HEALTH LAW

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CONTENTS

INTRODUCTION 685
I. NEW YORK STATE CASE LAW 686
A. *New York Court of Appeals* 686
II. NEW YORK STATE LEGISLATION 688
A. *New York State Medical Indemnity Fund* 688
B. *New Provisions of New York Civil Practice Law and Rules in Medical Malpractice Actions* 691
III. FEDERAL CASE LAW 692
A. *Challenges to the Patient Protection and Affordable Care Act* 692
B. *Medicare "Improvement Standard" Litigation* 698
IV. FEDERAL LEGISLATION 703
A. *Liability Medicare Set-Aside Arrangements* 703
CONCLUSION 707

INTRODUCTION

At the federal level, the historic challenges to the Patient Protection and Affordable Care Act (PPACA), primarily the controversial individual mandate contained therein, topped the significant health care developments in 2011. Along with this opposition were challenges to Medicare's application of the "improvement standard" or "stability presumption" in denying patients Medicare coverage for necessary medical services. Also pertaining to Medicare, parties to liability settlements and awards continue to struggle to understand the implications of the Medicare Secondary Payer Act and section 111 and also struggle to ensure they are in compliance with the same in considering Medicare's future interest for payment of medical care.

At the state level, the New York State Medical Indemnity Fund was created to provide for future health care costs associated with birth-related neurological injuries. In addition, new provisions in the Civil Practice Law and Rules (CPLR) were enacted which will effect medical

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malpractice actions in New York. Further, the New York Court of Appeals addressed the Health Insurance Portability and Accountability Act (HIPAA) Privacy Law in relation to New York's Kendra's Law.

I. NEW YORK STATE CASE LAW

A. New York Court of Appeals

The Court reversed the order of the appellate division in *In re Miguel M.*,[1] holding that the HIPAA[2] barred disclosure of a patient's medical records to a state agency for use in a proceeding to compel the patient to undergo mental health treatment under Kendra's Law,[3] "where the patient has neither authorized the disclosure nor received notice of the agency's request for the records."[4]

In *In re Miguel M.*, the respondent health official applied for an order under Mental Hygiene Law section 9.60, also known as "Kendra's Law,"[5] to require the appellant to undergo assisted outpatient treatment (AOT).[6] Kendra's Law permits a mentally ill person to be subject to AOT pursuant to a court order if a proper showing has been made that the individual's lack of compliance with treatment has caused him or her to be hospitalized twice within the last thirty-six months.[7] The respondent alleged, inter alia, that Miguel suffered from mental illness, had a history of not complying with treatment, and needed AOT to prevent a relapse or deterioration of mental status.[8] At the hearing for the petition to compel AOT, the health official offered Miguel's medical records from three hospital visits into evidence, which had been furnished to the official in response to his request pursuant to Mental Hygiene Law section 33.13(c)(12), but without notice to Miguel.[9] After the hearing, Miguel was ordered to receive AOT for six months.[10]

As a preliminary matter, the Court addressed the issue of mootness, as appellant completed the six month AOT by the time the

1. 66 A.D.3d 51, 882 N.Y.S.2d 698 (2d Dep't 2009), *rev'd*, 17 N.Y.3d 37, 950 N.E.2d 107, 926 N.Y.S.2d 371 (2011).

2. Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996) (codified as amended at 42 U.S.C. §§ 201-300aaa (2006)).

3. N.Y. MENTAL HYG. LAW § 9.60 (McKinney 2011).

4. *In re Miguel M.*, 17 N.Y.3d at 40, 950 N.E.2d at 109, 926 N.Y.S.2d at 373.

5. Kendra's Law was named for Kendra Webdale, who died after being pushed off a subway platform by a mentally ill man. *Id.* at 41, 950 N.E.2d at 110, 926 N.Y.S.2d at 374.

6. *Id.*, 950 N.E.2d at 109, 926 N.Y.S.2d at 373.

7. N.Y. MENTAL HYG. LAW § 9.60(c).

8. *In re Miguel M.*, 17 N.Y.3d at 40, 950 N.E.2d at 109, 926 N.Y.S.2d at 373.

9. *Id.* at 40-41, 950 N.E.2d at 109, 926 N.Y.S.2d at 373.

10. *Id.* at 41, 950 N.E.2d at 109, 926 N.Y.S.2d at 373.

appellate division decided his case.[11] The Court determined that it would hear the case because it presented "a novel and substantial issue that is likely to recur and likely to evade review" and thus qualified as an exception to the mootness rule.[12]

At issue in *In re Miguel M.* was whether HIPAA Privacy Rule, 45 C.F.R. section 164.508(a)(1), preempted Mental Hygiene Law section 33.13(c)(12).[13] Pursuant to 45 C.F.R. section 160.203(b), a contrary state law is preempted by HIPAA unless the state law offers greater privacy protections than those of the federal law.[14] The Privacy Rule proscribes disclosure of a patient's health information without the patient's consent, subject to exceptions related to public health, treatment, and pursuant to court order or subpoena.[15] In contrast, N.Y. Mental Hygiene Law section 33.13(c)(12) allows disclosure of a patient's medical records to a director of community services who requests it in furtherance of his or her duties.[16]

The Court disagreed with respondent's argument that the HIPAA Privacy Rule public health and treatment exceptions applied to Miguel.[17] It determined that the official's interpretation of the legislation was too literal and was not consistent with the intent of the legislation.[18] Hence, the exceptions did not apply.[19] The Court reasoned that the purpose of the public health exception[20] "is to facilitate government activities that protect large numbers of people from epidemics, environmental hazards, and the like, or that advance public health by accumulating valuable statistical information."[21] It concluded that the exception was not applicable to Miguel because there was no "generalized public benefit" achieved by permitting the disclosure.[22] Similarly, the Court reasoned that the treatment

11. *Id.* at 41, 950 N.E.2d at 109-10, 926 N.Y.S.2d at 373-74.

12. *Id.*; *see also* Hearst Corp. v. Clyne, 50 N.Y.2d 707, 714-15, 409 N.E.2d 876, 878, 431 N.Y.S.2d 400, 402 (1980).

13. *In re Miguel M.*, 17 N.Y.3d at 41-42, 950 N.E.2d at 110, 926 N.Y.S.2d at 374.

14. *See* 45 C.F.R. § 160.203(b) (2010). The Court noted that the latter did not apply in this case. *In re Miguel M.*, 17 N.Y.3d at 42, 950 N.E.2d at 110, 926 N.Y.S.2d at 374.

15. 45 C.F.R. § 164.508(a)(1); *see also* 45 C.F.R. § 164.512(b) (public health exception); 45 C.F.R. §§ 164.501, 164.506 (treatment exception); 45 C.F.R § 164.512(e) (orders and subpoenas exception).

16. N.Y. MENTAL HYG. LAW § 33.13(c)(12) (McKinney 2011).

17. *See In re Miguel M.*, 17 N.Y.3d at 43-44, 950 N.E.2d at 111-12, 926 N.Y.S.2d at 375-76.

18. *Id.* at 43, 950 N.E.2d at 111, 926 N.Y.S.2d at 375.

19. *Id.*

20. 45 C.F.R. § 164.512(b)(1)(i).

21. *In re Miguel M.*, 17 N.Y.3d at 42-43, 950 N.E.2d at 111, 926 N.Y.S.2d at 375.

22. *Id.* at 43, 950 N.E.2d at 111, 926 N.Y.S.2d at 375.

exception[23] did not apply because "the thrust of the treatment exception is to facilitate the sharing of information among health care providers working together."[24]

However, the Court commented that the respondent could have obtained Miguel's medical records by way of the court order or subpoena exceptions, which would have provided notice to Miguel that his medical records were being disclosed and would have complied with the Privacy Rule.[25] The Court reasoned that "unauthorized disclosure without notice is, under circumstances like those present here, inconsistent with the Privacy Rule."[26] The Court further held that since Miguel's medical records were obtained in violation of HIPAA they were inadmissible in a proceeding to compel AOT.[27] However, it acknowledged that in a criminal case the result might be different and the records might not be suppressed.[28]The Court concluded:

It is one thing to allow the use of evidence resulting from an improper disclosure of information in medical records to prove that a patient has committed a crime; it is another to use the records themselves, or their contents, in a proceeding to subject to unwanted medical treatment a patient who is not accused of any wrongdoing.[29]

II. NEW YORK STATE LEGISLATION

A. New York State Medical Indemnity Fund

On March 31, 2011, Governor Cuomo signed into law the 2011-2012 budget for the State of New York which contained language amending Article 29-D of the Public Health Law to create the New York State Medical Indemnity Fund (the "Fund").[30] The Fund, administered by the Department of Financial Services, was created to provide for future health care costs associated with birth-related neurological injuries in an attempt to lower medical malpractice

23. 45 C.F.R. § 164.501.

24. *In re Miguel M.*, 17 N.Y.3d at 43, 950 N.E.2d at 111, 926 N.Y.S.2d at 375.

25. *Id.* at 43-44, 950 N.E.2d at 111, 926 N.Y.S.2d at 375.

26. *Id.* at 44, 950 N.E.2d at 112, 926 N.Y.S.2d at 376.

27. *Id.* at 45, 950 N.E.2d at 112, 926 N.Y.S.2d at 376.

28. *Id.*

29. *In re Miguel M.*, 17 N.Y.3d at 45, 950 N.E.2d at 112, 926 N.Y.S.2d at 376.

30. N.Y.A. 04009, 234th Sess. (2011); New York State Medical Indemnity Fund, Act of March 31, 2011, ch. 59, 2011 McKinney's Sess. Laws of N.Y. 309 (codified as N.Y. PUB. HEALTH LAW § 2999(g)-(j) (McKinney 2011)). For more information, including a copy of the Act itself, readers are directed to the New York State Medical Indemnity Fund's webpage on the New York Department of Financial Services website, http://www.dfs.ny.gov/insurance/mif/mif_indx.htm.

insurance premiums.[31] The following is a summary of the basic mandates of the Fund, and related provisions, based upon the statutory text.[32]

Operations of the Fund commenced on October 1, 2011, however the provisions enacting the Fund apply to all actions for birth-related neurological injury for which there has been no judgment or settlement as of April 1, 2011.[33] The amount set aside for the 2011-2012 fiscal year is $30 million, funded through a 1.6% quality contribution assessed on general hospitals' revenue from inpatient obstetrical patient care services as of July 1, 2011.[34] The contribution percentage is subject to change in the event that the projected amounts fall short or exceed the Fund's target each year.[35] the Fund amount is also set to increase annually.[36]

The Fund is set up to pay for "qualifying health care costs of qualified plaintiffs."[37] "Qualified plaintiff" is defined in the statute and includes plaintiffs in medical malpractice actions who have received a court-approved settlement or judgment deeming the plaintiffs' neurological impairments (motor or developmental disabilities) to be birth-related.[38] Once qualified, the Fund will pay for future qualifying health care costs not otherwise covered by private health insurance or

31. New York State Medical Indemnity Fund, Act of March 31, 2011, ch. 59, 2011 McKinney's Sess. Laws of N.Y. 309 (codified as N.Y. PUB. HEALTH LAW § 2999(g)). The provision will also likely effect substantial savings to Medicaid since, pursuant to section 2999(j)(3) and (12) of the law, Medicaid is expressly exempted as a collateral source (primary payer) under the law. As such, The Fund will pay for qualifying health care expenses that might have otherwise been paid by Medicaid—a direct savings to the Medicaid program.

32. The details regarding how The Fund will be administered will be addressed more specifically in regulations to be enacted by the New York Superintendent of Financial Services. These regulations were not yet promulgated by the end of the 2010-11 *Survey* year and therefore will not be discussed.

33. New York State Medical Indemnity Fund, Act of March 31, 2011, ch. 59, 2011 McKinney's Sess. Laws of N.Y. 339 (to be codified as N.Y. PUB. HEALTH LAW § 111).

34. New York State Hospital Quality Initiative, Act of March 31, 2011, ch. 59, 2011 McKinney's Sess. Laws of N.Y. 313 (codified as N.Y. PUB. HEALTH LAW §§ 2807(v)(1)(iii), 2807-d-1).

35. *Id*. (codified as N.Y. PUB. HEALTH LAW § 2807-d-1(1)).

36. *Id*. (codified as N.Y. PUB. HEALTH LAW § 2807-d-1(2)).

37. New York State Medical Indemnity Fund, Act of March 31, 2011, ch. 59, 2011 McKinney's Sess. Laws of N.Y. 311 (codified as N.Y. PUB. HEALTH LAW § 2999-j(1)).

38. *Id.* at 309 (codified as N.Y. PUB. HEALTH LAW § 2999-h(4)) ("every plaintiff or claimant who (i) has been found by a jury or court to have sustained a birth-related neurological injury as the result of medical malpractice, or (ii) has sustained a birth-related neurological injury as the result of alleged medical malpractice, and has settled his or her lawsuit or claim therefor [sic]").

other collateral sources, excluding Medicare and Medicaid.[39] Private health insurers will remain primary payers and will have no right of recovery or lien against the Fund or any other person or entity.[40] Qualifying health care costs can include medical, hospital and surgical expenses, rehabilitative and custodial expenses, medical equipment, home and vehicle modification and other assistive technology expenses, medication expenses, as well as other expenses incurred by qualified individuals which are necessary to meet their health care needs.[41]

All settlement agreements and judgments in related medical malpractice actions will now be required to set forth a portion of the amount awarded which is intended to compensate the plaintiff for future medical expenses. The agreement or judgment must also provide that if the plaintiff is enrolled in the Fund, all future medical expenses will be paid by the Fund in accordance with the Act.[42] As such, once enrolled, that portion of the settlement or judgment will be forfeited and defendants (and their insurers) will no longer be required to satisfy that portion of the award.[43] Plaintiff's attorney's fees will still be based on the total or gross amount awarded, even though defendants may not pay the award in its entirety.[44] In the event the plaintiff becomes enrolled in the Fund, thereby forfeiting that portion of the award attributed to future medical costs, the plaintiff's attorney's fees generated from that portion of the award must still be paid by defendants, or their insurers (not deducted from the remainder of the settlement or judgment amount at the cost of the plaintiff).[45] As such, while defendants will not be required to pay for the qualified plaintiff's future medical costs, they will still be required to pay the attorney's fees attributed to that portion of the settlement or judgment award.

An application for enrollment can be made by either a plaintiff or defendant, on notice to all opposing parties.[46] All qualified plaintiffs will be enrolled, except when enrollment is suspended.[47] Enrollment

39. *Id*. at 311-12 (codified as N.Y. PUB. HEALTH LAW § 2999-j(3), (12)).

40. *Id*. at 312 (codified as N.Y. PUB. HEALTH LAW § 2999-j(12)).

41. *Id*. at 309 (codified as N.Y. PUB. HEALTH LAW § 2999-h(3)).

42. New York State Medical Indemnity Fund, Act of March 31, 2011, ch. 59, 2011 McKinney's Sess. Laws of N.Y. 311 (codified as N.Y. PUB. HEALTH LAW § 2999-j(6)(a)).

43. *Id*. at 312 (codified as N.Y. PUB. HEALTH LAW § 2999-j(13)).

44. *Id*. (codified as N.Y. PUB. HEALTH LAW § 2999-j(14)).

45. *Id*.

46. *Id*. at 311 (codified as N.Y. PUB. HEALTH LAW § 2999-j(7)). Instructions, including an application, for enrollment in The Fund are available at http://www.dfs.ny.gov/insurance/mif/mif_apps.htm.

47. New York State Medical Indemnity Fund, Act of March 31, 2011, ch. 59, 2011 McKinney's Sess. Laws of N.Y. 311 (codified as N.Y. PUB. HEALTH LAW § 2999-j(7)).

will be suspended if the Fund's liabilities equal or exceed eighty percent of its assets.[48] During the suspension period, all applications for enrollment will be denied and qualifying judgments and settlements will be satisfied as if the Act (and the Fund) did not exist.[49] In other words, qualifying plaintiffs will be entitled to collect the entire settlement or judgment amount awarded, including that portion awarded for future medical expenses, but will be responsible for those expenses that would have otherwise been paid for by the Fund. Such a suspension, however, will have no impact on qualified plaintiffs already approved and enrolled in the Fund at the time of suspension.[50] Should a suspension occur, notice of the same will be promptly posted to the Department of Financial Services website.[51] Parties to obstetrical malpractice actions should pay close attention to the financial health of the Fund when establishing reserves, negotiating settlements, or preparing for trial to ensure that they know which set of rules will apply.[52]

In addition to the changes made to create and finance the Fund, Article 29-D of New York State's Public Health was further amended to include Title 5: New York State Hospital Quality Initiative.[53] The initiative, which will include an Obstetrical Patient Safety Workgroup, will oversee the general dissemination of initiatives, guidance, and best practices to general hospitals.[54] The Workgroup will work collaboratively to improve obstetrical care outcomes and quality of care.[55]

B. New Provisions of New York Civil Practice Law and Rules in Medical Malpractice Actions

New York's CPLR was also amended with an impact on medical malpractice litigants. Newly added section 3409 requires a mandatory settlement conference to be held within forty-five days of the note of issue filing in all dental, podiatric, and medical malpractice actions.[56] While persons authorized to act on behalf of party can attend, only

48. *Id*. at 310 (codified as N.Y. PUB. HEALTH LAW § 2999-i(6)(a)).

49. *Id*. (codified as N.Y. PUB. HEALTH LAW § 2999-i(6)(b)).

50. *Id*. (codified as N.Y. PUB. HEALTH LAW § 2999-i(6)(d)).

51. *Id*. (codified as N.Y. PUB. HEALTH LAW § 2999-i(6)(b)).

52. Daniel S. Ratner, *New York State's New Medical Indemnity Fund*, MARTINDALE (August 11, 2011), http://www.martindale.com/medical-malpractice-law/article_Heidell-Pittoni-Murphy-Bach-LLP_1328126.htm.

53. N.Y. PUB. HEALTH LAW § 2999-m.

54. *Id.*

55. *Id.*

56. N.Y. C.P.L.R. 3409 (McKinney 2011).

attorneys familiar with, and authorized to settle, the case will be permitted.[57] Additionally, the court may require other interested parties, including insurance representatives, to attend the conference.[58]

Section 306-c was also added to New York's CPLR, which requires a recipient of public medical assistance (i.e. Medicaid, Family Health Plus, etc.) who has suffered personal injuries, and has received medical assistance on or after the date of such injury, to notify the Social Services District in which the recipient resides, or the NYS Department of Health, of the commencement of an action by or on behalf of the recipient.[59] The provision goes hand-in-hand with the newly amended section 104-b of the Social Services Law (permitting public welfare offices to impose liens against personal injury suits), which now requires notice when a personal injury action is commenced by a recipient of public assistance.[60] The new notice requirement will likely improve Medicaid lien collection. While this provision is not limited to medical malpractice actions, it would certainly include them. The requisite notice must be provided within sixty days after service of all parties and proof of sending such notice must be filed with the court.[61]

III. FEDERAL CASE LAW

A. Challenges to the Patient Protection and Affordable Care Act

Once again, topping the list of items to discuss in the survey of health law in New York is the federal health care reform, now law—the Patient Protection and Affordable Care Act. The PPACA has provoked enormous opposition since its inception and only minutes after President Obama signed the legislation into law on March 23, 2010, the resistance efforts moved from Congress to the courthouse.[62]

57. *Id.*

58. *Id.*

59. N.Y. C.P.L.R. 306-c (McKinney 2011); *see also New Medicaid Reporting Requirements in New York*, THE LIEN RESOL. GROUP BLOG (September 14, 2011), http://lienresolutiongroup.com/new-medicaid-reporting-requirements-in-new-york.

60. N.Y. SOC. SERV. LAW § 104-b (McKinney 2011); *see also* THE LIEN RESOL. GROUP BLOG, *supra* note 59.

61. N.Y. C.P.L.R. 306-c.

62. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010); Associated Press, *13 Attorneys General Sue On Healthcare Bill*, USA TODAY (Mar. 23, 2010), http://www.usatoday.com/news/nation/2010-03-23-attorneys-general-health-suit_N.htm; Kevin Arts, *Legal Challenges to Health Reform*, ALLIANCE FOR HEALTH REFORM (May 18, 2010), *available at* http://www.allhealth.org/publications/Uninsured/Legal_Challenges_to_New_Health_Reform_Law_97.pdf.

Often referred to as "Obamacare" by opponents, PPACA changes the health care landscape in every state.[63] An overview of some of the more significant aspects of the law was previously provided in the 2010 *Survey* and will not be repeated here.[64] Rather, this survey article will focus on the challenges brought against PPACA and provide an overview of the most significant constitutional challenges to the legislation to date. Again, attorneys who need specific guidance with respect to PPACA health reform are directed to the numerous academic or practice-based legal articles generally available that focus on the many different aspects of PPACA.[65]

Although PPACA is very comprehensive and broad in its reach, most of the controversy surrounding the Act centers on one very significant provision of the law: the "Individual Responsibility" mandate.[66] Often referred to as the "individual mandate," this controversial provision requires that nearly all persons not otherwise covered by health insurance (Medicare, Medicaid, etc.) purchase an approved private insurance policy for each month beginning in January 2014.[67] Taxpayers who fail to do so will be subject to a federal penalty.[68]

By the fall of 2011, a majority of states (not New York), numerous organizations, and some individual persons filed federal actions challenging the constitutionality of the Act.[69] Almost all of the suits target the individual mandate, but also include a sprinkling of

63. *See* Liz White, *Stewart Calls It: "Obamacare" Derogatory*, NEWSWEEK (Apr. 21, 2010), http://www.thedailybeast.com/newsweek/blogs/the-gaggle/2010/04/21/stewart-calls-it-obamacare-derogatory.html; Marilyn Werber Serafini, *Rebranding "Obamacare,"* KAISER HEALTH NEWS (Jan. 3, 2011), http://www.kaiserhealthnews.org/Stories/2010/December/27/rebranding-obamacare.aspx.

64. *See* Edward F. McArdle & Kirsten A. Lerch, *Health Law, 2009-2010 Survey of New York Law*, 61 SYRACUSE L. REV. 801, 814-23 (2011).

65. A full copy of the Act is available at http://www.ncsl.org/documents/health/ppaca-consolidated.pdf. A LexisNexis search for secondary sources referencing the federal health care reform (PPACA) returned more than 150 hits.

66. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 § 1501 (codified at 26 U.S.C. §5000A(a) (Supp. 2010)) (individual mandate).

67. *Id.* (codifed at 26 U.S.C. §5000A(a)) (individual mandate).

68. *Id*. (codified at 26 U.S.C. §5000A(b-c)) (penalty).

69. Sarah Kliff, *FAQ: Everything You Wanted To Know About The Health Reform Lawsuits, But Were Afraid To Ask*, WASHINGTON POST WONKBLOG (Nov. 14, 2011, 9:00 AM), http://www.washingtonpost.com/blogs/ezra-klein/post/faq-everything-you-wanted-to-know-about-the-health-reform-lawsuits-but-were-afraid-to-ask/2011/11/13/gIQAXKPhKN_blog.html; Bara Vaida & Karl Eisenhower, *Scoreboard: Tracking Health Law Court Challenges*, KAISER HEALTH NEWS (Nov. 14, 2011), http://www.kaiserhealthnews.org/Stories/2011/March/02/health-reform-law-court-case-status.aspx.

challenges to other provisions, including the expansion of Medicaid as an undue financial burden on state governments and the penalty imposed for not obtaining health insurance as an illegal tax.[70]

With respect to the individual mandate, opponents of the law argue that the provision is an unconstitutional expansion of federal power under the Commerce Clause.[71] While Congress admittedly has very broad power to regulate commerce and interstate economic activity as granted by the Commerce Clause, opponents argue that an individual's decision to *not* buy health insurance is economic *in*activity, and therefore not a behavior the government can regulate.[72] In other words, Congress cannot compel Americans to participate in commerce that they seek to regulate. If the government can regulate individual decisions to not purchase health insurance, opponents argue there will be no meaningful limits on federal power.[73]

On the other hand, the federal government argues that individuals who chose not to purchase health insurance are making an active economic decision to "self-insure."[74] Such a decision has a significant economic effect on the universal health care market (interstate commerce).[75] Congress' power to regulate the interstate market includes the power to regulate the substantially related activity of self-insurance.[76] Furthermore, failing to regulate this class of activity (self-insurance) would undercut the overarching purpose of the health care reform legislation.[77]

The federal district and appellate courts in these cases have reached

70. Associated Press, *supra* note 62; Kliff, *supra* note 69; Vaida & Eisenhower, *supra* note 69.

71. Granted, there are other arguments raised in most, if not all, of the actions which have been filed challenging the Act, but the debate over the extent of Congress' power under the Commerce Clause has been the primary dispute among the parties. Arguments based upon Congress' power pursuant to the Necessary and Proper Clause as well as the Taxing and Spending Powers, among others, have also been made. *See* J. Logan Murphy et al., *Patient Protection and Affordable Care Act Litigation*, 53 FOR THE DEF. 41, 43 (Oct. 2011); *see also* Associated Press, *supra* note 62; Kliff, *supra* note 69.

72. *See* Murphy et al., *supra* note 71, at 43; *see also* Bruce Platt et al., *Florida v. HHS takes Health Care Reform to High Court*, REUTERS (Dec. 28, 2011), http://newsandinsight.thomsonreuters.com/Legal/Insight/2011/12_-_December/Florida_v__HHS_takes_health_care_reform_to_high_court/ (citing Response Brief of Appellee at 19, Florida v. U.S. Dep't of Health & Human Servs., 648 F.3d 1235 (11th Cir. 2011) (Nos. 11-11021, 11-11067), 2011 WL 1944107, at *19).

73. *See* Platt et al., *supra*, note 72.

74. Murphy et al., *supra* note 71, at 43; *see also* Kliff, *supra* note 69.

75. Murphy et al., *supra* note 71, at 43; *see also* Platt et al., *supra* note 72.

76. Murphy et al., *supra* note 71, at 43.

77. *Id.*

widely varying conclusions with respect to the constitutionality of the law, particularly the individual mandate provision.[78] Some courts, including the Fourth Circuit Court of Appeals, have failed to reach the substance of the dispute due to lack of standing or subject matter jurisdiction.[79] Of those that have reached the substance of the dispute, the courts are split as to whether the individual mandate, and the law as a whole, is constitutional.[80] Unsurprisingly, the decisions split, for the most part, along partisan lines, with Democratic judicial appointees upholding the law, and those judges appointed by Republicans typically rejecting it as unconstitutional.[81]

The controversy has reached several federal circuit courts of appeal, including the Fourth, Sixth, Eleventh, and D.C. Circuits.[82] As set forth above, the Fourth Circuit has failed to address the substance of the dispute and has dismissed both suits that came before it on procedural grounds.[83] The Sixth Circuit and the D.C. Circuit have both upheld the law as Constitutional in two to one margin decisions. In *Thomas More Law Center v. Obama*, the Sixth Circuit majority held that the individual mandate was constitutional given the current state of Commerce Clause jurisprudence.[84] Rather than forcing economic activity, the majority held that Congress was merely regulating the "self insurance" market and that Congress had a rational basis to believe that self-insurance substantially effects interstate commerce.[85] Referencing the Supreme Court's decision in *Wickard v. Filburn*,[86] the court paralleled Congress' legitimate interest in regulating wheat grown for personal consumption based upon its effects on the wheat industry as a

78. *See* Kliff, *supra* note 69; Murphy et al., *supra* note 71, at 43; Vaida & Eisenhower, *supra* note 69.

79. *See* Virginia *ex rel.* Cuccinelli v. Sebelius, 656 F.3d 253, 266 (4th Cir. 2011) (ruling that there was no evidence of injury and thus no standing); *see also* Liberty Univ., Inc. v. Geithner, No. 10-2347, 2011 WL 3962915, at *1 (4th Cir. 2011) (Fourth Circuit ruling that it had no subject matter jurisdiction because the penalty is a "tax" and under the federal Anti-Injunction Act, no suits challenging the penalty can be brought until it comes into effect and is imposed after 2014).

80. Kliff, *supra* note 69; Vaida & Eisenhower, *supra* note 69; Murphy et al., *supra* note 71, at 42.

81. Kliff, *supra* note 69.

82. *Id.*; Vaida & Eisenhower, *supra* note 69.

83. *Sebelius*, 656 F.3d at 266, 272 (no evidence of injury so no standing); *Geithner*, 2011 WL 3962915, at *1, *16 (court had no subject matter jurisdiction because the penalty is a "tax" and under the federal Anti-Injunction Act no suits challenging the penalty can be brought until it comes into effect and is imposed after 2014).

84. 651 F.3d 529, 534 (6th Cir. 2011).

85. *Id.* at 543.

86. 317 U.S. 111 (1942).

whole to the Congressional interest put forth by the federal government in this case—to regulate the "self insurance" market based upon its effect on the universal health care market as a whole (interstate commerce).[87] The D.C. Circuit closely examined the text of the Constitution and Commerce Clause precedents and the majority came to a similar conclusion.[88] While the court recognized the mandate was an "encroachment on individual liberty," the majority held that the decision whether or not to purchase health insurance is an economic behavior that substantially affects interstate commerce.[89]

At the other end of the spectrum, on August 12, 2011, a two-to-one majority of the Eleventh Circuit Court of Appeals in *Florida v. United States Department of Health & Human Services* held that the individual mandate was unconstitutional.[90] This suit, the first of its kind—filed minutes after President Obama signed PPACA into law—has been the most successful suit challenging the law.[91] A majority of the states joined the suit (twenty-six total but not New York), as well as the National Federation of Independent Businesses and two individuals.[92] The arguments are essentially the same, but both District Court Judge Roger Vinson and a majority of the Eleventh Circuit panel agreed with the plaintiffs—that the decision to avoid purchasing insurance is not economic activity and therefore cannot be regulated under the Commerce Clause.[93] Judge Vinson also held that the individual mandate was not severable and therefore the entire PPACA was void, but the Eleventh Circuit disagreed, holding instead that the unconstitutional mandate was severable and the other provisions of the Act could remain legally operative.[94]

In light of the overwhelming confusion and differing case law in several federal districts and circuits, many predict that the final word on the constitutionality of the individual mandate provision, and the severability of the same, will come from the U.S. Supreme Court.[95]

87. *Thomas More Law Ctr.*, 651 F.3d at 542.

88. Seven-Sky v. Holder, 661 F.3d 1, 20 (D.C. Cir. 2011).

89. *Id.*

90. 648 F.3d 1235, 1241 (11th Cir. 2011).

91. Platt et al., *supra* note 72.

92. *Id.*

93. Florida v. U.S. Dep't of Health & Human Servs., 780 F. Supp. 2d 1256, 1295 (N.D. Fla. 2011), *aff'd in part*, 648 F.3d at 1235.

94. *Florida*, 780 F. Supp. 2d at 1304, *rev'd in part*, 648 F.3d at 1328; *see also* Platt et al., *supra* note 72.

95. Murphy et al., *supra* note 71, at 44; James Vicini, *Obama Healthcare Battle Appealed to Supreme Court*, REUTERS (Jul. 27, 2011),

Even Sixth Circuit Court of Appeals Judge Jeffrey Sutton recognizes that the federal court of appeals decisions on the issue "are not just fallible but utterly non-final."[96] As predicted, on November 14, 2011, the U.S. Supreme Court agreed to decide the constitutionality of the Act when it granted review of the appeal in *Florida v. United States Department of Health & Human Services*.[97] While it may consider other issues as well, the Court is expected to address the issues splitting most districts and circuits across the country—namely standing, the constitutionality of the individual mandate, and its severability.[98] The High Court heard oral argument in March 2012 and is expected to issue its decision by the end of its term in June of 2012.[99] Notably, the decision is expected just months before the 2012 presidential election.

In addition to the challenges put forth in federal lawsuits, state legislatures have also taken action in an attempt to counteract the application of certain elements, primarily the individual mandate, in their states. Virginia and Idaho led the effort, passing laws that forbid a health insurance requirement for any residents of their states before PPACA was officially enacted.[100] Several other states, including New York, have since approved or proposed similar statutes, resolutions and/or state constitutional amendments that attempt to "nullify" elements of PPACA.[101] Of course, a key problem facing most—if not all—of these state based legislative attempts is the Supremacy Clause of

http://www.reuters.com/article/2011/07/27/us-usa-healthcare-court-idUSTRE76Q7AB20110727.

96. Thomas More Law Ctr. v. Obama, 651 F.3d 529, 555 (6th Cir. 2011).

97. Platt et al., *supra* note 71.

98. *Id.*; Jill Wechsler, *Historic Judgments Now on the Docket*, MANAGED HEALTH CARE EXECUTIVE (Dec. 1, 2011), http://managedhealthcareexecutive.modernmedicine.com/mhe/News+Analysis/Historic-judgments-now-on-the-docket/ArticleStandard/Article/detail/750635.

99. Platt et al., *supra* note 72; *Factobox: Supreme Court's Lengthiest Oral Arguments*, REUTERS (Nov. 16, 2011), http://newsandinsight.thomsonreuters.com/Legal/News/2011/11_-_November/Factbox__SCOTUS_s_lengthiest_oral_arguments_ever/; *Analysis—Chief Justice Roberts: Man in middle is man of the moment*, REUTERS (Mar. 29, 2012), http://newsandinsight.thomsonreuters.com/Legal/News/2012/03_-_March/Analysis-Chief_Justice_Roberts__Man_in_middle_is_man_of_the_moment/.

100. VA. CODE ANN. § 38.2-3430.1:1 (Supp. 2011), *available at* http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+38.2-3430.1C1; *see also* Judson Berger, *States Plot to Block, Limit Health Care Reform Law*, FOXNEWS.COM (Mar. 23, 2011), http://www.foxnews.com/politics/2010/03/23/states-plot-block-limit-health-care-reform/; Arts, *supra* note 62, at 1-2; Richard Cauchi, *State Legislation and Actions Challenging Certain Health Reforms, 2011*, NAT'L CONF. OF ST. LEGISLATURES (Dec. 19, 2011), http://www.ncsl.org/?tabid=18906.

101. Berger, *supra* note 100; Arts, *supra* note 62; Cauchi, *supra* note 100.

the United States Constitution.[102] As enforced by the Supreme Court on several occasions, the Supremacy Clause provides that when federal laws conflict with state laws, the federal law will trump or preempt the conflicting state statute.[103] As a result, PPACA, a federal law, would trump any conflicting state law, including those attempting to limit the application of its individual mandate on state residents.[104] However, if the conflicting federal provision is deemed unconstitutional, and therefore null and void, then no conflict would exist. Other alternatives to deflate the legislation include federal legislation to repeal the statute and/or an amendment to the U.S. Constitution, both of which are unlikely due to the current political composition of Congress and the White House.[105] Given the obstacles these efforts would face, including President Obama's power to veto any repeal efforts, many opponents are now looking to the Supreme Court as their final hope.[106]

B. Medicare "Improvement Standard" Litigation

In *Papciak v. Sebelius*[107] and *Anderson v. Sebelius*,[108] U.S. district courts in Pennsylvania and Vermont, respectively, held that the "improvement standard"[109] or "stability presumption"[110] was not the proper legal standard for determining whether plaintiffs received Medicare coverage.[111]

After going through the proper administrative channels[112] dictated by the Medicare statute,[113] plaintiffs in *Papciak*[114] and *Anderson*[115]

102. U.S. CONST. art. VI, cl. 2.

103. *Id. See, e.g.*, Altria Grp. v. Good, 555 U.S.70, 91 (2008); Maryland v. Louisiana, 451 U.S. 725, 760 (1981).

104. Berger, *supra* note 100.

105. Brian Montopoli, *House to Vote to Repeal Health Care Reform on Jan. 12th*, CBSNEWS.COM (Jan. 3, 2011), http://www.cbsnews.com/8301-503544_162-20027095-503544.html; *Senate Votes Down GOP Effort to Repeal Healthcare Law*, FOXNEWS.COM (Feb.2, 2011), http://www.foxnews.com/politics/2011/02/02/senate-debates-health-care-law-anew-wholesale-repeal-unlikely/.

106. Arts, *supra* note 62; Platt et al., *supra* note 72.

107. 742 F. Supp. 2d 765 (W.D. Pa. 2010).

108. No. 5:09-cv-16, 2010 WL 4273238 (D. Vt. 2010).

109. *See* Dan D'Ambrosio, *Class Action Lawsuit Targets Denial of Medicare Coverage*, BURLINGTON FREE PRESS.COM (Jan. 19, 2011), http://www.burlingtonfreepress.com/article/20110119/NEWS02/101190309/Class-action-lawsuit-targets-denial-Medicare-coverage; Gill Deford et al., *How the "Improvement Standard" Improperly Denies Coverage to Medicare Patients with Chronic Conditions*, 43 CLEARINGHOUSE REV. 422, 423 (2010).

110. *Anderson*, 2010 WL 4273238, at *3.

111. *See id.*; *Papciak*, 742 F. Supp. 2d at 770-72.

112. 20 C.F.R. § 404.900 (2011).

113. 42 U.S.C. §§ 1395-1395ff (2006).

commenced actions against the Secretary of the U.S. Department of Health challenging the application of the improvement standard after Medicare coverage for their skilled nursing services were denied.[116] At issue in both cases was whether the Administrative Law Judge (ALJ) improperly denied plaintiffs coverage for these skilled nursing services and applied the wrong legal standard in denying coverage for the same.[117]

In *Papciak*, the eighty-one-year-old plaintiff was prescribed skilled nursing care, physical therapy, and occupational therapy after undergoing hip replacement surgery and hospitalization for a subsequent urinary tract infection.[118] She was admitted to Manor Care on June 3, 2008 for receipt of these services, which were provided to her through July 19, 2008.[119] Medicare paid for the skilled care plaintiff received from June 3, 2008 to July 9, 2008, but denied coverage for skilled care from July 10, 2008 through July 19, 2008, because it determined that plaintiff "had made only minimal progress in some areas, had regressed in other areas, and had been determined to have met her maximum potential for her physical and occupational therapy" and hence no longer required skilled care.[120] Medicare classified the care she received from July 10, 2008 through July 19, 2008 as "custodial care".[121] Of note, plaintiff was subsequently hospitalized for possible infection and generalized weakness and was discharged to Baldwin Health Center where she received physical and occupational therapy, and ultimately improved.[122]

The *Papciak* court articulated that it must determine whether there was "substantial evidence" to support the Secretary's final decision and whether the Secretary applied the appropriate legal standard in denying Medicare coverage.[123] The court noted that "custodial care" is excluded from coverage under the Medicare Act[124] and is described as "any care that does not meet the requirements for coverage as [skilled nursing facility (SNF)] care as set forth in [sections] 409.31 through 409.35 of

114. *Papciak*, 742 F. Supp. 2d. at 766-67.
115. *Anderson*, 2010 WL 4273238, at *3.
116. *Id.*; *Papciak*, 742 F. Supp. 2d at 769.
117. *Anderson*, 2010 WL 4273238, at *3; *Papciak*, 742 F. Supp. 2d at 767.
118. *Papciak*, 742 F. Supp. 2d at 767.
119. *Id.*
120. *Id*.
121. *Id*.; *see also* 42 U.S.C. § 1395y(a) (2006); 42 C.F.R. § 411.15(g) (2010).
122. *Papciak*, 742 F. Supp. 2d at 767.
123. *Id.* at 768.
124. *Id.* (citing 42 U.S.C. § 1395y(a)(9)).

this chapter."[125] Skilled Nursing Care (SNC) provided at a SNF is defined as services that (1) are prescribed by a doctor, (2) require personnel with technical or professional skills such as registered nurses, physical therapists, occupational therapists and so forth, and (3) are "furnished directly by, or under the supervision of, such personnel."[126] In addition, to qualify for SNC, "the beneficiary must require skilled nursing or skilled rehabilitation services, or both, on a daily basis" and "the daily skilled services must be ones that . . . can only be provided in a SNF, on an inpatient basis."[127] The court further observed that prior courts interpreted custodial care "to be care that can be provided by a lay person without special skills and not requiring or entailing the continued attention of trained or skilled personnel."[128]

The court agreed with plaintiff that the Secretary failed to apply the correct legal standard and did not consider plaintiff's potential need for a rehabilitative maintenance program.[129] It noted that the ALJ and Medicare Appeals Council both supported their conclusions with the fact that plaintiff had made "little to no progress in therapy" or that additional therapy was not going to improve her function.[130] The court observed that the Medicare Skilled Nursing Facility Manual provides that:

> The services must be provided with the expectation, based on the assessment made by the physician of the patient's restoration potential, that the condition of the patient will improve materially in a reasonable and generally predictable period of time *or* the services must be necessary for the establishment of a safe and effective maintenance program.[131]

Further, the court pointed out that the Secretary's regulations state "[t]he restoration potential of a patient is not the deciding factor in determining whether skilled services are needed. Even if full recovery or medical improvement is not possible, a patient may need skilled services to prevent further deterioration or preserve current

125. *Id.* (quoting 42 C.F.R. § 411.15(g)).

126. 42 C.F.R. § 409.31(a) (2010).

127. *Id.* § 409.31(b).

128. *Papciak*, 742 F. Supp. 2d at 769 (citing Kuebler v. Sec'y of U.S. Dep't of Health & Human Servs., 579 F. Supp. 1436, 1438 (E.D.N.Y. 1984); Reading v. Richardson, 339 F. Supp. 295, 300 (E.D. Mo. 1972)).

129. *Id.* at 770.

130. *Id.*

131. *Id.* at 769 (citing SKILLED NURSING FACILITY MANUAL ch. 2, § 214.3 (A)(1), *available at* https://www.cms.gov/manuals/Downloads/bp102c08.pdf) (emphasis added).

capabilities."[132]

Additionally, the court concluded that the Secretary's decision in denying plaintiff Medicare benefits was not supported by substantial evidence.[133] Thus, the court reversed the prior decision and remanded the case to the Secretary with instruction to award plaintiff benefits.[134]

In *Anderson*, the sixty-year-old plaintiff received home health services after being discharged from the hospital after her second stroke.[135] Plaintiff suffered from urinary incontinence, cerebrovascular disease, diabetes, cognitive impairments, and limited physical mobility, which required twenty-four hour supervision at home to ensure her safety.[136] As a result, her treating physician ordered skilled nursing services and both physical and occupational therapy from June 7, 2004 to June 2, 2005.[137] However, the fiscal intermediary contracted by Medicare only covered the services provided from June 7, 2004 to August 6, 2004, and denied coverage for the remaining time period.[138]

As a threshold matter, the court concluded that the case was not moot and that it had jurisdiction to consider plaintiff's claim.[139] The court then discussed the applicable regulations in determining whether the ALJ imposed a "stability presumption"[140] in plaintiff's case. Pursuant to 42 C.F.R. section 409.42 (a)-(d), a Medicare beneficiary must meet the following requirements to receive Medicare coverage for home health care services: the beneficiary must be "(a) confined to the home; (b) under the care of a physician; (c) in need of skilled services;[141] and (d) under a plan of care."[142] To qualify for Medicare

132. *Id.* at 770 (citing 42 C.F.R. § 409.32 (c)) (2010).

133. *Papciak*, 742 F. Supp. 2d at 771.

134. *Id.* at 771-72.

135. Anderson v. Sebelius, No. 5:09-cv-16, 2010 WL 4273238, at *2 (D. Vt. 2010).

136. *Id*.

137. *Id*.

138. *Id*.

139. *Id.* at *4.

140. *Anderson*, 2010 WL 4273238, at *5. Plaintiff argues that a stability presumption was applied by the ALJ in her case in as much as it "evaluat[ed] [p]laintiff's need for skilled services from the benefit of hindsight rather than from the perspective of the attending physician at the time the services were ordered." *Id.* Plaintiff further maintains that this stability presumption is "an unlawful presumption that Medicare coverage should be denied for all patients whose condition is chronic or stable" and that the presumption "contradicts Medicare regulations requiring individualized assessments and explicitly proscribing the denial of coverage based solely on a patient's stability." *Id.*

141. In accordance with 42 C.F.R. § 409.44 (b)(3)(i) (2010), covered skilled services "must be consistent with the nature and severity of the beneficiary's illness or injury, his or her medical needs, and accepted standards of medical and nursing practice."

142. 42 C.F.R. § 409.42 (a)-(d).

Part A coverage, the care provided must be "reasonable and necessary for the diagnosis or treatment of illness or injury."[143] The court cited to various sections of the Medicare Benefit Policy Manual (MBPM) which state that in determining whether skilled services are "reasonable and necessary," the services are viewed from the perspective of the patient's injury or illness at the time he or she was ordered by his or her physician and whether such services constituted appropriate treatment at that time.[144] Further, the MBPM provides that this assessment should be based exclusively on the patient's "unique condition and individual needs" without consideration of whether the condition is "acute, chronic, terminal or expected to extend over a long period of time."[145]

The court refuted the Magistrate Judge's conclusion that skilled services for observation and assessment of a beneficiary's illness or injury are covered "only when there is a reasonable potential for a complication or further acute episode, and *not* when a patient's condition is stable and unlikely to change."[146] It reasoned that the stability of a patient's condition determines the duration of skilled services needed, but it does not mean that skilled services will no longer be "necessary" for the patient.[147]

The court held that the ALJ evaluated plaintiff's condition from the benefit of hindsight and denied Medicare coverage to plaintiff because her condition was stable.[148] In reaching this conclusion, the court relied on prior cases which addressed this particular issue.[149] As a result, the court remanded the case to the ALJ to determine plaintiff's need for skilled services at the time the services were ordered "free from any presumption that if hindsight reveals [p]laintiff's condition was stable throughout the covered period, coverage for skilled services should be denied."[150]

Papciak v. Sebelius and *Anderson v. Sebelius* are particularly significant for the population of Medicare patients whose conditions are

143. 42 U.S.C. 1395y(a)(1)(A) (Supp. 2008); *Anderson*, 2010 WL 4273238, at *7.

144. MEDICARE BENEFIT POLICY MANUAL ch. 7, § 40.1.1, *available at* https://www.cms.gov/manuals/Downloads/bp102c08.pdf; *Anderson*, 2010 WL 4273238, at *7.

145. *Anderson*, 2010 WL 4273238, at *6.

146. *Id.*

147. *Id*. at *7 (citing MEDICARE BENEFIT POLICY MANUAL ch. 7, § 40.1.1).

148. *Id.* at *7-8.

149. *Id. See also* Colton v. Sec'y of Health & Human Servs., 1991 WL 350050 (D. Vt. 1991); Folland *ex rel.* Smith v. Sullivan, 1992 WL 295230 (D. Vt. 1992); Smith *ex rel.* McDonald v. Shalala, 855 F. Supp. 658 (D. Vt. 1994); Exec. Dir. of the Office of Vt. Health Access *ex rel.* Carey v. Sebelius, 698 F. Supp. 2d 436 (D. Vt. 2010).

150. *Anderson*, 2010 WL 4273238, at *8.

considered to have "stabilized," for instance, those who suffer from chronic conditions such as multiple sclerosis or Alzheimer's disease, as they support the continuation of Medicare coverage for necessary medical services under these circumstances. Further, continuation of this Medicare coverage may prevent the deterioration of these patients' conditions, which could lead to "more intense, more expensive services, hospital or nursing home care."[151]

IV. FEDERAL LEGISLATION

A. Liability Medicare Set-Aside Arrangements

An issue that parties to personal injury litigation are currently struggling with is how to ensure that Medicare's interests are fully considered in the context of settlements and verdicts. This analysis includes the consideration of Medicare's past and future interests.[152] For purposes of this article, the primary focus will be on Medicare's future interest and the Liability Medicare Set-Aside Arrangement (LMSA).[153]

By way of brief background, under the Medicare Secondary Payer (MSP) statute, Medicare is designated as a secondary payer which makes "conditional payments" to its beneficiaries, and then looks to the primary payer to reimburse Medicare for these "conditional payments."[154] 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.[155] The MSP provisions make clear that a primary plan, entities that make payment on behalf of a primary plan, and an entity that receives payment from a primary payer must

151. Robert Pear, *Medicare Standards Are Too Strict, 2 Courts Find*, N.Y. TIMES, Nov. 2, 2010, at A21.

152. *Liability Medicare Set-side Arrangements: Required, Recommended or Ridiculous?* DRI , http://www.legalspan.com/dri/onlinecle.asp?CategoryID=&ItemID=20111219-272095-85151 (last visited Feb. 23, 2012).

153. 42 U.S.C. § 1395y(b) (2006); *see also* Memorandum from Charlotte Benson to Consortium Administrator for Financial Management and Fee-for-Service Operations (Sept. 30, 2011) (on file with the Dep't of Health & Human Servs.), *available at* https://www.cms.gov/COBGeneralInformation/Downloads/FutureMedicals.pdf.

154. 42 U.S.C. § 1395y(b)(2)(B)(i); *see also* Roy Umlauf & Thomas Thornton, *Medicare Secondary Payer Reporting and Section 111 of MMSEA: The Nuts and Bolts*, DRI, http://www.legalspan.com/dri/onlinecle.asp?UGUID=&CategoryID=&%20ItemID=20100526-272095-155310 (last visited Feb. 23, 2012).

155. 42 U.S.C. § 1395y.

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.[156] Further, as discussed in the previous article, section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (MMSEA) imposes reporting requirements upon liability insurers that pay settlements or judgments to any personal injury plaintiff who is a Medicare beneficiary.[157] Hence, Medicare's "past interest" includes reimbursement for injury-related services provided from the date of injury to the date of payment or judgment, and its "future interest"[158] includes payment for injury-related care which occurs after settlement or verdict.[159] The latter is encompassed in an LMSA whose purpose is to "pay for future injury-related care which would otherwise be covered by Medicare."[160]

However, LMSAs constitute a "gray area" within the Medicare lien resolution process. At present, there are no regulations which require their use and very little guidance provided from the Centers for Medicare and Medicaid Services (CMS) regarding their use.[161] Although regulations note Medicare's future payment interest,[162] with respect to the vehicles of payment, namely LMSAs, the only source of

156. *Id.*

157. 42 U.S.C. § 1395y(b)(8); Medicare, Medicaid, and SCHIP Extension Act of 2007, Pub. L. No. 110-173, § 111, 121 Stat. 2492 (2007).

158. The contemplation of a future interest can be seen in 42 U.S.C. § 1395y(b)(2) which provides that payment may not be made by Medicare for covered items of services to the extent "that payment has been made, *or can reasonably be expected to be made*, with respect to the item or service." 42 U.S.C. § 1395y(b)(2) (emphasis added). In addition, although a worker's compensation regulation, 42 C.F.R. § 411.46(d) sets forth that "if the settlement agreement allocates certain amounts for *specific future medical services*, Medicare does not pay for those services until medical expenses related to the injury or disease equal the amount of the lump-sum settlement allocated to *future medical expenses*." 42 C.F.R. § 411.46(d) (2010) (emphasis added); *see also* Handout from Sally Stalcup, Centers for Medicare & Medicaid Services, http://providiomedisolutions.com/Assets/CMSDallasRegionalOfficeSallyStalcupResponsetoQuestionsRegardingLiabilityMSAs.pdf.

159. *Liability Medicare Set-side Arrangements: Required, Recommended or Ridiculous?*, *supra* note 152.

160. GARRETSON RESOLUTION GROUP, THE USE AND PROPRIETY OF MEDICARE SET ASIDES IN LIABILITY SETTLEMENTS 2 (August 31, 2011), *available at* http://www.scwcea.org/2011_compcamp/presentations/LMSA%20White%20Paper%20August%2031,%202011.pdf (last visited Apr. 11, 2012).

161. *See* Stalcup, *supra* note 158, at 1-3; *Liability Medicare Set-side Arrangements: Required, Recommended or Ridiculous?*, *supra* note 152; GARRETSON RESOLUTION GROUP, *supra* note 160, at 2.

162. *See* 42 U.S.C. § 1395y.

guidance from Medicare has been through non-binding documents[163] such as memorandums, handouts, or information through courts that have attempted to articulate the LMSA process.[164] For instance, a handout issued by a Texas MSP Regional Coordinator in May of 2011 acknowledges that set-aside arrangements are not required by law and are thus voluntary, with the proviso that "Medicare's interests must be protected."[165] The handout further explains that "[t]he law requires that the Medicare Trust Funds be protected from payment for future services whether it is a Workers' Compensation or liability case. There is no distinction in the law."[166]

For a LMSA to be appropriate, the plaintiff must be a Medicare beneficiary and it must be determined that plaintiff will incur future care related to the underlying lawsuit or injury which would otherwise be covered by Medicare.[167] Hence, in *Finke v. Hunter's View*,[168] the court determined that an LMSA was not needed because plaintiff's future medical care would be covered by his wife's private health insurance, not Medicare.[169] Irrespective of the response to these inquiries in the negative or affirmative, the parties are encouraged by CMS to document the file regarding their consideration of Medicare's future interest.[170] To this end, CMS instructs that the parties obtain written certification from the plaintiff's treating physician that "treatment for the alleged injury related to the liability insurance (including self-insurance) "settlement" has been completed as of the date of the "settlement," and that future medical items and/or services for that injury will not be required.[171] According to this memorandum, Medicare then will

163. *See generally* Bradley v. Sebelius, 621 F.3d 1330 (11th Cir. 2010); Christensen v. Harris Cnty., 529 U.S. 576 (2000).

164. *See generally* Big R Towing, Inc. v. Benoit, No. 10-538, 2011 WL 43219 (W.D. La. 2011); Schexnayder v. Scottsdale Ins. Co., No. 6:09-cv-1390, 2011 U.S. Dist. LEXIS 83687 (W.D. La. 2011).

165. Stalcup, *supra* note 158, at 3.

166. *Id.*

167. *Liability Medicare Set-side Arrangements: Required, Recommended or Ridiculous?*, *supra* note 152.

168. No. 07-4267, 2009 WL 6326944 (D. Minn. 2009).

169. *Id.* at *3.

170. Stalcup, *supra* note 158, at 2-3 ("We . . . urge counsel to consider this issue when settling a case and recommend that their documentation as to whether or not their case provided recovery funds for future medical be documented in their records. Should they determine that future services are funded, those dollars must be used to pay for future otherwise Medicare covered case related services."); *see also* Transcript of Barbara Wright, Address at CMS Town Hall Teleconference (Oct. 22, 2009), http://www.cms.gov/MandatoryInsRep/Downloads/Oct2209NGHPTranscripts.pdf.

171. Memorandum from Charlotte Benson, *supra* note 153.

consider its future interest with regard to the plaintiff "satisfied."[172] However, the parties are directed to simply maintain this documentation in their records and should not submit the same to CMS for review, as it will not provide them with confirmation that Medicare's interest has been satisfied.[173] Further, if a settlement is being reached, the parties should consider documenting that they have considered Medicare's future interest in the settlement or release agreement.[174]

If the first two inquiries above are answered in the affirmative, then the parties should determine what amount of the settlement or award should be allocated to future medical care.[175] This is much more challenging in the liability context than in a worker's compensation case. In worker's compensation, three distinct avenues of recovery are permitted: indemnity/wage loss, past medicals, and future medicals.[176] Hence, if you can figure out the first two amounts, then the balance of the settlement constitutes future medicals.[177] However, in the liability context, there are more items to consider in addition to economic damages, for instance non-economic losses such as pain and suffering, mental anguish, loss of society, and so forth. Therefore, it is much more difficult to determine the amount of future medical expenses in liability cases. The parties may want to consider contacting a CMS regional office to review the amount allocated for future expenses for its blessing once the future medical payments are determined, or obtaining court approval of the amount.[178]

Although the MSP statute seems to contemplate Medicare's past interest only with respect to penalties,[179] the danger in failing to properly consider Medicare's future interest is that "CMS could [potentially] terminate future benefits related to an injury or file a recovery action for mistaken payments it may make for those future

172. *Id.*

173. *See id.*

174. GARRETSON RESOLUTION GROUP, THE USE AND PROPRIETY OF MEDICARE SET ASIDES IN LIABILITY SETTLEMENTS 8, 11 (July 12, 2011*), available at* http://www.primerus.com/wp-content/uploads/2011/09/LMSA-White-Paper-July-12-2011-3.pdf

175. *Liability Medicare Set-Aside Arrangements: Required, Recommended or Ridiculous?*, *supra* note 152.

176. *Id.*; GARRETSON RESOLUTION GROUP, *supra* note 174, at 8.

177. *Liability Medicare Set-Aside Arrangements: Required, Recommended or Ridiculous?*, *supra* note 152; GARRETSON RESOL. GROUP, *supra* note 174, at 8.

178. Big R Towing, Inc. v. Benoit, No. 10-538, 2011 WL 43219 (W.D. La. 2011); *Liability Medicare Set-Aside Arrangements: Required, Recommended or Ridiculous?*, *supra* note 152.

179. 42 U.S.C. § 1395y(b)(2)(B) (2006); *Liability Medicare Set-Aside Arrangements: Required, Recommended or Ridiculous?*, *supra* note 152.

benefits" and if a recovery action is commenced, the statute allows CMS to recover double damages.[180] With respect to use of LMSAs, parties should take a "reasonable interpretation" approach.[181] As noted in *General Electric Co. v. United States EPA*:

> Where, as here, the regulations and other policy statements are unclear, where the [party's] interpretation is reasonable, and where the agency itself struggles to provide a definitive reading of the regulatory requirements, a regulated party is not "on notice" of the agency's ultimately interpretation of the regulations, and may not be punished.[182]

LMSAs currently present a litany of issues for practitioners, including how to value future medical care covered by Medicare and logistically how to set up and administer the LMSA. Hopefully, CMS will provide greater guidance, if not additional regulation, going forward as to these issues and the LMSA process.

CONCLUSION

Looking ahead, the Supreme Court's decision regarding the constitutionality of PPACA's individual mandate and other related issues likely to be addressed by the High Court in 2012 will surely be a large part of the health law agenda for the upcoming *Survey* year. Additionally, efforts to implement PPACA in New York remain stalled as a result of Republican opposition in the State Senate majority from the challenges facing PPACA.[183] While the state has already received approximately $39 million in federal starter grants, New York is not eligible to receive further "Level 2" grants, applications for which are due by June 2012, until it establishes a rubric for operating its required health care exchange.[184] The Supreme Court's decision, also expected

180. Roy Franco et al., *Resolution of a Case with a Medicare Claimant?*, 51 FOR THE DEF. 8, 12 (May 2009). In addition, the court in *United States v. Stricker* held that "a three year statute of limitations applied to the attorney defendants who did not secure a reimbursement for Medicare, and a six year statute applied to the corporate defendants, measured at the latest by the date payment was made into the settlement fund." GARRETSON RESOLUTION GROUP, *supra* note 174, at 3-4 (citing United States v. Stricker, 2010 WL 6599489 (N.D. Ala. 2010)).

181. Gen. Elec. Co. v. U.S. EPA, 53 F.3d 1324, 1333-34 (D.C. Cir. 1995).

182. *Id.*

183. Maria Amor, *Federal Healthcare Reform Stalls in New York*, PIPE DREAM NEWS (October 11, 2011), http://www.bupipedream.com/news/federal-healthcare-reform-stalls-in-new-york-1.2641342. For more information about new developments in implementing PPACA, *see Federal Healthcare Reform in New York*, NY.GOV, http://www.healthcarereform.ny.gov/grants/ (last visited Feb. 23, 2012).

184. Amor, *supra* note 183; *see also Health Insurance Exchange Establishment Grants Fact Sheet*, HEALTHCARE.GOV,

in June 2012, is sure to impact implementation efforts in New York and other states that remain plagued by the uncertainty surrounding PPACA's constitutionality.

With respect to Medicare, continued application of the "improvement standard" or "stability presumption" in coverage determinations will likely provoke more claimants to bring suit against Medicare. Also, perhaps in the next *Survey* year the Legislature or CMS will provide greater clarity on the use of LMSAs and alleviate the uncertainty that personal injury parties presently face.

On the state law level, we will likely see the beginning effects of the Medical Indemnity Fund, good and bad, in the next *Survey* year. Regulations should also be enacted which will add some more specific guidance as to how the Fund will be administered and what litigants trying to navigate the Act should expect. Additionally, the new notice requirements in CPLR 306-c are sure to provoke increased imposition of liens in personal injury actions in New York, including medical malpractice proceedings.

http://www.healthcare.gov/news/factsheets/2011/01/exchestannc.html (last visited Feb. 23, 2012). For a summary of grants received by New York State for implementing the "exchange" requirements of PPACA, *see Federal Healthcare Reform in New York*, *supra* note 183.