the individual's ability to opt out of receiving such communications.

4. *Marketing*.—The new rules revise the definition of marketing to exclude certain types of communications from the term. Under HIPAA, marketing is defined as “a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.”³³⁵ HITECH maintained that definition but clarified that “marketing” does not include several types of communications. First, it does not include communications for treatment of an individual by a health care provider—“including case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.”³³⁶ Second, it does not include communications to “provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual, only if any financial remuneration received by the covered entity in exchange for making the communication is reasonably related to the covered entity's cost of making the communication.”³³⁷

Furthermore, communications for the following health care operations activities are not “marketing,” except where the covered entity receives financial remuneration in exchange for making the communication:

- (A) To describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity making the communication, including communications about: The entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part

334. *Id.*

335. *Id.* at 40,918.

336. *Id.*

337. *Id.*

of, a plan of benefits; or (B) For case management or care coordination, contacting of individuals with information about treatment alternatives, and related functions to the extent these activities do not fall within the definition of treatment.³³⁸

If marketing involves direct or indirect financial remuneration, the authorization obtained from the individual must disclose that such remuneration is involved.³³⁹

a. Sale of PHI.—Under the proposed rules, the sale of PHI for any direct or indirect financial remuneration generally would necessitate a prior written authorization, which must explain that the covered entity will receive remuneration for the disclosures.³⁴⁰ Such PHI could be exchanged for direct or indirect remuneration in the following circumstances without prior written authorization:

- (1) Disclosures of PHI for public health activities;
- (2) Disclosures of PHI for research purposes if the remuneration received is a reasonable cost-based fee to cover the actual cost of providing the PHI;
- (3) Disclosures of PHI for treatment or payment purposes;
- (4) Disclosures of PHI for “the sale, transfer, merger, or consolidation of all or part of the covered entity and for related due diligence”;
- (5) Disclosure of PHI to the individual or to provide an accounting of disclosures to the individual;
- (6) Disclosures required by law;
- (7) Disclosures otherwise permitted by the privacy rule; and
- (8) Disclosures of PHI for payment purposes.³⁴¹

b. Fundraising.—The proposed rules require a covered entity’s notice of privacy practices to disclose that the individual may be contacted for fundraising purposes and that the individual may opt out of being contacted at any time.³⁴² In addition, every fundraising communication must include a “clear and conspicuous” option to opt out of further fundraising communications. The opt-out method cannot be unduly burdensome or cause the individual to incur more than a nominal cost.³⁴³

c. Minimum necessary rule.—The HITECH Act currently provides that a covered entity will be deemed to have complied with the minimum necessary principle if it limits uses and disclosures of PHI to a limited data set, to the extent

338. *Id.*

339. For these purposes, “financial remuneration” means “direct or indirect payment from or on behalf of a third party whose product or service is being described. Direct or indirect payment does not include any payment for treatment of an individual.” *Id.* at 40,919.

340. *Id.* at 40,890.

341. *Id.*

342. *Id.* at 40,896.

343. *Id.*

practicable.³⁴⁴ This statutory requirement is currently effective but will sunset on the effective date of guidance HHS is required to issue on this topic. To prepare for its release of that guidance, HHS has requested comments on what aspects of the minimum necessary standard covered entities and business associates would find most helpful to have HHS address, as well as any questions about how to appropriately determine what constitutes the “minimum necessary” to comply with the privacy rule.³⁴⁵

*d. Compound authorization for research.*³⁴⁶—In general, authorizations required by the privacy rule cannot be combined with other documents, and the provision of treatment or payment, enrollment in a health plan, or eligibility for benefits may not be conditioned on receipt of an authorization unless the treatment is research-related. In the proposed rule, HHS set forth limited exceptions for research authorizations whereby covered entities would be permitted to combine conditioned and unconditioned authorizations presented for research purposes—provided that the authorizations clearly denote which, if any, research components are conditioned upon receipt of authorization and clearly disclose individuals’ right to opt in to any unconditioned research activity. In addition, HHS is seeking comment on whether and how the privacy rule could be amended to permit authorization for future or secondary research uses of PHI.³⁴⁷

*e. Decedent’s health information.*³⁴⁸—HHS has proposed to remove from the definition of PHI decedent’s health information after fifty years of the decedent’s death. Also, the proposed rule revises the definition of “individually identifiable health information” so that information regarding persons who have been deceased for more than fifty years will not constitute PHI.³⁴⁹ Also, the proposed rule will expand access to a decedent’s PHI to family members and others involved in the care of the patient prior to death, unless doing so is inconsistent with the decedent’s previously expressed preference.

f. Disclosure of student immunization records.—The proposed rule acknowledges that state law may now require schools to acquire student immunization records prior to enrollment.³⁵⁰ In states with such requirements, covered entities would be permitted to disclose student immunization records to schools based on a parent’s oral agreement, as opposed to written authorization.³⁵¹

*g. Changes to the enforcement rule.*³⁵²—HITECH modified the potential civil money penalties under HIPAA, creating a structure whereby penalties are

344. *Id.*

345. *Id.*

346. *Id.* at 40,907.

347. *Id.*

348. *Id.* at 40,894.

349. *Id.*

350. *Id.* at 40,895.

351. *Id.* (with codification to be at 45 C.F.R. § 164.512(b)).

352. *Id.* at 40,875.

tiered based on the covered entity's perceived culpability for the violation. Accordingly, violations would become more severe based on whether the circumstances involved "reasonable cause" or "willful neglect."³⁵³ HHS published an interim final rule in October of 2009 clarifying the penalty structure,³⁵⁴ and the proposed rule further clarified that structure.

The proposed rule modified the definition of "reasonable cause" to mean "an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated an administrative simplification provision, but in which the covered entity or business associate did not act with willful neglect."³⁵⁵

VII. INDIANA LEGISLATIVE UPDATE

A. *Bodily Substance Samples Procedures in Hospitals*

Effective March 12, 2010, Senate Enrolled Act 342 amends a provision of the state's implied consent law, clarifying that bodily substance samples taken in a hospital may be taken by any person who is trained in taking such samples and who is acting under the direction of, or under a protocol approved by, a physician.³⁵⁶ The clarification in the law was sought by the Indiana Prosecuting Attorneys Council as a result of a 2009 Indiana Court of Appeals case in which the court ruled that blood drawn by a certified lab technician within a hospital was inadmissible as evidence in a criminal investigation because a "certified lab technician" was not listed in the law as an individual authorized to take samples for evidentiary purposes.³⁵⁷ In addition, the court held that the evidence was inadmissible because the certified lab technician did not technically adhere to the hospital's physician-approved protocol when drawing the blood.³⁵⁸

B. *Paternity Affidavits Executed in Hospitals*

Effective July 1, 2010, Senate Enrolled Act 178 made changes to the legal consequences of paternity affidavits executed for children born out of wedlock, ultimately allowing the mother and the supposed father to agree to share joint legal custody of the child.³⁵⁹ Notably for hospitals and their staff, paternity affidavits executed in the hospital within seventy-two hours of the child's birth must be presented to the mother and the supposed father separately before they are signed.³⁶⁰ In addition, hospital staff must offer individuals under the age of

353. *Id.*

354. HIPAA Administrative Simplification: Enforcement, 74 Fed. Reg. 56,123 (Oct. 30, 2009).

355. 75 Fed. Reg. at 40,878.

356. *See generally* IND. CODE § 9-30-6-6(j) (2011).

357. *Brown v. State*, 911 N.E.2d 668, 673 (Ind. Ct. App. 2009).

358. *Id.* at 672-73.

359. *See generally* 2010 Ind. Acts 321-27, 329-30.

360. IND. CODE § 16-37-2-2.1(p).

eighteen an opportunity to consult with an adult regarding the contents of the paternity affidavit before signing it.³⁶¹

C. Uniform Cease and Desist Order

Effective July 1, 2010, Senate Enrolled Act 356, the state's omnibus professional licensing bill, made several changes that will affect the state's health care practitioners. Most notably, the act establishes a uniform procedure to allow the board of a regulated profession to issue a cease and desist order against a person who is participating in activities that require a license, certification, or registration.³⁶² The uniform process will allow a board to file a complaint with the attorney general.³⁶³ The attorney general will then investigate and may file a motion for a cease and desist order with the appropriate board.³⁶⁴ The board will have the option of holding a "show cause" hearing, and based on the findings of that hearing, it may issue a cease and desist order regarding the same.³⁶⁵ A cease and desist order issued under the new uniform process is enforceable in the circuit or superior courts.³⁶⁶

D. Dispensing to an Individual Unknown to a Retail Pharmacist

Effective July 1, 2010, Senate Enrolled Act 356 also prohibits a retail pharmacist, pharmacy technician, or person authorized by a pharmacist to dispense a controlled substance ("dispensing individual") from dispensing a controlled substance to a customer who is not personally known to the dispensing individual, unless the customer provides proof of identification.³⁶⁷

E. INSPECT: Good Faith Reporting to Law Enforcement

Effective July 1, 2010, Senate Enrolled Act 356 also amends the state's collection and tracking program (INSPECT) by attempting to grant practitioners civil and criminal immunity when they, in good faith, report possible drug seeking patients to law enforcement.³⁶⁸ It should be noted that despite the civil and criminal immunity, practitioners are still bound by state and federal privacy laws, including HIPAA.³⁶⁹ As a result, practitioners will still need to have either the patient's authorization or meet a HIPAA exception prior to releasing any INSPECT information to law enforcement.

361. *Id.* § 16-37-2-2.1(r).

362. *See generally* 2010 Ind. Acts 932-1010, 947-48.

363. IND. CODE § 25-1-7-14(a).

364. *Id.* § 25-1-7-14(a)(1).

365. *Id.* § 25-1-7-14(a)(2).

366. *Id.* § 25-1-7-14(d).

367. *See generally* 2010 Ind. Acts 932-1010, 1002.

368. *See generally id.* at 1006.

369. *See generally id.* at 1002-06.

F. Abandoned Medical Records

Effective July 1, 2010, Senate Enrolled Act 356 establishes procedures for the attorney general to take possession of, store, maintain, transfer, protect, and destroy abandoned health records and other records containing personally identifying information.³⁷⁰ The law requires the attorney general to make reasonable efforts to notify the patients named in the records that the attorney general has taken possession of the records.³⁷¹ Unless prohibited by law, the law also authorizes the attorney general to notify professional organizations, hospitals, law enforcement agencies, and government units, “who may be able to assist in notifying persons whose records were abandoned and secured by the attorney general.”³⁷²

370. *See generally id.* at 933-35.

371. IND. CODE § 4-6-14-7(a).

372. *Id.* § 4-6-14-7(b).