HEALTH LAW

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CONTENTS

INTRODUCTION

At the federal level, historic health legislation reform that should provide access to affordable and comprehensive health insurance coverage for practically all Americans—but carries with it the controversial individual mandate to be covered by health insurance—topped the significant health care developments this survey year. Also

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at the federal level, an expansion in Medicare lien reporting requirements applicable to attorneys who bring or who defend personal injury lawsuits, and President Obama's Executive Order directing equal visitation rights for same sex partners of hospitalized patients, are discussed in this Article.

At the state level, the Family Health Care Decisions Act, which provides family members with legal authority to make medical treatment decisions for incapacitated patients who never executed a health care proxy or otherwise made their wishes known, was finally enacted into law after nearly twenty years of legislative logjam. Also becoming law was the Midwifery Modernization Act, which expanded the practice of midwifery by removing the requirement that a midwife have an agreement with a physician in order to engage in the profession.

In state courts, the Court of Appeals took on the difficult issue of inmate access to life-sustaining but experimental medical treatment that is available to non-incarcerated New Yorkers. Lower New York courts also took on novel issues related to the confidentiality of quality assurance and peer review process in hospitals and the duty of health care providers to the spouses of their patients for exposing the spouse to a sexually transmitted disease.

I. NEW YORK STATE CASE LAW

A. New York State Court of Appeals

1. Wooley v. New York State Department of Corrections

In *Wooley v. New York State Department of Corrections Services*, the New York State Court of Appeals upheld limits by the state prison system on inmate access to non-FDA approved medical treatments.[1]

Inmates in New York have a well established right to reasonable and adequate medical treatment.[2] This right is derived in part from a state law requirement that inmates be treated humanely.[3] It is also

1. 15 N.Y.3d 275, 283, 934 N.E.2d 310, 316, 907 N.Y.S.2d 741, 747 (2010), *reh'g denied*, 15 N.Y.3d 841, 841, 935 N.E.2d 807, 807, 909 N.Y.S.2d 15, 15 (2010) (mem.).

2. *See* Rivers v. New York, 159 A.D.2d 788, 789, 552 N.Y.S.2d 189, 189 (3d Dep't 1990), *appeal denied*, 76 N.Y.2d 701, 701, 557 N.E.2d 114, 114, 557 N.Y.S.2d 878, 878 (1990); Kagan v. New York, 221 A.D.2d 7, 8, 646 N.Y.S.2d 336, 337 (2d Dep't 1996); Powlowski v. Wullich, 102 A.D.2d 575, 587, 479 N.Y.S.2d 89, 98 (4th Dep't 1984).

3. N.Y. CORRECT. LAW § 70(2) (McKinney Supp. 2011) ("Correctional facilities shall be used for the purpose of providing places of confinement and programs of treatment for persons in the custody of the department . . . . In furtherance of this objective the department may establish and maintain any type of institution or program of treatment, not inconsistent with other provisions of law, but with due regard to . . . (b) [t]he right of every person in the

founded upon the U.S. Constitution's Eighth Amendment, which prohibits cruel and unusual punishment.[4] The scope of this right, and whether it extends to treatments not approved by the Federal Food and Drug Administration (FDA) but recommended by a physician, was examined by the Court of Appeals in *Wooley*.[5] In a 4-3 decision the Court held that the inmate's request for the non-approved treatment was not arbitrary and capricious.

In *Wooley*, an inmate ill with hepatitis C challenged a decision by the chief medical officer for the state prison system which denied his request to be treated with a new treatment after he had failed the standard treatment for hepatitis C.[6] Hepatitis C is "a viral infection which increases the risk of liver cancer and often leads to cirrhosis of the liver, which can cause liver failure and, ultimately, death."[7] The standard treatment for hepatitis C is interferon and ribivarin.[8]

Wooley's prison physician approved him for up to forty-eight weeks of a new treatment, pegylated interferon and ribivarin.[9] However, the inmate sought approval for additional low-dose maintenance pegylated interferon treatment.[10] Although pegylated interferon had been approved by the FDA for treatment of other medical conditions, it had not been approved by the FDA for treatment of hepatitis C.[11] Accordingly, its use to treat hepatitis C would be considered an off-label use of the drug.[12] To be an off-label use, it must have been approved by the FDA for some uses.[13] "Off-label use refers to the use of an approved treatment for any purpose, or in any manner, other than what is described in the product's labeling."[14]

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custody of the department to receive humane treatment; and (c) [t]he health and safety of every person in the custody of the department.").

4. U.S. CONST. amend. VIII; *see* Estelle v. Gamble, 429 U.S. 97, 101 (1976) (holding that actions by government officials that demonstrate "deliberate indifference" to an inmate's "serious illness or injury" violate the Eighth Amendment).

5. *Wooley*, 15 N.Y.3d at 278, 934 N.E.2d at 313, 907 N.Y.S.2d at 744.

6. *Id.* at 278, 934 N.E.2d at 312, 907 N.Y.S.2d at 743.

7. *Id.*

8. *Id.* at 278, 934 N.E.2d at 313, 907 N.Y.S.2d at 744.

9. *Id.* at 279, 934 N.E.2d at 313, 907 N.Y.S.2d at 744.

10. *Wooley*, 15 N.Y.3d at 279, 934 N.E.2d at 313, 907 N.Y.S.2d at 744.

11. *Id.* at 278, 934 N.E.2d at 313, 907 N.Y.S.2d at 744.

12. *Id.*

13. Henry F. Fradella, *Criminal Law Implications of "Off-Label" Drug Use*, 44 CRIM. L. BULL. 285, 285 (2008) (defining off-label as "when a drug is prescribed and used for reasons outside the terms of the FDA product license.").

14. *Approval Process for New Cancer Treatments*, NAT'L CANCER INST., http://www.cancer.gov/clinicaltrials/education/approval-process-for-cancer-drugs/allpages (last visited Feb. 27, 2011).

Although an off-label use, an infectious disease specialist who examined Mr. Wooley recommended its use, "noting that '[t]here is evidence in published literature for this approach although [it is] not FDA approved or proven in long[-]term studies yet.'"[15] "[A]ll five doctors who examined petitioner recommended that he receive low-dose maintenance pegylated interferon."[16]

Because there were no long-term studies showing its value, the State's chief prison medical officer denied it as maintenance therapy.[17] He concluded that its use was experimental and not FDA approved.[18]

In upholding the denial, the Court emphasized that the State's decision was because the treatment was "unproven in long-term studies and not yet approved by the FDA, as even those doctors who suggested the maintenance treatment recognized."[19] There was a rational basis for Department of Correctional Services' (DOCS) determination and so, therefore, it was not arbitrary and capricious.[20] Even if the Court had found otherwise, under the rational basis review standard it must defer to the agency's determination.[21] The Court "decline[d] to weigh the varying studies available in the medical literature."[22] The determination was not a "reflexive application of DOCS policy" prohibiting experimentation on inmates.[23] Rather, all of the physicians agreed that low-dose maintenance pegylated interferon "was not yet proven effective, and we conclude that such recognition of the lack of documented success of maintenance levels of pegylated interferon constitutes a rational basis for DOCS determination denying treatment with a non-FDA-approved protocol."[24]

The Court also found that DOCS's denial did not constitute a violation of the Eighth Amendment's prohibition on "cruel and unusual punishment."[25] An inmate must demonstrate that "prison officials acted

15. *Wooley*, 15 N.Y.3d at 279, 934 N.E.2d at 313, 907 N.Y.S.2d at 744.

16. *Id.*; *see also* Wooley v. New York State Dep't of Corr. Servs., 61 A.D.3d 1189, 1190, 876 N.Y.S.2d 568, 569 (3d Dep't 2009) (explaining that use of low-dose maintenance pegylated interferon "would be a reasonable strategy to stave off progression" of Wooley's disease).

17. *Wooley*, 15 N.Y.3d at 279, 934 N.E.2d at 313, 907 N.Y.S.2d at 744.

18. *Id.*

19. *Id.* at 280, 934 N.E.2d at 314, 907 N.Y.S.2d at 745.

20. *Id.*

21. *Id.*

22. *Wooley*, 15 N.Y.3d at 281, 934 N.E.2d at 314, 907 N.Y.S.2d at 745.

23. *Id.*

24. *Id.* at 281, 934 N.E.2d at 314-15, N.Y.S.2d at 745-46.

25. *Id.* at 282-83, 934 N.E.2d at 316, 907 N.Y.S.2d at 747.

with 'deliberate indifference to [his or her] serious medical needs.'"[26] Further, inmates must be provided with "adequate" medical care.[27]

In *Wooley*, the inmate had been given two courses of the forty-eight week standard treatment for his disease when only one was required and had been seen by several specialists, all of whom agreed that the treatment denied by DOCS was "unproven in long-term studies and not yet approved by the FDA."[28] Further, DOCS promised to evaluate future treatment regiments for the inmate.[29] The Court concluded that this was neither arbitrary and capricious, nor a violation of the Eighth Amendment.[30]

Three judges joined in a dissent, finding it arbitrary and capricious for DOCS to deny treatment to an inmate where all five of his physicians recommended the treatment and it was "undisputed, on this record, that the treatment offers at least some possibility of protecting petitioner against a life-threatening illness."[31] There was no evidence that the risks outweighed the benefits.[32] Although cost could be considered by DOCS in determining whether to deny a treatment, this was not mentioned by DOCS as a basis for its denial.[33]

Accordingly, the dissent concluded that denying an inmate a lifesaving treatment recommended by all of his physicians, for the reasons stated by DOCS (i.e., there were no long-term studies and it was not FDA approved) was arbitrary and capricious.[34]

This is a potentially far-reaching decision because the off-label use of medication is a common practice in medicine.[35] Although, as the dissent notes, low dose pegylated interferon was classified as experimental for the purpose of treating hepatitis C, the FDA "does not forbid doctors from prescribing it for their patients."[36] In fact, in the treatment of some medical conditions, drugs used off-label are the

26. *Id.* at 282, 934 N.E.2d at 315, 907 N.Y.S.2d at 746 (citing Estelle v. Gamble, 429 U.S. 97, 104 (1976)).

27. *See* Farmer v. Brennan, 511 U.S. 825, 832 (1994).

28. *Wooley*, 15 N.Y.3d at 283, 934 N.E.2d at 316, 907 N.Y.S.2d at 747.

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.*

33. *Wooley*, 15 N.Y.3d at 284, 934 N.E.2d at 317, 907 N.Y.S.2d at 748.

34. *Id.* at 283, 934 N.E.2d at 316, 907 N.Y.S.2d at 747 (Smith, J., dissenting).

35. *See, e.g.*, James O'Reilly & Amy Dalal, *Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs*, 12 ANNALS HEALTH L. 295, 298 (2003); Fradella, *supra* note 13, at 285.

36. *Wooley*, 15 N.Y.3d at 283, 934 N.E.2d at 316, 907 N.Y.S.2d at 747 (Smith, J., dissenting).

standard of care.[37] Further, there are federal laws and laws in New York and most other states requiring that certain types of off-label uses of drugs be covered by Medicare and private health insurance plans.[38]

Under the Court's reasoning in *Wooley*, inmates would not have access to non-FDA approved medical treatments which in some instances are easily accessible by non-inmates and in other instances constitute the standard of care. This could impair the ability of inmates to receive accepted, although not FDA approved, medical treatments that are commonly prescribed off-label to treat some medical conditions.

B. New York State Supreme Court, Appellate Division

The appellate division decided two recent cases on the issue of confidentiality of the quality assurance and peer review process in hospitals. *Stalker v. Abraham*[39] and *Learned v. Faxton-St. Luke's Healthcare*[40] both address a hospital's ability to satisfy its burden in invoking this privilege.

In *Stalker*, the Third Department reinforced the long held position that a hospital's privileging information is confidential.[41] However, *Stalker* is most significant in the guidance it gives defendant hospitals in what specifically to include in a hospital's papers to ensure that its burden in asserting the confidentiality privilege is met. This prevents

37. *Approval Process for New Cancer Treatments*, *supra* note 14; *see also* O'Reilly & Dalal, *supra* note 35, at 296 ("an 'off-label' claim is one that has not undergone the FDA scrutiny and approval. To say that a claim is off-label signifies that government scientists have not yet approved that claim based on scientific studies; it does not necessarily mean that the drug does not have the effect that it is claimed to have."); Fradella, *supra* note 13, at 285-86 (citations omitted) ("[f]or more than a decade, 'off-label' drug use has been widespread, perhaps accounting for as much as 60% of all prescription drug usage. That percentage is higher—as much as 80%—for patients under the age of eighteen, and as much as 90% for cancer patients. As strange as it may seem, physicians are permitted to prescribe drugs for their patients for off-label uses because '[n]either the FDA nor the Federal government regulate the practice of medicine. Any approved product may be used by a licensed practitioner for uses other than those stated in the product label.'"); O'Reilly & Dalal, *supra* note 35, at 299 ("a medical practitioner [is permitted] to lawfully prescribe an FDA approved drug for an unapproved use, provided that there is a benefit to the patient, the patient is completely aware of the nature of his treatment, and the patient has consented to the use of such treatment."); Rebecca Dresser, *The Curious Case of Off-Label Use*, HASTINGS CTR. REP., May-June 2007, at 9 ("[s]urveys show that off-label prescribing occurs routinely . . . ."); O'Reilly & Dalal, *supra* note 35, at 299 (as per the FDA chief drug official in 1997, "the fear of tort liability and medical malpractice claims serves as a check on the prescribing practices of physicians.").

38. *Approval Process for New Cancer Treatments*, *supra* note 14.

39. 69 A.D.3d 1172, 897 N.Y.S.2d 250 (3d Dep't 2010).

40. 70 A.D.3d 1398, 894 N.Y.S.2d 783 (4th Dep't 2010).

41. *Stalker*, 69 A.D.3d at 1175, 897 N.Y.S.2d at 253.

the result where the plaintiff is permitted disclosure of the hospital's quality assurance materials as illustrated in previous cases.[42]

Plaintiff commenced a medical malpractice action against her doctor and the hospital where her procedure was performed, alleging that the defendant hospital knew or should have known that the defendant doctor was incompetent and unfit to practice medicine, but nonetheless had permitted him to continue practicing at its hospital.[43] The issue of privilege arose when plaintiff moved to compel testimony from a hospital representative concerning the hospital's physician certification process in general and its decision to certify and recertify the doctor.[44] The defendant hospital cross-moved for a protective order on the basis that the information sought was confidential and not discoverable, and the supreme court granted the hospital's motion.[45]

The court discussed the provisions of New York Education Law section 6527(3) and New York Public Health Law section 2805-m in conferring complete confidentiality upon a hospital for information collected and maintained pursuant to sections 2805-j and 2805-k, and in guarding against Article 31 disclosure of the same.[46] The court further reasoned, "[t]he Education Law expressly precludes a plaintiff from questioning deponents with respect to the proceedings of a hospital's credentials committee, which performs 'a "medical review function" within the meaning of *section 6527*.'"[47]

The appellate division explained the burden a party must meet to successfully invoke the Education Law privilege. At a minimum, a hospital is "'required . . . to show that it has a review procedure and that the information for which the exemption is claimed was obtained or maintained in accordance with that review procedure.'"[48] If this burden is not met, any information a hospital may have as to a staff physician's

42. *See generally* Kivlehan v. Waltner, 36 A.D.3d 597, 827 N.Y.S.2d 290 (2d Dep't 2007); Little v. Highland Hosp. of Rochester, 280 A.D.2d 908, 721 N.Y.S.2d 189 (4th Dep't 2001); Maisch v. Millard Fillmore Hosps., 262 A.D.2d 1017, 692 N.Y.S.2d 536 (4th Dep't 1999).

43. *Stalker*, 69 A.D.3d at 1172-73, 897 N.Y.S.2d at 252.

44. *Id.* at 1173, 897 N.Y.S.2d at 252.

45. *Id.*

46. *See* N.Y. PUB. HEALTH LAW §§ 2805-j, 2805-k, 2805-m (McKinney Supp. 2011); N.Y. EDUC. LAW § 6527(3) (McKinney Supp. 2011).

47. *Stalker*, 69 A.D.3d at 1173, 897 N.Y.S.2d at 252 (quoting Larsson v. Mithallal, 72 A.D.2d 806, 806, 421 N.Y.S.2d 922, 922 (2d Dep't 1979)).

48. *Stalker*, 69 A.D.3d at 1173, 897 N.Y.S.2d at 252 (citing Kivlehan v. Waltner, 36 A.D.3d 597, 827 N.Y.S.2d 290 (quoting Bush v. Dolan, 149 A.D.2d 799, 800-01, 540 N.Y.S.2d 21, 22 (3d Dep't 1989))).

alleged incompetence is relevant and subject to disclosure.[49] The court explained specifically that which the defendant hospital provided to satisfy this burden:

> Defendant submitted a detailed affidavit from Christie Harris, its medical staff credentialing specialist, who stated that she was familiar with defendant's records and procedures with respect to credentialing. She described the information that Abraham was required to submit for his initial credentialing and subsequent bi-annual re-credentialing, and she stated that "[t]he only way [defendant] would be permitted to obtain such information . . . would be through the credentialing process." She explained the steps that defendant takes to independently ascertain whether a physician has provided full and complete information in applying for privileges, and affirmed that such steps had not revealed any issues with respect to medical care and treatment provided by Abraham. Harris noted that defendant monitors the quality of care provided by physicians to whom it has issued privileges, and the legal obligation defendant has to report any incidents involving such physicians to the Department of Health. She described the role of defendant's credentialing committee in reviewing an applicant's information and in any disciplinary action taken, including any restriction of privileges. Harris stated that the sole purpose for the credentialing process was to comply with legal requirements mandating that hospitals have a mechanism in place to prevent medical malpractice. She noted that defendant would only become aware of a malpractice claim against a physician through the credentialing process. Finally, Harris stated that all of the information sought by plaintiff was "gathered through the peer review, credentialing and quality assurance process" and that defendant relied on the statutory privileges against disclosure of that information in conducting internal investigations and maintaining the effectiveness of its statutorily required medical malpractice prevention program.[50]

The court therefore held that the defendant hospital adequately invoked the Education Law and Public Health Law privilege.[51] It further elaborated that the plaintiff's need for evidence to make out her cause of action was outweighed by the legislative policy of providing confidentiality to promote the peer review process.[52]

In contrast, in *Learned v. Faxton-St. Luke's Healthcare*, the Fourth Department held that the defendant hospital failed to satisfy its burden

49. *Stalker*, 69 A.D.3d at 1173, 897 N.Y.S.2d at 252 (citing Van Caloen v. Poglinco, 214 A.D.2d 555, 557, 625 N.Y.S.2d 245, 247 (2d Dep't 1995)).

50. *Stalker*, 69 A.D.3d at 1173-74, 897 N.Y.S.2d at 252-53.

51. *Id.* at 1174, 897 N.Y.S.2d at 253.

52. *Id.*

of establishing that committee meeting minutes were protected from disclosure.[53] Plaintiff sustained postoperative infections and brought a medical malpractice action against defendants for, inter alia, failing to ensure that the operating room and surgical equipment were adequately sterilized.[54] Plaintiff moved to compel various documents from defendants, including minutes from Infectious Control Committee meetings during 2002, and defendants cross-moved for a protective order.[55] The supreme court granted plaintiff's motion in part, directing the defendants to produce the minutes, subject to any objection that would be applicable pursuant to New York Education Law section 6527(3)(b).[56]

In upholding the supreme court's decision in regards to the Infectious Control Committee minutes, the appellate division determined that "defendants did not establish that those minutes were 'generated in connection with a quality assurance review function pursuant to Education Law § 6527 (3) or a malpractice prevention program pursuant to Public Health Law § 2805-j.'"[57] The court further held that the Infectious Control Committee minutes would be subject to an in camera review to determine whether the minutes were privileged under the Public Health Law and Education Law.[58]

C. New York State Supreme Court

The Westchester County Supreme Court decided an interesting case in *Levine v. Werboff*, which, according to the court, was one of first impression.[59] The issue in *Levine* was whether the duty to warn a partner of a sexually transmitted disease should be extended to a partner's spouse.[60] The court held that this duty should be extended, as a spouse is a narrowly defined class of persons, and because extending the duty comports with fairness.[61]

Plaintiff commenced a claim against defendant for, inter alia, intentional infliction of emotional distress (IIED), negligence, fraud, misrepresentation, and gross negligence, when plaintiff's wife had

53. 70 A.D.3d 1398, 1399, 894 N.Y.S.2d 783, 784 (4th Dep't 2010).
54. *Id.*, 894 N.Y.S.2d at 783.
55. *Id.* at 1398-99, 894 N.Y.S.2d at 783.
56. *Id.*
57. *Id.* at 1399, 894 N.Y.S.2d at 783 (citing Maisch v. Millard Fillmore Hosps., 262 A.D.2d 1017, 1017, 692 N.Y.S.2d 536, 536 (4th Dep't 1999)).
58. *Learned*, 70 A.D.3d at 1399, 894 N.Y.S.2d at 784.
59. N.Y.L.J., June 8, 2010, at 28 (Sup. Ct., Westchester Cnty. May 21, 2010).
60. *Id.*
61. *Id.*

sexual relations with the defendant psychiatrist who had a sexually transmitted disease (STD), Herpes Simplex Disease ("herpes"), and plaintiff's wife contracted the disease and passed it on to plaintiff.[62] Plaintiff alleged that defendant knew he had herpes when he had sexual relations with plaintiff's wife, and that defendant was also aware that she was married.[63] Therefore, plaintiff maintained that defendant had a duty to disclose his condition and/or take steps to prevent the transmission of the disease.[64] Defendant moved to dismiss the IIED action as untimely and the remaining actions for failure to state a cause of action.[65]

The court held that the IIED action was timely as the date that plaintiff learned about contracting herpes was controlling, not the date plaintiff's wife discovered she had contracted herpes.[66] However, the court granted defendant's motion to dismiss the fraud and negligent misrepresentation claims as any representations made by defendant were made to plaintiff's wife, not to plaintiff.[67]

The court denied the defendant's motion to dismiss the IIED, negligence and gross negligence actions.[68] The court discussed Public Health Law section 2307, which sets forth that it is a misdemeanor for a person who knows himself to be infected with an infectious disease to have sexual intercourse with another.[69] In fact, the failure of a member of a sexual union to inform the other of having a known STD has been held to constitute gross negligence.[70] The court reasoned that a defendant as a general rule does not have a duty to control the conduct of third persons and prevent them from harming others.[71] The rationale for this is concern for limitless liability and unfairness.[72]

However, the court explained that the extension of this duty to a spouse is to a "narrowly defined class of persons, not a broader undefined community at large."[73] It reasoned that, "[t]he alleged tortfeasor is in the best position in both instances to prevent the

62. *Id.*
63. *Id.*
64. *Levine*, N.Y.L.J., June 8, 2010, at 28.
65. *Id.*
66. *Id.*
67. *Id.*
68. *Id.*
69. *Levine*, N.Y.L.J., June 8, 2010, at 28.
70. *Id.* (citing Maharam v. Maharam, 123 A.D.2d 165, 170-71, 510 N.Y.S.2d 104, 107 (1st Dep't 1986)).
71. *Id.*
72. *Id.*
73. *Id.*

transmission of a venereal disease. Further, the potential for harm to the married person who becomes infected and the spouse of the married person who thereafter becomes infected is the same."[74] Therefore, the court extended the duty to warn to the spouse plaintiff.[75] However, the court found that since there was no statutory requirement in Public Health Law section 2307[76] to warn a sexual partner's other known sexual partners, there was no basis for negligence per se, and defendants motion to dismiss this action was also granted.[77]

II. NEW YORK STATE LEGISLATION

A. Family Health Care Decisions Act

The Family Health Care Decisions Act (FHCDA) was discussed in last year's *Survey* in the context of pending legislation.[78] By way of a brief follow up, the FHCDA was signed into law on March 16, 2010,[79] and added two new articles to New York Public Health Law, 29-CC and 29-CCC.[80] The legislation permits an individual's family members, domestic partner, and close friends to make health care treatment decisions in the event that the individual becomes incapacitated and does not have a health care proxy or other health directive in place.[81]

Under current New York law, an incapacitated individual cannot be denied essential medical care unless there is clear and convincing evidence that the person wishes to decline treatment or the individual has signed a health care proxy.[82] Thus, in the absence of a health proxy

74. *Levine*, N.Y.L.J., June 8, 2010, at 28.

75. *Id.* (quoting Mussivand v. David, 45 Ohio St. 3d 314, 321 (1989) ("If one negligently exposes a married person to a sexually transmissible disease without informing that person of his exposure, it is reasonable to anticipate that the disease may be transmitted to the married person's spouse.")).

76. N.Y. PUB. HEALTH LAW § 2307 (McKinney 2002).

77. *Levine*, N.Y. L.J., June 8, 2010, at 28.

78. Matthew J. Van Beveren & Kirsten A. Lerch, *Health Law, 2008-09 Survey of New York Law*, 60 SYRACUSE L. REV. 983 (2010).

79. Family Health Care Decisions Act, 2010, ch. 8, 2010 McKinney's Sess. Laws of N.Y. 17-42 (codified at N.Y. PUB. HEALTH LAW §§ 2994-a to 2994-gg (McKinney Supp. 2011) (repealed scattered sections of N.Y. MENTAL HYG. LAW art. 81 (McKinney Supp. 2011) (codified as amended at N.Y. SURR. CT. PROC. ACT LAW § 1750-b (McKinney Supp. 2011); *see also* Tracy E. Miller, *New York Adopts Broad Changes to Law on Treatment Decisions*, N.Y.L.J., Mar. 29, 2010, at 4.

80. N.Y. PUB. HEALTH LAW art. 29-CC, 29-CCC (McKinney Supp. 2011).

81. N.Y. PUB. HEALTH LAW § 2994-d (McKinney Supp. 2011); *see also* Miller, *supra* note 79.

82. *See* N.Y. PUB. HEALTH LAW art. 29-C (McKinney 2007 & Supp. 2011); *In re* Westchester Cnty. Med. Ctr., 72 N.Y.2d 517, 529-32, 531 N.E.2d 607, 612-14, 534 N.Y.S.2d 886, 891-93 (1988) (holding that life support of incompetent patient could not be

or clear and convincing evidence of the patient's wishes, spouses, relatives, or close friends, prior to the FHCDA, had no authority to make medical decisions for a loved one who could no longer make health care decisions for themselves. The FHCDA establishes a process to select a surrogate who is authorized to make health care decisions for the incapacitated patient.

The Act provides a priority list of potential surrogates, with guardians authorized to make medical decisions pursuant to Article 29-CC on the Public Health Law to be considered first followed by the patient's spouse or domestic partner, a son or daughter eighteen years or older of the patient to be considered third, followed by parents, brothers or sisters eighteen years or older, and close friends, respectively.[83] The Act dictates that "(a) [t]he surrogate shall make health care decisions: (i) in accordance with the patient's wishes, including the patient's religious and moral beliefs; or (ii) if the patient's wishes are not reasonably known and cannot with reasonable diligence be ascertained, in accordance with the patient's best interests."[84] In the event there is any conflict over the surrogate chosen or treatment decisions made for the incapacitated patient, the FHCDA establishes an ethics committee to provide advice if requested or if there is a dispute, and also to review certain sensitive surrogate decisions.[85]

In addition, the FHCDA eliminates much of New York's do-not-resuscitate (DNR) law in regard to hospitals, and sets forth that "DNR decision-making in hospitals [accord] with the standards and procedures in the FHCDA."[86] Subject to some limitations and requirements,[87] the Act also grants health care providers and facilities the right refuse to carry out a surrogate's decision to request or forgo treatment on the basis of religious or moral conscience.[88]

terminated because "clear and convincing evidence" was not met when patient's daughter claimed that it was contrary to her mother's wishes expressed prior to becoming incompetent); *In re* Storar, 52 N.Y.2d 363, 379-79, 420 N.E.2d 64, 72, 438 N.Y.S.2d 266, 274 (1981) (holding that "clear and convincing evidence" that a patient intended to decline medical treatment must be satisfied to deny a patient essential medical care).

83. N.Y. PUB. HEALTH LAW § 2994-d.

84. *Id.* § 2994-d 4(a)(i)-(ii).

85. *Id.* § 2994-m; *see also* Robert N. Swidler, *The Family Health Care Decisions Act: A Summary of Key Provisions*, 15 N.Y. ST. B. A. HEALTH L.J., Spring 2010, at 32, 33.

86. Swidler, *supra* note 85, at 34 (citation omitted); *see also* N.Y. PUB. HEALTH LAW 2994-a (19); *see also* Miller, *supra* note 79.

87. *See* N.Y. PUB. HEALTH LAW § 2994-n; Swidler, *supra* note 85, at 33-34.

88. *See* N.Y. PUB. HEALTH LAW § 2994-n; Swidler, *supra* note 85, at 33.

B. Midwifery Modernization Act

On July 30, 2010, the Midwifery Modernization Act (MMA) was signed into law by Governor Patterson.[89] The MMA amends section 6951 of New York Education Law by eliminating the requirement for a written practice agreement,[90] and deletes references to the written practice agreement in New York Insurance Law.[91] Instead, the legislation adds the requirement that a midwife have collaborative relationships that "provide for consultation, collaborative management and referral," and "emergency medical gynecological and/or obstetrical coverage," as indicated by the health status of the patient,[92] thereby rendering a midwife an independent professional.[93] The purpose of the Act is to promote and enhance access to healthcare services for women, particularly to those in rural and lower-income urban areas, by removing the requirement that a physician or hospital sign a contractual agreement with a midwife.[94] Presently, fifteen states permit midwifery practice without a written practice agreement.[95]

Prior to this legislation, a midwife was required to sign a contractual agreement with a physician or hospital.[96] Physicians were sometimes reluctant to sign this contract based on a fear of liability for patients they would never see.[97] In addition, "[m]edical malpractice insurers have increasingly restricted how the OB/GYN physicians they insure can collaborate with midwives, thus preventing some supportive physicians from signing practice agreements with midwives."[98] The end result was that some midwives were unable to practice if they could not find a physician who would sign the practice agreement and/or if their OB/GYN discontinued practicing obstetrics, retired, moved away,

89. *See* Act of July 30, 2010, ch. 238, 2010 McKinney's Sess. Laws of N.Y. 980 (codified at N.Y. EDUC. LAW § 6951 (McKinney Supp. 2011)).

90. N.Y. EDUC. LAW § 6951.

91. N.Y. INS. LAW §§ 3216, 3221, 4303 (McKinney Supp. 2011).

92. *Id.* § 3221.

93. Taryn Fitsik, *Controversy Surrounding the Current Midwifery Laws Continues*, NEWS 10 (June 17, 2010, 6:31 PM), http://www.wten.com/global/story.asp?s=12669031.

94. Karla Cruz, *Midwives Want More Autonomy*, LEGIS. GAZETTE, Apr. 20, 2010, at 3, *available at* http://www.legislativegazette.com/Articles-c-2010-04-19-66953.113122-Midwives-want-more-autonomy.html.

95. This practice is authorized in Arkansas, Arizona, Connecticut, Idaho, Iowa, Maine, Minnesota, New Hampshire, New Jersey (pending), New Mexico, Oregon, Rhode Island, Washington, Wyoming, and also in the District of Columbia. *Factsheet 2: The Midwifery Modernization Act*, N.Y. STATE ASS'N OF LICENSED MIDWIVES, http://www.nysalm.org/Talking%20Points%20MMA.pdf [hereinafter *Factsheet 2*].

96. *Id.*

97. *Id.*

98. *Id.*

or died.[99] Another concern for physicians was competition for services with midwives.[100]

The legislation was opposed by some physicians on the grounds that it would jeopardize patient safety inasmuch as there is no written contract in place with a physician who must step in and provide emergency services if a problem develops which the midwife cannot handle.[101] In addition, some physicians feared that the MMA would result in midwives expanding their practices and "pave the way for midwives to open their own independent birthing centers."[102]

However, those in support of the Act argue that the legislation does not alter the scope of the midwife practice.[103] Further, midwives will develop referral and consulting relationships with physicians without a written agreement in place in accordance with fulfilling their professional duties.[104] Midwives propose that the relationship would parallel that of a doctor referring a patient to a specialist, whereby there is no written agreement in place but instead, when a patient's medical condition is outside the expertise of a midwife, the midwife will be obligated to consult, collaborate, and/or transfer care to a higher level practitioner.[105]

III. FEDERAL LEGISLATION

A. Federal Health Care Reform—the Patient Protection and Affordable Care Act (PPACA)

A survey of health law in New York would not be complete without a discussion of landmark federal health care reform legislation that was signed into law in March 2010.[106] Called the Patient Protection and Affordable Care Act (PPACA), it changes the health care landscape in every state. When fully implemented, virtually all citizens and legal residents of the United States will have access to affordable

99. *Id.*; James T. Mulder, *Midwives Hope New York State Delivers Right to Practice on Their Own*, POST-STANDARD, June 18, 2010, at A1, A6.

100. *Factsheet 2*, *supra* note 95; Cathleen F. Crowley, *Seeking Independent Practices*, TIMES-UNION, June 12, 2010, at A3; Mulder, *supra* note 99, at A1.

101. Mulder, *supra* note 99, at A6; Cathleen F. Crowley, *Doctors Say Bill Endangers Lives*, TIMES-UNION, June 18, 2010, at A3.

102. Anemona Hartocollis, *Doctors' Group Fights a Bill That Would Ease Restrictions on Midwives*, N.Y. TIMES, June 17, 2010, at A22.

103. *See id.*; *see also* Crowley, *supra* note 100; Crowley, *supra* note 101.

104. Crowley, *supra* note 100, at A6; *see also* Mulder, *supra* note 99, at A6.

105. Crowley, *supra* note 100, at A3; *see also* Mulder, *supra* note 99, at A6.

106. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), *amended by* Pub. L. No. 111-152, 124 Stat. 1029 (2010).

and comprehensive health insurance. Limited benefit plans, uninsurable individuals, annual limits, lifetime limits and denials based on pre-existing conditions will no longer be obstacles to individuals obtaining and employers offering comprehensive health insurance coverage.[107]

According to the United States Congressional Budget Office (CBO), PPACA will lead to health insurance for an estimated thirty-two million people who are currently uninsured.[108] According to the Federal Centers for Medicare and Medicaid Services (CMS), many millions more will pay less for complete health coverage.[109]

Further, the United States will no longer see the multi-million increases in the numbers of uninsured that we have seen in recent years.[110] There will, however, continue to be millions who are either excluded from PPACA eligibility, such as undocumented immigrants, or others who can opt out because of low income, special group status, or the decision to pay a tax penalty rather than obtain health insurance.[111]

PPACA accomplishes its purpose to insure more Americans through a variety of incentives, subsidies, and penalties, including the controversial "individual responsibility" mandate, which requires that individuals not otherwise covered purchase health insurance or face a

107. *See generally PPACA Compliance Summary—New York Health*, N.Y. STATE INSUR. DEP'T, www.ins.state.ny.us/health/PPACA_chklist.pdf.

108. *See* CONG. BUDGET OFFICE, PRELIMINARY ESTIMATE, tbl. 2 (2010), *in* Letter from Douglas W. Elmendorf, Director, Congressional Budget Office, to Nancy Pelosi, Speaker, U.S. House of Representatives (Mar. 18, 2010), at 7, *available at* http://www.cbo.gov/ftpdocs/113xx/doc11355/hr4872.pdf [hereinafter PRELIMINARY ESTIMATE].

109. *See* Memorandum from Richard S. Foster, Chief Actuary, Office of the Actuary, Ctrs. for Medicare & Medicaid Servs., Estimated Financial Effects of the "Patient Protection and Affordable Care Act," as Amended, 18 (April 22, 2010), *available at* http://www.cms.gov/Actuarialstudies/Downloads/PPACA_2010-04-22.pdf ("Based on the net impact of (i) the substantial coverage expansions, (ii) the significant cost-sharing subsidies for low-to-middle-income persons, (iii) the maximum out-of-pocket limitations associated with the qualified health benefit, and (iv) the increases in workers' cost-sharing obligations in plans affected by the excise tax on high-cost employer-sponsored health insurance coverage, we estimate that overall out-of-pocket spending would be reduced significantly by the PPACA (a net total decline of $237 billion in calendar years 2010-2019).").

110. *See* Centers for Disease Control and Prevention, *Vital Signs: Health Insurance Coverage and Health Care Utilization–United States 2006–2009 and January–March 2010*, MORBIDITY & MORTALITY WEEKLY REPORT, Nov. 9, 2010, at 1, *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/mm59e1109a1.htm ("In the first quarter of 2010, an estimated 59.1 million persons had no health insurance for at least part of the year before their interview, an increase from 58.7 million in 2009 and 56.4 million in 2008.").

111. *See* discussion *infra* Part III.A.1.

tax penalty.[112]

A full discussion of the many new legal and regulatory requirements contained in PPACA is well beyond the scope of this Article.[113] However, this Article will provide an overview of some of the more significant aspects of the law that New York attorneys ought to know. Attorneys who need specific PPACA health reform information will likely be able to find guidance from numerous academic or practice-based legal articles that address specific aspects of PPACA.[114]

1. Expansion in Coverage

By 2014, about thirty-two million uninsured U.S. citizens and legal residents will be able to find health benefits coverage. For lower income individuals, this will be primarily accomplished through an expansion of eligibility for Medicaid, an indigent care Federal program.[115] Middle and higher income individuals not otherwise covered by an employer plan will be able to shop for coverage from a variety of private plans competing with each other for subscribers.[116] Excluded from PPACA are undocumented individuals who are

112. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1501, 124 Stat. 119, 242 (2010).

113. For instance, H.R. 3590, the bill which was enacted as PPACA, totals 906 mostly single-spaced pages. Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. (2010); *see also, e.g.*, William Pitsenberger, *What Health Care Reform Means to Your Clients (and You)*, J. KAN. B. ASS'N, Nov./Dec. 2010, at 28, 37 ("The Patient Protection and Affordable Care Act is so comprehensive and so broad in its reach that an exhaustive description of all elements that might be of interest to any given attorney or anyone interested in health care financing as a policy matter would be well beyond the limitations of this article.").

114. *See, e.g.*, *Patient Protection and Affordable Care Act—Section by Section*, PROCON.ORG, http://healthcarereform.procon.org/view.resource.php?resourceID=003700 (last visited Feb. 27, 2011). A Westlaw search on 12/27/10 found 263 law review and other journal articles covering various aspects of PPACA. Primarily, these articles review numerous new requirements for health care providers, including new criminal fraud and abuse provisions, new employee whistleblower protections, as well as insuring billing and collection compliance with PPACA, new employer responsibilities under PPACA, including the new employer responsibility mandate that both encourage employers to insure employees as well as penalize some employers who do not, and debate the constitutionality of the individual mandate in PPACA that requires that most United State citizens and legal residents be covered by health insurance.

115. *See, e.g.*, FAMILIES USA, A SUMMARY OF THE HEALTH REFORM LAW 1, 3 (2010), http://www.familiesusa.org/assets/pdfs/health-reform/summary-of-the-health-reform-law.pdf.

116. *Id.* at 9.

uninsured, now estimated to be total about seven million.[117]

Medicaid, a federal/state operated indigent care program, has been expanded with federal funding so that an additional sixteen million low-income individuals will be covered.[118] Health exchanges operated by the federal government and by states that choose to do so will provide a "regulated marketplace" for consumers and employers to purchase insurance.[119] Plan benefits are standardized by PPACA to ensure good health coverage and make it easier for consumers to shop for plans.[120]

Individuals with incomes under four hundred percent of the federal poverty level will be eligible for tax credits to apply toward payment of insurance premiums.[121]

Finally, the "doughnut hole" in Medicare coverage under the Medicare Part D prescription drug benefit will be gradually closed by 2020.[122]

However, not all of those who are uninsured will be covered by PPACA. Undocumented immigrants in the United States, estimated by the Congressional Budget Office to number approximately seven million, are expressly excluded from PPACA.[123]

There are also an estimated additional sixteen million who are eligible for coverage but will remain uninsured.[124] This group consists primarily of people of limited means who are exempt from the individual mandate because they cannot find a health plan that costs less than eight percent of income or who fall below the threshold for filing an income tax return.[125] Others will likely simply choose to go without insurance and pay the penalty.[126] There are also others who are exempt from the mandate because of religious objection, are Native American,

117. *See* Maggie Mertens, *Health Care for All Leaves 23 Million Uninsured*, Shots, NPR's HEALTH BLOG (March 24, 2010, 10:37 AM), http://www.npr.org/blogs/health/2010/03/health_care_for_all_minus_23_m.html.

118. *See* Patient Protection and Affordable Care Act § 2001, 124 Stat. at 271; *see also* FAMILIES USA, *supra* note 115, at 3-4.

119. FAMILIES USA, *supra* note 115, at 5.

120. *Id.* at 13 (reciting to essential benefits that must be covered); *see also* Patient Protection and Affordable Care Act § 1302, 124 Stat. at 163 (defining "essential health benefits").

121. FAMILIES USA, *supra* note 115, at 6.

122. Mertens, *supra* note 117.

123. *Id.*

124. *Id.*

125. *Id.*

126. *Id.*; *see also* Lawrence O. Gostin, *The National Individual Health Insurance Mandate*, HASTINGS CTR. REP., Sept.-Oct. 2010, at 8, 8 (2010) ("If anything, the tax penalty is too low compared with the cost of insurance, so it may not provide sufficient incentive for healthy individuals to purchase insurance.").

or have a gap in health coverage of less than three months.[127]

2. Consumer Protections

PPACA adds new consumer protections which bar insurance denials of coverage for children based on preexisting conditions in 2010 and for adults in 2014, requires that health plans cover uninsured adult children on parent plans until age twenty-six, and ends annual and lifetime dollar limits for "essential health benefits."[128] These new protections help all New Yorkers because there are no existing state laws on point.[129]

Further, PPACA mandates that plans provide a number of appeal, grievance and other protections designed to increase health plan transparency and fairness.[130] Unlike existing state laws already providing comparable protections for people in insured health plans, PPACA reaches employer self-insured health plans that are covering increasing numbers of people.[131] These plans have become increasingly popular because they cost less for employers primarily because they are not subject to benefit mandates under state law and those covered under self-insured employer health plans are generally healthier than the at large community.[132] Under the Federal Employee Retirement Income Security Act (ERISA), they are exempt from virtually all state regulation.[133]

In particular, PPACA provides for an external appeal process for plan coverage denials.[134] Enrollees in all health plans will have the right to appeal denials of coverage, including an external appeal heard by a reviewer that is not affiliated with the plan.[135] Other PPACA consumer protections include a right to receive out-of-network emergency services at in-network rates, direct access to women's health providers, and a choice of primary care doctors, including

127. Mertens, *supra* note 117.

128. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 2001, 124 Stat. 119, 271 (2010).

129. *Id.*

130. *Id.* §§ 2717-18, 124 Stat. at 137-38 (requiring establishment of an internal claims appeal process and an external review process).

131. *Id.* § 1562, 124 Stat. at 269-70 (PPACA applies to all ERISA plans, including self-insured plans previously exempted from state health regulation).

132. *What is a Self-Insured Employer?*, LIVESTRONG.COM, http://www.livestrong.com/article/74296-selfinsured-employer (last visited Feb. 27, 2011).

133. 29 U.S.C. § 1144(a)-(b)(2)(B) (2006).

134. Patient Protection and Affordable Care Act § 2719, 124 Stat. at 138.

135. *Id.* (external review process to provide "at a minimum" the consumer protections in the Uniform External Review Model Act (UERMA) issued by the National Association of Insurance Commissioners).

pediatricians.[136]

3. The Mandate

All of these improvements in accessible and affordable coverage and consumer protections are not without cost, however. In the short term, there will be additional financial outlays by the federal government in the form of a lower threshold for Medicaid eligibility, increased Medicare prescription coverage, tax incentives, and funding of insurance pools and exchanges, although the Congressional Budget Office has determined that it will actually reduce the federal budget deficit in the long term.[137]

More controversial, however, is one of the revenue sources of revenue for PPACA, which is the insurance mandate for individuals—as of 2014, there will be an "individual responsibility" requiring that individuals have health coverage or pay a tax penalty.[138] There is also an "employer responsibility" that kicks in for employers with more than 200 employees, whether they offer health insurance benefits to their employees or not, if an employee receives a tax credit for exchange coverage.[139]

Proponents of PPACA argue that the individual mandate is both fair and crucial to success of universal insurance because it provides motivation to healthy people to purchase health insurance.[140] Currently, many people are uninsured because they cannot afford the cost of insurance.[141] However, there are also millions more who have the financial wherewithal to pay for health insurance but choose not to obtain it.[142] If everyone participates, healthy and sick alike, the cost of health insurance for all will drop dramatically. It should add healthy people into the insurance pools, which will bring down the cost of insurance.[143] "Free riding" by healthy people until they become sick, resulting in "adverse selection" problems for insurers where sick people

136. NAT'L ASS'N OF INS. COMM'RS, PATIENT PROTECTION AND AFFORDABLE CARE ACT OF 2009: IMMEDIATE HEALTH INSURANCE MARKET REFORMS 4 (Apr. 20, 2010), *available at* www.naic.org/documents/committees_b_Immediate_Improvements.pdf (summary with reference to PPACA citation provided by the National Association of Insurance Commissioners).

137. *See* PRELIMINARY ESTIMATE, *supra* note 108, at 2 (noting that PPACA will reduce the Federal deficit by $138 billion over ten years).

138. *Id.* § 5000A, 124 Stat. at 244.

139. *Id.* § 1421, 124 Stat. at 238-40.

140. *See* Gostin, *supra* note 126, at 9.

141. *Id.* at 8.

142. *Id.*

143. *See, e.g.*, FAMILIES USA, *supra* note 115, at 15.

are more likely to apply for coverage than healthy people, will end.[144] Insurance practices that deny sick people coverage, charge sick people more in premiums, or create waiting periods before benefits are paid for preexisting conditions can then be eliminated.[145] Proponents conclude that the mandate offers a valuable social benefit because it brings everyone into the health care system.[146]

Opposition to the mandate has been loud and widespread.[147] Critics argue from an individual perspective that the mandate interferes with economic freedom and personal choice.[148] They argue that Congress does not have the power to require that individuals enter into a contract to purchase health insurance from a private party.[149] Twenty states (not New York) have filed lawsuits challenging the constitutionality of the individual mandate.[150] They assert that the mandate exceeds Congress' power to tax and spend under the Commerce Clause.[151] They also allege that PPACA places an unconstitutional burden on states to expand Medicaid and to create insurance exchanges in violation of the Tenth Amendment.[152]

Unlike states, which face no federal constitutional impediments to mandating health coverage, the federal government has the limited "principal enumerated powers . . . to regulate interstate commerce and to tax for the general welfare."[153] However, traditional constitutional jurisprudence provides strong support for the argument that the individual mandate is a constitutional exercise of federal power to regulate activity that affects interstate commerce.[154] However, the argument that federal taxes should be primarily revenue raising and that the mandate is an unconstitutional regulatory tax has been championed by some legal scholars and challenged by others as not on a firm footing

144. *See* Gostin, *supra* note 126, at 8.

145. *See id.*

146. *Id.* at 9 ("If the Court were to reach the merits and invalidate the mandate, however, comprehensive health care reform could unravel . . . . Absent a mandate, the insurance market would become highly dysfunctional.").

147. *See, e.g.*, Renee M. Landers, *"Tomorrow" May Finally Have Arrived—The Patient Protection and Affordable Care Act: A Necessary First Step Toward Health Care Equity in the United States*, 6 J. HEALTH & BIOMED. L. 65, 75 (2010).

148. *See*, Gostin, *supra* note 126, at 8.

149. *Id.*

150. *See*, Landers, *supra* note 147, at 75.

151. *Id.*

152. *Id.*

153. Gostin, *supra* note 126, at 8.

154. *Id.*

because the penalty helps to pay for the costs of health care reform.[155]

B. How will this affect New Yorkers and the Practice of Law?

PPACA will likely have a significant impact on attorneys in New York. Personally, attorneys will benefit from easier access to affordable health insurance. Many attorneys could be among the 1.2 million currently uninsured New Yorkers who will become insured under PPACA.[156] Attorneys are often self-employed or operate small business practices, groups which have historically had difficulty obtaining adequate health insurance at reasonable rates.[157] Like other small businesses, small law firms will also be eligible for a small employer health insurance credit totaling $40 billion contained in PPACA.[158]

Further, many attorney practice areas will be affected.[159] Those who advise health care facilities, health insurers, or employers are most obviously affected because of PPACA's direct and immediate effect on these entities.[160]

However, PPACA will also affect many, if not most, attorney practice areas.[161] For instance, the practice of criminal law will be affected in a big way. PPACA tightens restrictions on physician self-referral, with violation enforced by anti-kickback laws.[162] It also makes

155. *Id.*; *see also* Randy Barnett, *The Insurance Mandate in Peril*, WALL ST. J., Apr. 29, 2010, at A19 (argues for the unconstitutionality of the mandate); *contra* Mark A. Hall, *The Constitutionality of Mandates to Purchase Health Insurance* 3 (O'Neill Institute, 2009), *available at* http://scholarship.law.georgetown.edu/cgi/viewcontent.cgi?article=1020&context=ois_papers.

156. *See*, DEBORAH BACHRACH, N.Y. STATE HEALTH FOUND., IMPLEMENTING FEDERAL HEALTH CARE REFORM: A ROADMAP FOR NEW YORK STATE 4 (2010), *available at* http://www.nyshealthfoundation.org/userfiles/file/RoadmapPaper_Aug2010.pdf .

157. *See, e.g.*, Pitsenberger, *supra* note 113, at 29 (recounting a personal experience of his law firm when, in 2008, health insurance premiums increased by 63%. The law firm ended up contributing more toward the cost of health insurance for its employees and their families and also had to move to a less generous plan with much higher patient deductibles.).

158. *See, e.g.*, Mark E. Battersby, *What Health Care Reform Means to Law Practices*, PA. LAW., July-Aug. 2010, at 36, 37-38 (noting that law practices with up to twenty-five full-time employees and average wages of no more than $50,000 can qualify for tax credits of up to thirty-five percent. The purpose of the credit is to "encourag[e] small businesses to explore and, if qualified, claim the new small employer health insurance credit [which was] created for eligible small business either to maintain their current health insurance coverage or to begin offering health insurance coverage to their employees.").

159. *See* Francis J. Serbaroli, *Health Care Reform Law's Anti-Fraud Provisions*, N.Y.L.J., May 25, 2010, at 3.

160. *Id.*

161. *Id.*

162. *Id.*

it easier for whistleblowers to bring *qui tam* lawsuits by expanding the ability to bring such suits based upon publicly available information.[163] Further, it will be more difficult for such lawsuits to be dismissed by providing the federal government with the opportunity to oppose dismissal.[164]

If, as widely reported, medical debt contributes to the filing of more than half of all bankruptcies, bankruptcy attorneys are likely to see a drop-off in business by 2014, when PPACA takes full effect.[165]

It also seems likely that PPACA will have an influence on the number of personal injury lawsuits commenced. It could mean fewer lawsuits because one of the primary motivators for bringing personal injury actions, large unpaid medical bills, will no longer be there. One commentator has speculated that PPACA will lead to fewer medical malpractice lawsuits because it will lead to a better quality of care and fewer "adverse events" that are the basis of medical malpractice claims.[166] He acknowledges the counterargument, however, that there will be thirty-two million more insured individuals, leading to more patient visits and with no increase in the numbers of physicians, thereby increasing the risk of errors.[167]

On the other hand, it could lead to more lawsuits because, with more insured plaintiffs, there will be better access to medical care, leading to convincing corroboration of the seriousness of a plaintiff's injuries.[168]

Finally, the individual responsibility mandate under PPACA requiring that most citizens and legal residents obtain comprehensive health insurance could create a collateral source for defendants in New York courts to offset court awards for the cost of medical care. New York Civil Practice Law and Rules (CPLR) 4545 authorizes defendants

163. *Id.*; *see also* Gordon J. Apple, *Federal Health Care Reform: A Renewed Commitment to Program Integrity*, BENCH & B. MINN., May-June 2010, at 22, 26 ("The Affordable Care Act has opened a back door to qui tam plaintiffs by expanding the definition of original source to include an individual 'who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.'").

164. *See* Serbaroli, *supra* note 159.

165. *See, e.g.*, David U. Himmelstein et al., *Medical Bankruptcy in the United States, 2007: Results of a National Study*, 122 AM. J. MED. 741, 743 (2009) (finding that in 2007, 62.1% of all bankruptcies have a medical cause).

166. *See, e.g.*, Mark A. Rothstein, *Health Care Reform and Medical Malpractice Claims*, 38 J.L. MED. & ETHICS 871, 871 (2010).

167. *Id.*

168. *See id.*

in personal injury, property damage or wrongful death actions to seek offset against damages recoveries for "past or future cost or expense [which] was or will, with reasonable certainty, be replaced or indemnified, in whole or in part, from any collateral source."[169] "Reasonable certainty" has been defined to mean "clear and convincing evidence that the result is 'highly probable.'"[170] New York courts have been reluctant to consider health insurance payments as a collateral source, reasoning that pre-PPACA there was no right to health insurance or individual responsibility to maintain it, and therefore no "reasonable certainty" that the health insurance will continue.[171] Starting in 2014, defendants will certainly be on stronger footing to revisit this issue and argue that health insurance constitutes a collateral source under CPLR 4545.[172]

C. Medicare, Medicaid, and SCHIP Extension Act of 2007, Section 111

On July 1, 2009, the reporting of non-group health plan information pursuant to section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA)[173] became effective.[174] Section 111 of the Act imposes new reporting requirements upon all entities that pay settlements or judgments to any personal injury plaintiff who is a Medicare beneficiary.[175] This includes providers of liability insurance (including self-insurance), no fault insurance and workers' compensation insurance.[176] Within the MMSEA framework,

169. N.Y. C.P.L.R. 4545(c) (McKinney 2007).

170. Firmes v. Chase Manhatten Auto. Fin. Corp., 50 A.D.3d 18, 33, 852 N.Y.S.2d 148, 160 (2d Dep't 2008).

171. *See, e.g.*, Giventer v. Rementeria, 184 Misc. 2d 744, 746, 705 N.Y.S.2d 863, 866 (Sup. Ct. Richmond Cnty. 2000).

172. *See* N.Y. CPLR 4545(c).

173. 42 U.S.C. § 1395 y(b)(8) (Supp. II 2008). This was signed into law by President Bush on December 26, 2007 and amended Section 1862(b) of the Social Security Act. Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. No. 110-173, 121 Stat. 2492.

174. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., SUPPORTING STATEMENT FOR THE MEDICARE SECONDARY PAYER (MSP) MANDATORY INSURER REPORTING REQUIREMENTS OF SECTION 111 OF THE MEDICARE MEDICAID, AND SCHIP EXTENSION ACT OF 2007 2 (2008), *available at* https://www.cms.gov/MandatoryInsRep/Downloads/SupportingStatement082808.pdf [hereinafter SUPPORTING STATEMENT].

175. Roy Umlauf & Thomas Thornton, *Medicare Secondary Payer Reporting and Section 111 of MMSEA: The Nuts and Bolts*, DEF. RESEARCH INST. (May 18, 2010), http://www.legalspan.com/dri/onlinecle.asp?UGUID=&CategoryID=&ItemID=20100526-272095-155310.

176. *Defense Practitioner's Guide to Medicare Secondary Payer Issues* (Def. Research Inst. CD-ROM, 2010) (on file with author).

these entities are referred to as "Responsible Reporting Entities" (RRE).[177] The information collected through the mandatory reporting will then be used by the Centers for Medicare and Medicaid Services (CMS) to process claims billed to Medicare.[178] It will also be used to assist in the Medicare Secondary Payer (MSP) statute recovery program.[179] It is important to note that section 111 "does not eliminate any existing statutory provisions or regulations."[180] Rather, it merely formalizes the reporting requirements of an RRE.

Specifically, section 111 requires an RRE to: (1) determine if a claimant is entitled to Medicare benefits; and (2) submit information as mandated by CMS which will allow CMS to make the appropriate determination concerning the coordination of future benefits and recovery of any associated claim or lien.[181] If a plaintiff is determined to be a Medicare beneficiary, the triggering event which then requires an RRE to report the mandatory information to CMS occurs either (a) when a payment has been made or (b) when a judgment has been entered between the Medicare beneficiary plaintiff and the RRE.[182]

Under the MSP, Medicare is designated as a secondary payer which makes "conditional payments" to its beneficiaries (i.e., those aged sixty-five and older, those with specified disabilities, and those with permanent kidney failure), and then looks to the primary payer to reimburse Medicare for these "conditional payments."[183] The MSP provisions require certain primary plans, including liability insurers, self-insured entities, and no-fault insurance plans to be the primary payer for items and services provided to Medicare beneficiaries.[184] The MSP provisions also make clear that a primary plan, entities that make payment on behalf of a primary plan, and an entity that receives

177. Umlauf & Thornton, *supra* note 175.

178. *Id.*

179. *Id.*

180. CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUMAN SERVS., MMSEA SECTION 111 MEDICARE SECONDARY PAYER (MSP) MANDATORY REPORTING: LIABILITY INSURANCE (INCLUDING SELF-INSURANCE), NO-FAULT INSURANCE, AND WORKERS' COMPENSATION USER GUIDE 11 (July 12, 2010), *available at* https://www.cms.gov/MandatoryInsRep/Downloads/NGHPUserGuideV3.1.pdf [hereinafter USER GUIDE].

181. Starting January 1, 2011, each RRE must report to CMS the required information during an assigned seven day window. *See* Umlauf & Thornton, *supra* note 175. Consult the CMS website for additional deadlines. *Overview Mandatory Insurer Reporting*¸ CTRS. FOR MEDICARE & MEDICAID SERVS., http://www.cms.gov/mandatoryinsrep (last visited Feb. 27, 2011).

182. Umlauf & Thornton, *supra* note 175.

183. SUPPORTING STATEMENT, *supra* note 174, at 1.

184. *Id.*

payment from a primary payer must reimburse Medicare for any such payments made for an item or service if it is shown that such primary payer has or had the responsibility to make payment for such item or service.[185] The existence of a judgment or a payment conditioned upon a recipient's compromise or release as to what is claimed or released for the primary plan is sufficient to demonstrate a responsibility to make such a payment.[186] Therefore, any business or entity that either pays a settlement or judgment to a tort claimant or pays a deductible towards the defense of a claim is self-insured under the MSP and is subject to its requirements.[187]

Further, any entity subject to the MSP provisions is now subject to Section 111 and must register as an RRE in order to provide the required information to CMS.[188] Each RRE must maintain specific data related to the beneficiary, including claimant name, social security number, gender, date of birth, litigation information and injury information.[189] Additionally, each RRE must register with a coordination of benefits contractor (COBC).[190] Regardless of how a settlement is structured between a claimant and the insurance entity, the RRE is responsible for reporting the same to CMS through the COBC. A chart detailing the reporting process is provided below:

185. *Id.* at 2.

186. *Id.* at 13.

187. *Id.*

188. SUPPORTING STATEMENT, *supra* note 174, at 5.

189. MONIQUE COOPER, MEDICARE SECONDARY PAYER RECOVER CONTRACTOR, MEDICARE SECONDARY PAYER (MSP) LIABILITY INSURANCE (INCLUDING SELF-INSURANCE), NO-FAULT INSURANCE, & WORKER'S COMPENSATION RECOVERY PROCESS 15 (Nov. 12, 2009), *available at* http://www.msprc.info/forms/Town%20Hall%20Presentation.pdf.

190. *Id.*

MEDICARE RRE REPORTING REQUIREMENTS FLOW CHART[191]

Is Plaintiff a Medicare recipient at time of payment or judgment?

The RRE must report the required items to the COBC (HICN, DOB, date of incident, etc.). For settlements, the report must be made within 60 days.

- Starting 1/1/11, RREs must report payments made to Medicare recipient plaintiffs quarterly, during an assigned 7-day window.

↓

Note: this step should be done as soon as a Medicare recipient is identified through the discovery process rather than waiting for the triggering event (settlement, award or judgment), and then supplemented later to expedite the Medicare process.

MSPRC issues a "MSP Rights and Responsibilities Letter," which includes a Consent to Release.

↓

Within 65 days, MSPRC issues a Conditional Payment Letter which contains a "payoff summary."

↓

If possible, have Plaintiff provide a Consent to Release giving the RRE/RRE counsel access to his/her Medicare records.

↓

MSPRC & parties then negotiate which conditional payments are related to Plaintiff's suit.

↓

MSPRC will issue a final Recovery Demand Letter for the amount owed.

↓

The RRE must respond to Medicare's Demand letter within 60 days. If settlement/award, this response must include payment.

↓

MSPRC will issue a Closing Letter.

191. *Id.* at 8, 17, 21, 27, 30; *see* Umlauf & Thornton, *supra* note 175. Deadlines may change, therefore, please consult CMS for updates. *Overview Mandatory Insurer Reporting*, *supra* note 181.

These requirements are not to be taken lightly, as the penalties for failure to report the mandatory information are severe. Any RRE that fails to comply with reporting requirements shall be subject to a civil monetary penalty of $1,000 for each day of noncompliance, for each individual for which the information should have been submitted.[192] Further, if an RRE does not respond to Medicare's Demand Letter for reimbursement, and Medicare initiates legal action to recover its lien, "CMS may recover twice the amount of Medicare's conditional payment claim as it existed on the date of settlement."[193]

Therefore, plaintiff and defense counsel should engage with one another regarding MMSEA reporting early in the litigation process to ensure that they fully understand the significance of obtaining and accurately reporting this information to CMS. The obligation of RREs to obtain and report accurate information on Medicare beneficiaries places a large responsibility on all parties during the litigation process.[194]

IV. EXECUTIVE ORDERS

A. Hospital Visitation for Same Sex Partners

Gay and lesbian advocates have long complained that same sex partners have been denied the same rights to visit and to make medical decisions for their hospitalized partners as those afforded to immediate family members and to married couples.[195] These concerns came to a head in 2009 when a lawsuit arising from a 2007 incident in which a lesbian partner alleged that she had been kept away from her dying patient's bedside in a hospital trauma unit was dismissed.[196] Her lawsuit on behalf of her partner's estate alleged that she and their children were denied visitation and that she was denied requested medical information even though she was also the patient's designee for

192. Umlauf & Thornton, *supra* note 175.

193. *Id.*

194. Please note that this is an evolving area and deadlines are subject to change. *Overview Mandatory Insurer Reporting*, *supra* note 181.

195. *See, e.g.*, Michael D. Shear, *Obama Extends Hospital Visitation Rights to Same Sex Couples*, WASH. POST, Apr. 16, 2010, at A1 ("Hospitals often bar visitors who are not related to an incapacitated patient by blood or marriage, and gay rights activists say many do not respect same-sex couples' efforts to designate a partner to make medical decisions for them if they are seriously ill or injured.").

196. *See* Tara Parker-Pope, *No Visiting Rights for Hospital Trauma Patients*, N.Y. TIMES WELL BLOG (Sept. 30, 2009, 1:28 PM), http://well.blogs.nytimes.com/2009/09/30/no-visiting-rights-for-hospital-patients; *see also* Langbehn v. Pub. Health Trust of Miami-Dade Cnty., 661 F. Supp. 2d 1326, 1347 (S.D. Fla. 2009).

making medical decisions under a power of attorney.[197] In dismissing the lawsuit, the judge did not minimize the seriousness of the allegations—if true, the hospital showed a "lack of sensitivity" and "a lack of compassion" that caused the patient's partner and children "needless distress during a time of anguish and vulnerability."[198] However, he found that there was no legal duty under Florida law that required that a hospital permit visitation in a trauma unit.[199] His decision was limited to trauma units, where he noted that "decisions as to visitation should be left to the medical personnel in charge of the patient, without second-guessing by juries and courts."[200]

The President's April 2010 Memorandum for the Secretary of Health and Human Services (HHS) ends hospital practices that permit more restrictive visitation for patient friends, partner, and health care proxy designees than for family members.[201] It directs that the HHS Secretary draft new regulations to ensure that hospitals that participate in Medicare and Medicaid "respect the rights of patients to designate visitors."[202] Same sex partners, friends, and patient designated advance directive agents "should enjoy visitation privileges that are no more restrictive than those that immediate family members enjoy."[203]

The Memorandum notes that "uniquely affected are gay and lesbian Americans who are often barred from the bedsides of the partners with whom they may have spent decades of their lives . . . ."[204] It also requires that the HHS Secretary provide additional recommendations related to "hospital visitation, medical decision making, or other health care issues that affect [gay and lesbian] patients and their families."[205]

Finally, the Memorandum also directs the HHS Secretary to ensure that hospitals comply with existing Medicare and Medicaid rules that require that "all patients' advance directives, such as durable powers of attorney and health care proxies, are respected . . . ."[206]

The Memorandum is limited to hospitals that participate in the Medicare and Medicaid programs, but that is virtually all hospitals.

197. *Langbehn*, 661 F. Supp. 2d at 1331-32.
198. *Id.* at 1347.
199. *Id.* at 1337-38.
200. *Id.* at 1338.
201. *See* Memorandum from President Barack Obama for Sec'y of Health and Human Servs., 75 Fed. Reg. 20,511 (Apr. 15, 2010).
202. *Id.*
203. *Id.*
204. *Id.*
205. *Id.*
206. Memorandum, *supra* note 201.

Hospitals can't afford not to participate—hospitals receive the bulk of their revenues from these federally funded programs. The HHS regulations, once implemented, along with the HHS efforts to ensure that already existing rights under patient advance directives are respected, and HHS recommendations on other actions it could take to ensure the rights of gay and lesbian patients and their partners, should go a long way toward ending any continuing hospital resistance or confusion about what they are required to do.

CONCLUSION

Challenges to the constitutionality of PPACA's individual mandate and issues related to the implementation of PPACA will likely top the health law agenda for the upcoming survey year. As discussed in this year's *Survey*, the "individual mandate," which requires that most Americans find insurance coverage or pay a tax penalty, has been challenged by many state Attorney Generals. The issue could well find itself before the Supreme Court in 2011 or 2012.

Further, with the House of Representatives having switched party control, it is likely that there will be efforts to repeal portions of, or all of, PPACA.[207]

Moreover, other related issues, such as the federal government's promulgation of regulations authorizing physician payment for end-of-life counseling, will likely also be controversial.[208] Similar language which had been contained in earlier versions of PPACA had been removed because of claims that it would lead to "death panels" and "government-encouraged euthanasia."[209]

PPACA will also likely dominate developments in state government because of the large role of New York and other states in creating high risk pools, insurance exchanges, and in implementing and ensuring compliance with PPACA.[210]

207. *See, e.g.*, Lawrence R. Jacobs & Theda Skocpol, *Obamacare's Prognosis; Republicans Want to Overturn the New Law, but Lacking the Votes, They'll Probably Have to Settle for Small* Changes, L.A. TIMES, Oct. 31, 2010, at A40; *see also* Caitlin Dickson, *New Republican House Sets Date for Obamacare Repeal Vote*, THE ATLANTIC WIRE (Jan. 4, 2011, 10:39 AM), http://www.theatlanticwire.com/opinions/view/opinion/New-Republican-House-Sets-Date-for-Obamacare-Repeal-Vote-6425.

208. *See, e.g.*, Robert Pear, *Obama Institutes End-of-Life Plan That Caused Stir*, N.Y. TIMES, Dec. 26, 2010, at A1.

209. *Id.*

210. For new developments in implementation of PPACA, see *Fed. Health Care Reform Implementation in New York State*, NY.GOV, http://www.healthcarereform.ny.gov (last visited Feb. 27, 2011).