

HEALTH LAW

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INTRODUCTION

At the state level, *Muhammad v. Fitzpatrick* was decided with significant ramifications to the defense of medical malpractice actions. Regulations have been promulgated to provide structure for the New York State Medical Indemnity Fund (the “Fund”) and the first case interpreting the application of the Fund to a settlement was decided. Further, the Family Health Care Decisions Act was amended to encompass patients who receive hospice care outside of the hospital or nursing home setting. At the federal level, historic challenges to the Patient Protection and Affordable Care Act (“PPACA”) continued, and the constitutionality of PPACA was addressed by the United States Supreme Court in *National Federation of Independent Business v.*

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This *Survey* addresses recent developments in New York State and federal health care law from July 1, 2011 to June 30, 2012.

Sebelius.¹ The two main issues under consideration were the constitutionality of the Individual Mandate and the Medicaid Expansion. There were significant developments in the Medicare system, with the milestone “Improvement Standard” case of *Jimmo v. Sebelius*, which resulted in changes to the Medicare system and coverage determinations, as well as the Medicare Secondary Payer and “Future Medicals” Proposed Rule, which provided greater clarity concerning the satisfaction of Medicare’s interest in future medical expenses.

I. NEW YORK STATE CASE LAW

A. New York State Supreme Court & Appellate Division

In *Muhammad v. Fitzpatrick*, the court limited the defendant-obstetrician and defendant-hospital from employing a standard defense to a brachial plexus injury at trial.² The Appellate Division, Fourth Department affirmed the trial court’s grant of plaintiff’s motion to preclude defendants’ experts from testifying at trial that the infant plaintiff’s brachial plexus injury was caused by “maternal forces of labor,” or the birthing process.³

The plaintiff-mother in *Muhammad* commenced a medical malpractice action against the defendants for a brachial plexus injury her daughter sustained during birth,⁴ which resulted in Erb’s Palsy and a partially paralyzed arm.⁵ With respect to the causation element of medical malpractice, defendants’ experts intended to testify at trial that the injuries sustained by the infant plaintiff were caused by the birthing process, and therefore were unrelated to the care provided by the defendants.⁶ The court explained that there were two inquiries in assessing defendants’ theory, which were separate and distinct from one another: (1) whether the theory met the *Frye* standard; and (2) whether

1. See generally 132 S. Ct. 2566 (2012).

2. 91 A.D.3d 1353, 1354, 937 N.Y.S.2d 519, 521 (4th Dep’t 2012); John Caher, *Court Finds Invalid Standard Defense in Obstetrical Malpractice Cases*, N.Y. L.J., Feb. 8, 2012.

3. Caher, *supra* note 2. Defendants argued that after the baby’s head was delivered, her shoulder became lodged in the pubic symphysis, a cartilaginous joint in her mother’s pelvis, and the damage to the infant was caused by the forces of labor. Of note, defendants were initially permitted to offer the maternal forces of labor defense at trial. However, it resulted in a hung jury and was set for retrial when plaintiff moved to preclude the defense prior to the retrial. *Id.*

4. *Muhammad*, 91 A.D.3d at 1353, 937 N.Y.S.2d at 520; see also Caher, *supra* note 2.

5. See Caher, *supra* note 2. According to the court records, three nerve roots in the infant’s brachial plexus were torn from her spine. *Id.*

6. *Muhammad*, 91 A.D.3d at 1353, 937 N.Y.S.2d at 520.

it met the admissibility standard applicable to all evidence (i.e., whether there was a proper foundation to admit defendants' theory).⁷

The court held that the defendants' theory was "a novel theory subject to *Frye*⁸ analysis, and that [they] failed to rebut plaintiff's showing that their theory was not generally accepted within the relevant medical community."⁹ Judge Walker explained that defendants' theory was based on a "small number of articles written by a few authors, each of whom based their conclusions in part on the writings of other members of that small group" and therefore did not have the widespread acceptance required by *Frye*.¹⁰

The court further determined that defendants' causation theory lacked adequate foundation for its admissibility.¹¹ The court relied on the two-prong approach to causation (specific and general) articulated in *Parker v. Mobil Oil Corp.*¹² and rejected defense counsel's claim that *Parker* was confined to toxic torts.¹³ The court reasoned that

the opinion of defendants' experts on causation should set forth the 'exposure [of plaintiff's daughter] to a [harmful in-utero event], that the [event] is capable of causing the particular [injury] (general causation) and that plaintiff[']s daughter] was exposed to [a sufficiently harmful event] to cause the [injury] (specific causation).'¹⁴

In finding in favor of the plaintiffs, the court ruled that, even if defendants did offer sufficient evidence of their theory such that it met the *Frye* standard, their causation theory did not satisfy the admissibility standard since it failed to meet both the specific and general causation prongs of *Parker*.¹⁵

This ruling has significant implications for the defense of brachial plexus medical malpractice actions. In these cases, the plaintiff's theory

7. *Id.* at 1354, 937 N.Y.S.2d at 521 (quoting *Parker v. Mobil Oil Corp.*, 7 N.Y.3d 434, 447, 857 N.E.2d 1114, 1120, 824 N.Y.S.2d 584, 589 (2006)).

8. *Frye v. United States*, 293 F. 1013, 1014 (D.C. Cir. 1923), *superseded by* *Daubert v. Merrel Dow Pharms., Inc.*, 509 U.S. 579, 589 (1993). The *Frye* analysis consists of an inquiry into whether an expert opinion is based on scientific principles "sufficiently established to have gained general acceptance in the particular field in which it belongs." *Id.*; see Caher, *supra* note 2.

9. *Muhammad*, 91 A.D.3d at 1354, 937 N.Y.S.2d at 521. Although, plaintiffs' counsel was "unable to identify any similar appellate ruling in the nation." See Caher, *supra* note 2.

10. See Caher, *supra* note 2.

11. *Muhammad*, 91 A.D.3d at 1354, 937 N.Y.S.2d at 521.

12. 7 N.Y.3d 434, 447, 857 N.E.2d 1114, 1121, 824 N.Y.S.2d 584, 589 (2006).

13. *Muhammad*, 91 A.D.3d at 1354, 937 N.Y.S.2d at 521.

14. *Id.* (citing *Parker*, 7 N.Y.3d at 448, 857 N.E.2d at 1120-21, 824 N.Y.S.2d at 590).

15. *Muhammad*, 91 A.D.3d at 1354, 937 N.Y.S.2d at 521.

is usually that the injury was caused by excessive force or traction by the obstetrician during the delivery, and the defense's theory is that the injuries were caused by the natural forces of labor, such as uterine contractions.¹⁶ By taking the maternal forces of labor theory out of play, it could be argued that "the Fourth Department's holding seemingly precludes anything other than physician negligence."¹⁷ As such, this case represents a potential new obstacle for defense counsel in brachial plexus medical malpractice actions.

II. NEW YORK STATE LEGISLATION

A. *Medical Indemnity Fund Update*

Last year's *Survey* discussed the statutory provisions creating the Fund.¹⁸ Since then, the New York State Commissioner of Health ("Commissioner"), in consultation with the Superintendent of Financial Services ("Superintendent"), has promulgated regulations defining key aspects and procedures of the Fund's operation.¹⁹ In addition, the first case to interpret the application of the Fund to a settlement was decided on November 14, 2011.²⁰

The regulations promulgated by the Commissioner provide structure for the Fund's operation. First and foremost, the regulations define the application and enrollment process in the Fund.²¹ An application for enrollment is to be submitted in conjunction with a medical release form, a certified copy of the court-approved settlement or judgment, and documentation detailing "the specific nature and degree of the applicant's birth-related neurological injury or injuries," as well as the names, addresses and phone numbers of all providers currently providing services to the applicant, and documentation of all

16. See Caher, *supra* note 2.

17. *Id.*

18. For a general history and background of the Medical Indemnity Fund, see generally Hon. Douglas E. McKeon, *On the Table: An Examination of Medical Malpractice, Litigation, and Methods of Reform: New York's Innovative Approach to Medical Malpractice*, 46 NEW ENG. L. REV. 475 (2012). For a highly critical analysis of the Medical Indemnity Fund and its possible ramifications, see generally Michael W. Kessler & Matt Fahrenkopf, *The New York State Medical Indemnity Fund: Rewarding Tortfeasors Who Cause Birth Injuries by Rationing Care to Their Victims*, 22 ALB. L.J. SCI. & TECH. 173 (2012).

19. See generally N.Y. COMP. CODES R. & REGS. tit. 10, subpt. 69-10 (2012). The regulations were first issued on September 15, 2011, and have been reissued several times since. *Id.*

20. *Mendez v. N.Y. & Presbyterian Hosp.*, 34 Misc. 3d 735, 736, 934 N.Y.S.2d 662, 663 (Sup. Ct. Bronx Cnty. 2011).

21. 10 NYCRR 69-10.2.

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other present sources of health care coverage or reimbursement.²² It is important to note that the court-approved settlement or judgment must contain language to the effect that the plaintiff or claimant was found to have sustained a birth-related neurological injury as defined by the Medical Indemnity Fund and that the future medical expenses will be paid for by the Fund.²³ If this language is missing or ambiguous, the Fund Administrator “shall refer” the settlement or judgment back to the court for the inclusion of any necessary “clarifying language.”²⁴ Following the receipt of the application, the applicant will be notified within fifteen days of any missing information.²⁵ Once all the information has been received and the appropriate determinations have been made, the applicant shall be enrolled in the Fund within fifteen business days and a case manager will be assigned.²⁶

Claims by medical providers are to be submitted within ninety days of service, and all providers providing services to an enrollee must accept assignment of payment from the Fund.²⁷ Payment is set at the eightieth percentile for the usual and customary charges as reported by the FAIR Health, Inc. Usual, Customary and Reasonable database.²⁸ Where the service, supplies, equipment, or medications have a Medicaid fee or rate, payment shall be at that rate.²⁹ Certain expenses require prior approval, specifically, the regulations require prior approval for environmental modifications, vehicle modifications, assistive technology, private duty nursing, enteral nutritional formula, certain transportation, and certain payments or reimbursement not otherwise specified.³⁰ A decision will be rendered within thirty days of the receipt of the necessary documentation.³¹

The regulations provide for an expedited prior approval process,³² and a process to review denials.³³

An expedited approval determination will be made within two business days of receiving a prior approval request of a physician on the physician’s letterhead that states that the enrollee has an urgent

22. *Id.* § 69-10.2(b).

23. *Id.* § 69-10.2(d).

24. *Id.*

25. *Id.* § 69-10.2(e).

26. 10 NYCRR 69-10.2(f)-(g).

27. *Id.* § 69-10.5.

28. *Id.* § 69-10.20(a).

29. *Id.* § 69-10.20(b).

30. *See id.* §§ 69-10.6 to 69-10.13.

31. 10 NYCRR 69-10.6(b).

32. *Id.* § 69-10.14.

33. *Id.* §§ 69-10.15 to 69-10.16.

need for a service or item that requires prior approval and the reason the service or item is needed on an expedited basis.³⁴

However, in an emergency situation, the service or item can be provided pending the result of the expedited approval determination.³⁵

Where a claim is denied, a request for the review of same must be made within thirty days from the receipt of the denial.³⁶ The request shall specify whether the requester wants a review based on documentary evidence, a telephone hearing, or an in-person hearing.³⁷ The hearing officer shall provide a written recommendation to the Commissioner within thirty days of the hearing, and the Commissioner shall issue a decision within thirty days of the hearing officer's recommendation.³⁸

In addition, the regulations specify the actuarial calculations for the Fund.³⁹ The Superintendent is to conduct a quarterly actuarial calculation to estimate the liabilities from the enrollees in the Fund.⁴⁰ This analysis is to examine the number of qualifying plaintiffs, the mortality experience of same, the benefits paid for by the Fund, patterns of service utilization, inflationary patterns of the services provided, administration expenses, the impact of health insurance on the benefits paid for by the Fund, and the investment earnings of Fund assets.⁴¹ As noted last year, where the liabilities equal or exceed 80% of the Fund assets, enrollment is suspended.⁴²

The only case to discuss the Fund decided within this Article's scope of 2011-2012, is *Mendez v. New York and Presbyterian Hospital*.⁴³ In *Mendez*, the plaintiff claimed that the hospital staff failed to timely perform a cesarean section, and as a result the infant suffered hypoxia and ultimately cerebral palsy.⁴⁴ The parties settled the action for \$5,500,000.⁴⁵ There was no question that the Medical Indemnity Fund applied to the settlement, instead the issue was the proper

34. *Id.* § 69-10.14(a).

35. *Id.* § 69-10.14(b).

36. 10 NYCRR 69-10.15(a).

37. *Id.* § 69-10.15(b).

38. *Id.* § 69-10.15(k), (l).

39. *Id.* § 69-10.18.

40. *Id.* § 69-10.18(a).

41. 10 NYCRR 69-10.18(b).

42. Kirsten A. Lerch & Kristy L. Fischmann, *Health Law, 2010-11 Survey of New York Law*, 62 SYRACUSE L. REV. 685, 690-91 (2012); see 10 NYCRR § 69-10.19(a).

43. 34 Misc. 3d 735, 736, 934 N.Y.S.2d 662, 663 (Sup. Ct. Bronx Cnty. 2011).

44. *Id.*

45. *Id.*

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allocation of the damages to Fund and non-Fund portions.⁴⁶ The parties agreed with a fifty-fifty split.⁴⁷ In discussing other obstetrical cases and noting that a majority of the damage awards were for future medical damages, the court chose to “combine precedent with a healthy dose of practicality” and concluded that a fifty-fifty split was reasonable.⁴⁸ This was due to the impact of the Fund on the settlement process.⁴⁹ In passing, the court noted the interplay of the Fund, Medicare liens, and the settlement process.⁵⁰

B. Amendment to the Family Health Care Decisions Act

On July 20, 2011, Governor Andrew Cuomo signed into law an amendment to the Family Health Care Decisions Act (“FHCDA”),⁵¹ which extended the Act to decisions regarding hospice care.⁵² The legislation amended subdivision 18 of section 2994-a of New York Public Health Law and added two new subdivisions: 5-a and 17-a, and amended sections 2994-b through 2994-d, 2994-g, 2994-m and 2994-aa.⁵³

By way of brief background, the FHCDA 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.⁵⁴ In the absence of a health proxy or clear and convincing evidence of the patients’ wishes, spouses, relatives, or close friends, prior to the FHCDA, had no authority to make medical decisions for loved ones who could no longer make health care decisions for themselves.⁵⁵ The FHCDA established a process to select a surrogate who is authorized to make health care decisions for the incapacitated patient.⁵⁶

However, the FHCDA, as originally enacted, only applied to health

46. *Id.*

47. *Id.* at 738, 934 N.Y.S.2d at 664.

48. *Mendez*, 34 Misc. 3d at 745, 934 N.Y.S.2d at 669.

49. *Id.*

50. *Id.* at 745-46, 934 N.Y.S.2d at 669.

51. *See* Family Health Care Decisions Act, 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 2012)).

52. *Id.* The law was effective September 18, 2011. *Id.*

53. *Id.*

54. *See* N.Y. PUB. HEALTH LAW § 2994-d (McKinney 2012); *see also* Tracy E. Miller, *New York Adopts Broad Changes to Law on Treatment Decisions*, 243 N.Y. L.J., Mar. 29, 2010, at 4.

55. *See* N.Y. PUB. HEALTH LAW § 2994-d.

56. *See generally id.*

care decisions made in a hospital or nursing home.⁵⁷ Therefore, a patient receiving hospice care outside of a hospital or nursing home would not receive the benefit of the law.⁵⁸ “Under this . . . [amendment], surrogate decision makers can decide whether a patient will enter or leave hospice and agree to a hospice plan as well as any changes to that plan even if they are not in a hospital or nursing home.”⁵⁹ As such, this amendment provides greater access to the benefits of the FHCDA to hospice patients.

III. FEDERAL CASE LAW

A. *Supreme Court Decision on the Patient Protection and Affordable Care Act*

Perhaps the largest development in federal law as it relates to health care is the recent United States Supreme Court decision in *National Federation of Independent Business v. Sebelius*.⁶⁰ This decision, announced on June 28, 2012, upheld much of the PPACA and, in particular, upheld the controversial Individual Mandate.⁶¹ In addition, the decision also invalidated a portion of PPACA as it relates to a Medicaid Expansion.⁶²

As discussed in last year’s article,⁶³ the Supreme Court granted certiorari to the Eleventh Circuit to consider the appellate rulings in *Sebelius*,⁶⁴ *Department of Health and Human Services v. Florida*,⁶⁵ and *Florida ex rel. Attorney General v. United States Department of Health and Human Services*.⁶⁶ Under consideration were two major issues—the constitutionality of the individual mandate and the Medicare Expansion—and two ancillary issues—jurisdiction and severability.⁶⁷

The question of jurisdiction was raised by the Government but ultimately dropped by both parties by the time the decision reached the

57. *Cf. id.*

58. See Katie Miecznikowski, *Family Health Care Decisions Act extended*, LEGIS. GAZETTE (Aug. 1, 2011), <http://www.legislativegazette.com/Articles-c-2011-08-01-79741.113122-Family-Health-Care-Decisions-Act-extended.html>.

59. *See id.*

60. *See generally* 132 S. Ct. 2566 (2012).

61. *See id.* at 2608.

62. *Id.*

63. Lerch & Fischmann, *supra* note 42, at 696.

64. *See supra* text accompanying note 61.

65. *See generally* 132 S. Ct. 604 (2011).

66. *See generally* 648 F.3d 1235 (11th Cir. 2011), *cert. granted*, 132 S. Ct. 603 (2011), *aff’d in part, rev’d in part sub nom., Sebelius*, 132 S. Ct. 2566.

67. *Sebelius*, 132 S. Ct. at 2577, 2582.

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Supreme Court.⁶⁸ However, since it was a threshold issue, an amicus curiae was appointed to argue this position.⁶⁹ The argument was rooted in the Anti-Injunction Act of 1867,⁷⁰ an act which was designed to ensure timely tax collection and required that an entity must first pay a tax before having standing to challenge the tax collection law.⁷¹ This would ensure a steady stream of income for governmental purposes, as otherwise, entities could challenge any and all taxes before paying them, making it difficult for the government to function.⁷² As it relates to PPACA, the amicus curiae argued that as the penalty for failure to obtain insurance would not become enforceable until 2014 and the penalty was a tax because the Internal Revenue Code treated it as such,⁷³ the Anti-Injunction Act deprived the Court of jurisdiction to consider the merits of PPACA.⁷⁴

In an opinion authored by Chief Justice John Roberts, the Court determined that the shared responsibility penalty was not a tax within the meaning of the Anti-Injunction Act, and as such, it did not bar the Court from considering the parties' applications.⁷⁵ This decision was based on the rationale that both the Anti-Injunction Act and PPACA are Congressional creations, and Congress is free to define the terms of the statutes it passes and how those statutes interact.⁷⁶ In PPACA, Congress defined the "shared responsibility payment" as a "penalty" and not a "tax."⁷⁷ The Court stated that where Congress uses language in one portion of a statute and different language in another portion, Congress is deemed to have acted intentionally.⁷⁸ Thus, regardless of whether the penalty acts as a tax, Congress was defining how the two acts interacted by virtue of the language used.⁷⁹ Further, although PPACA directs the Internal Revenue Service ("IRS") to assess the penalty in the same manner as a tax, the Court determined that this was only a directive to the Secretary of Treasury as to the method of

68. *See id.* at 2582.

69. *Id.*

70. 26 U.S.C. § 7421 (2006).

71. 26 U.S.C. § 7421(a).

72. *Sebelius*, 132 S. Ct. at 2582.

73. *Id.*

74. *Id.*

75. *Id.* at 2583.

76. *Id.*

77. *Sebelius*, 132 S. Ct. at 2583 (quoting 26 U.S.C. §§ 5000 A(b), 5000A(g)(2) (2006)).

78. *Sebelius*, 132 S. Ct. at 2583.

79. *See id.*

collecting the penalty—it did not define the penalty as a tax.⁸⁰

With the standing, jurisdictional issue resolved, the Court went on to address the two provisions challenged—what are respectively called the Individual Mandate and the Medicaid Expansion.

1. *Individual Mandate*

The United States Supreme Court considered three bases for Congressional power to enact PPACA—the Commerce Clause,⁸¹ the Necessary and Proper Clause,⁸² and the Taxation Clause.⁸³ A majority of the Court found no support for Congressional power to enact PPACA under the Commerce Clause.⁸⁴ The Court found that utilization of the Commerce Clause presupposes that there is commerce to regulate and, if the power to regulate includes the power to create, then many provisions in the Constitution are superfluous.⁸⁵ Further, prior Commerce Clause jurisprudence described the commerce power as reaching “activity,” whereas here the individual mandate would compel an individual to become active in commerce and regulate a class of individuals defined by their commercial inactivity, rather than their activity.⁸⁶ This would allow Congress to justify regulation on the basis of *potential* decisions and then empower Congress to make those decisions for an individual.⁸⁷ The power to regulate that which we do not do would fundamentally change the relationship between a citizen and the federal government.⁸⁸ In addition, the Court made a distinction between health insurance and health care financing and concluded that they are not the same thing.⁸⁹ Thus, a compelled purchase of the first is not properly regarded as regulation of the second.⁹⁰

Next, the Court considered whether the Individual Mandate was permissible under the Necessary and Proper Clause of the Constitution, as part of a comprehensive scheme of economic regulation.⁹¹ Supreme Court jurisprudence provides that Congress can legislate on incidental powers, which by necessity are involved in the Constitution, but this

80. *Id.* at 2584.

81. U.S. CONST. art. I, § 8, cl. 3.

82. *Id.* art. I, § 8, cl. 18.

83. *Id.* art. I, § 8, cl. 1.

84. *Sebelius*, 132 S. Ct. at 2591.

85. *Id.* at 2586.

86. *Id.* at 2572-73.

87. *Id.* at 2587.

88. *Id.* at 2589.

89. *Sebelius*, 132 S. Ct. at 2591.

90. *Id.*

91. *Id.*

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Clause does not grant a license to exercise substantive or independent powers beyond those which are specifically enumerated.⁹² Here, the Individual Mandate could not be sustained under this Clause, as it would vest Congress with the power to create a predicate for the use of an enumerated power.⁹³ In short, the Individual Mandate was not a “proper” means for making the proposed economic reforms effective as it was not incidental to the exercise of the commerce power.⁹⁴

Lastly, the Court considered whether the Individual Mandate could be considered valid under the Taxation Clause of the Constitution.⁹⁵ Despite the fact that the Individual Mandate was determined to be not a tax for purposes of the Anti-Injunction Act, the Court determined that for constitutional purposes, the Individual Mandate could fairly be considered a tax, and thus it was upheld.⁹⁶ The Court relied on several facts, including that the shared responsibility payment is paid into the Treasury by tax payers and does not apply to those who do not pay federal income taxes,⁹⁷ the IRS enforces collection,⁹⁸ there is no scienter requirement, and the IRS could not use the means which were the most suggestive of a punitive sanction.⁹⁹ In addition, neither PPACA nor any other law attaches negative legal consequences to the failure to purchase health insurance.¹⁰⁰ These facts made the shared responsibility more tax-like than penalty-like, and thus the Individual Mandate could be fairly considered a tax on individuals who did not purchase health insurance.¹⁰¹ In short, the Court found that the Constitution does not guarantee that individuals can avoid taxes by not engaging in activity.¹⁰²

2. Medicaid Expansion

Prior to the enactment of PPACA, the states were required to cover only certain categories of their residents.¹⁰³ The Medicaid Expansion required the states to cover adults with incomes up to 133% of the federal poverty level, as well as to provide certain health benefits which

92. *Id.* at 2591 (quoting *McCulloch v. Maryland*, 17 U.S. 316, 411, 421 (1819)).

93. *Sebelius*, 132 S. Ct. at 2592-93.

94. *Id.* at 2593.

95. U.S. CONST. art. I, § 8, cl. 1.

96. *Sebelius*, 132 S. Ct. at 2594, 2600.

97. *Id.* at 2594 (citing 26 U.S.C. §§ 5000A(b), 5000A(e)(2) (Supp. V 2011)).

98. *Sebelius*, 132 S. Ct. at 2594.

99. *Id.* at 2596-97.

100. *Id.* at 2597.

101. *Id.* at 2594-97.

102. *See id.* at 2596-97.

103. *Id.* at 2601.

satisfied the requirements of the Individual Mandate.¹⁰⁴ PPACA provided federal funding for States' administrative costs in expanding their Medicaid programs (100% through 2016, and subsequently decreasing to 90% over the ensuing years), and if a particular state did not comply, it stood to lose all federal Medicaid funds, not simply the funds that were earmarked for the Expansion.¹⁰⁵

The Court determined that the Medicaid Expansion was unconstitutional as it coerced the states to implement a federal program.¹⁰⁶ The threat to withdraw all Medicaid funding if the State did not participate in the Expansion constituted a commandeering of the state's legislative or administrative apparatus for federal purposes, which is impermissible.¹⁰⁷ This would threaten the political accountability of our system.¹⁰⁸

Although Congress can condition the receipt of funds on the state's compliance with restrictions on the use of the funds, Congress cannot threaten to terminate other significant independent grants as this would constitute a means of pressuring the states to acquiesce to the policy changes.¹⁰⁹ The Court distinguished an earlier case whereby Congress threatened to withhold 5% of highway funds provided to the states if they did not raise the drinking age to twenty-one years of age, stating that the 5% constituted only "mild encouragement to the states."¹¹⁰ Citing economic data regarding the budgets of the states, the Court determined that the Medicaid Expansion constituted "economic dragooning" because a state which failed to participate in the Expansion would lose over 10% of its entire budget.¹¹¹ Furthermore, although the original Medicaid Act provided that Congress expressly reserved the right to "alter, amend, or repeal any provision," the Medicaid Expansion creates a shift in kind and not one in degree.¹¹² The spending power does not include surprising participating states with post-acceptance or retroactive conditions.¹¹³

Thus, the Court invalidated that portion of § 1396c, which provided the Secretary of Health and Human Services with the authority

104. *Sebelius*, 132 S.Ct. at 2601 (citing 42 U.S.C. § 1396a(a)(10)(A)(i) (2006)).

105. *Sebelius*, 132 S. Ct. at 2601.

106. *See id.* at 2608.

107. *Id.* at 2608.

108. *Id.* at 2602.

109. *Id.* at 2603-04.

110. *Sebelius*, 132 S. Ct. at 2604 (quoting *South Dakota v. Dole*, 483 U.S. 203, 211 (1987)).

111. *Sebelius*, 132 S. Ct. at 2604-05.

112. *Id.* at 2605 (quoting 42 U.S.C. § 1304 (2006)).

113. *Sebelius*, 132 S. Ct. at 2606.

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to revoke all Medicaid funding if a state declined to participate in the Medicaid Expansion.¹¹⁴ However, the rest of the Medicaid Expansion was left intact as the Court determined that Congress would have wanted to preserve the rest of the Act.¹¹⁵

3. Impact

Although it is outside the time constraints of this *Survey*, it is important to note that the litigation surrounding PPACA is not over. Various provisions of the statute will go into effect over the next few years and additional litigation is likely.¹¹⁶ In 2014, the State Run Health Insurance Exchanges are to be up and running.¹¹⁷ However, it is already apparent that many states did not meet the October 2012 deadline to declare whether they would participate.¹¹⁸ Those States which decline to create a State Run Health Insurance Exchange will have one created and run by the federal government.¹¹⁹ Other provisions, such as those prohibiting a denial based on pre-existing conditions,¹²⁰ the Medicaid Expansion,¹²¹ paying physicians based on value not volume,¹²² and the tax on so-called Cadillac insurance plans¹²³ are to be phased-in by 2018.¹²⁴

As it relates to New York State, on April 12, 2012, Governor

114. *Id.* at 2607.

115. *Id.*; see also 42 U.S.C. § 1303.

116. See e.g., Complaint at 2, *Sissel v. U.S. Dep't of Health & Human Servs.*, No. 1:10-CV-01263 (D.D.C. July 26, 2010), ECF No. 1. See generally *Coons v. Geithner*, No. CV-10-1714, 2012 U.S. Dist. LEXIS 180306 (D. Ariz. Dec. 19, 2012). See also *HHS Mandate Information Central*, BECKET FUND FOR RELIGIOUS LIBERTY, available at <http://www.becketfund.org/hhsinformationcentral/> (listing over forty-seven cases that have been filed to challenge PPACA); Timothy Stoltzfus Jost, *Religious Freedom and Women's Health—The Litigation on Contraception*, 368 NEW ENG. J. MED. 4, 4-6 (2013), available at <http://www.nejm.org/doi/full/10.1056/NEJMp1214605>.

117. 42 U.S.C. § 18031(b)(1) (Supp. V 2011).

118. See Robert Pear, *States Will Be Given Extra Time to Set Up Health Insurance Exchanges*, N.Y. TIMES, Jan. 14, 2013, at A15, available at <http://www.nytimes.com/2013/01/15/us/states-will-be-given-extra-time-to-set-up-health-insurance-exchanges.html> [hereinafter Pear, *States Will Be Given Extra Time*]; see also Press Release, U.S. Dep't of Health & Human Servs., *Additional States Conditionally Approved to Build Health Insurance Marketplaces* (Jan. 3, 2013), available at <http://www.hhs.gov/news/press/2013pres/01/20130103a.html>.

119. Pear, *States Will Be Given Extra Time*, *supra* note 118, at A15.

120. 42 U.S.C. § 300gg-3.

121. See generally 42 U.S.C. § 1396a (2006).

122. 42 U.S.C. § 1395w-4(p) (Supp. V 2011).

123. 26 U.S.C. § 4980I (Supp. V. 2011).

124. See generally HEALTHCARE.GOV, *Timeline of the Affordable Care Act*, <http://www.healthcare.gov/law/timeline/index.html> (last visited May 22, 2013); 26 U.S.C. § 4980I (Supp. V. 2011).

Cuomo established the exchange through an executive order.¹²⁵ In accordance with federal law, New York's health exchange is expected to become open for enrollment by October 1, 2013, ahead of the January 2014 deadline.¹²⁶

B. *Jimmo v. Sebelius*

In last year's *Survey*, the *Papciak v. Sebelius*¹²⁷ and *Anderson v. Sebelius*¹²⁸ cases were discussed in the context of the Medicare "Improvement Standard."¹²⁹ An additional case challenging this "Improvement Standard," *Jimmo v. Sebelius*, was filed in the U.S. District Court of Vermont on January 18, 2011 by six individual Medicare beneficiaries¹³⁰ and seven national organizations.¹³¹ In *Jimmo*, Defendant Kathleen Sebelius, the Secretary of Health and Human Services, moved to dismiss plaintiff's amended complaint for lack of subject matter jurisdiction under Federal Rule of Civil Procedure ("Fed. R. Civ. P.") 12(b)(1) and for failure to state a claim under Fed. R. Civ. P. 12(b)(6).¹³² The U.S. District Court denied in part and granted in part defendant's motion to dismiss for lack of subject matter jurisdiction, but denied defendant's motion to dismiss for failure to state a claim.¹³³

Plaintiffs alleged that defendant "adopted an unlawful and clandestine standard to determine whether Medicare beneficiaries

125. Governor's Exec. Order No. 42 (Apr. 12, 2012), *available at* <http://www.governor.ny.gov/executiveorder/42>.

126. Press Release, N.Y. Dep't of Health, Health Plans Invited to Participate in New York Health Benefit Exchange (Feb. 1, 2013), *available at* http://www.health.ny.gov/press/releases/2013/2013-02-01_health_benefit_exchange_health_plans_invited_to_participate.htm.

127. *See generally* 742 F. Supp. 2d 765 (W.D. Pa. 2010).

128. *See generally* No. 5:09-cv-16, 2010 U.S. Dist. LEXIS 113550 (D. Vt. Oct. 25, 2010).

129. Lerch & Fischmann, *supra* note 42, at 698.

130. No. 5:11-cv-17, 2011 U.S. Dist. LEXIS 123743, at *3 (D. Vt. Oct. 25, 2011). The individual plaintiffs are Glenda Jimmo, K.R. by her guardian Kenneth Roberts, Miriam Katz, Edith Masterman, Mary Patricia Boitano, and Rosalie McGill. *See* Opinion & Order Denying in Part & Granting in Part Defendant's Motion to Dismiss for Lack of Subject Matter Jurisdiction & Denying Defendant's Motion to Dismiss for Failure to State a Claim, *Jimmo v. Sebelius*, No.5:11-cv-17 (D. Vt. Oct. 25, 2011), ECF No. 25.

131. *Id.* The national organizations that plaintiffs consist of are the National Committee to Preserve Social Security and Medicare, the National Multiple Sclerosis Society, the Parkinson's Action Network, the Paralyzed Veterans of America, the American Academy of Physical Medicine and Rehabilitation ("AAPM&R"), the Alzheimer's Association, and United Cerebral Palsy.

132. *Id.* at *2-3.

133. *Id.* at *3-4.

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[were] entitled to coverage, resulting in the wrongful termination, reduction, and denial of Medicare coverage for beneficiaries with medical conditions that [were] not expected to improve.”¹³⁴ Plaintiffs maintained that the “Improvement Standard” violated the Medicare Act¹³⁵ and the Due Process Clause of the Fifth Amendment,¹³⁶ among others.¹³⁷ The Medicare “Improvement Standard” refers to the proposition that Medicare limits coverage for home health care, skilled nursing home stays, and outpatient therapies to patients who show an improvement in their condition.¹³⁸ Under this practice, coverage of skilled care is denied to beneficiaries whose conditions have plateaued, are medically stable, or need services for maintenance only.¹³⁹

Plaintiffs argued that the “Improvement Standard” was not supported by language in the Medicare Act and federal regulations.¹⁴⁰ Specifically, plaintiffs maintained that

it is the standard practice of providers, contractors, QIOs [quality improvement organizations], QICs [qualified independent contractors], and IREs [independent review entities] to apply LCDs [local coverage determinations] and internal guidelines and policies that establish the Improvement Standard as a rule of thumb on which Medicare coverage is conditioned, in disregard of the regulatory and manual provisions that require a coverage determination to be based on the beneficiary’s individual condition and needs.¹⁴¹

The court observed that “payment [by Medicare] is precluded for items and services that ‘are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member’” pursuant to the Medicare Act.¹⁴² The court further noted that “[c]overage determinations are required by law to be conducted on an individualized basis and cannot be the subject of rules of thumb.”¹⁴³

The *Jimmo* plaintiffs sought a declaration that the Improvement

134. *Id.* at *3.

135. 42 U.S.C. § 1395iii (Supp. V 2011).

136. U.S. CONST. amend. V.

137. *Jimmo*, 2011 U.S. Dist. LEXIS 123743, at *6.

138. See Gill Deford et al., *How the “Improvement Standard” Improperly Denies Coverage to Medicare Patients with Chronic Conditions*, 43 CLEARINGHOUSE REV. 422, 423 (2010); Robert Pear, *Accord to Ease Medicare Rules in Chronic Cases*, N.Y. TIMES, Oct. 23, 2012, at A1.

139. *Jimmo*, 2011 U.S. Dist. LEXIS 123743, at *5.

140. *Id.*

141. *Id.* at *5-6 (internal quotation marks omitted).

142. *Id.* at *4 (quoting 42 U.S.C. § 1395(y)(a)(1)(A) (Supp. V 2011)).

143. *Jimmo*, 2011 U.S. Dist. LEXIS 123743, at *4.

Standard was “unlawful,” a permanent injunction preventing the defendant from utilizing the “Improvement Standard” in coverage determinations, a declaration ordering defendant to correct any Medicare agency materials that endorse the application of the Improvement Standard, and an order “directing the Secretary to, *inter alia*, review all adverse coverage decisions for the named plaintiffs and class members that rely on the Improvement Standard and to reissue those decisions without application of the Improvement Standard.”¹⁴⁴

As threshold matters, the court made determinations regarding subject matter jurisdiction and standing. The court held that plaintiff Edith Masterman did not satisfy the jurisdictional requirement mandated by 42 U.S.C. § 405(g) and § 1331 of presenting her claims to the Secretary and, therefore, the defendant’s motion to dismiss her claim for lack of subject matter jurisdiction was granted.¹⁴⁵ However, the court determined that the “exhaustion requirement” for the remaining individual plaintiffs should be waived,¹⁴⁶ and as such, they had subject matter jurisdiction for the instant action.¹⁴⁷ The court also held that the organization-plaintiffs sufficiently established mandamus jurisdiction.¹⁴⁸ Therefore, defendant’s motion to dismiss the claims of the organization-plaintiffs and individual-plaintiffs (aside from Ms. Masterman), on the grounds of lack of subject matter jurisdiction, was denied.¹⁴⁹

The court also denied defendant’s motion to dismiss plaintiff Glenda Jimmo’s claim for lack of standing, holding that she alleged a “fairly traceable causal connection between the claimed injury and the challenged conduct of the defendant.”¹⁵⁰ The court observed that plaintiff K.R. had more of a mootness problem than one of standing and, as such, denied defendant’s motion to dismiss for lack of standing without prejudice to renew on the grounds of mootness.¹⁵¹ The court

144. *Id.* at *6-7.

145. *Id.* at *55.

146. *Id.* at *28. “Judicial waiver is appropriate where the plaintiffs’ legal claims are collateral to their demand for benefits, where exhaustion would be futile, or where the harm suffered pending exhaustion would be irreparable.” *Id.* at *20 (citing *Mathews v. Eldridge*, 424 U.S. 319, 330-32 (1976)).

147. *Jimmo*, 2011 U.S. Dist. LEXIS 123743, at *55.

148. *Id.* at *41. Under 28 U.S.C. § 1361 district courts have “original jurisdiction of any action in the nature of mandamus to compel an officer or employee of the United States or any agency thereof to perform a duty owed to the plaintiff.” *Id.* at *36 (quoting 28 U.S.C. § 1361 (2006)).

149. *Jimmo*, 2011 U.S. Dist. LEXIS 123743, at *42.

150. *Id.* at *45-48 (quoting *Banks v. Sec’y of Ind. Family & Soc. Servs. Admin.*, 997 F.2d 231, 239 (7th Cir. 1993)).

151. *Jimmo*, 2011 U.S. Dist. LEXIS 123743, at *48-49.

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further denied defendant's motion to dismiss plaintiff's claims for injunctive relief on grounds of lack of standing holding that "when the threatened acts that will cause injury are . . . part of a policy,' such as the Improvement Standard alleged in this case, 'it is significantly more likely that the injury will occur again,' and the existence of an official policy therefore supports the plaintiff's standing to pursue injunctive relief."¹⁵² However, the court granted defendant's motion to dismiss the organization American Academy of Physical Medicine and Rehabilitation (AAPM&R) for lack of standing on the basis that it did not allege that one of its members would have standing to sue, but permitted it leave to amend.¹⁵³ As to the remaining organizational plaintiffs, the court reasoned that since the presence of the organizational plaintiffs had no effect on the merits of the individual plaintiffs' cases, it did not need to reach the issue of standing with respect to them.¹⁵⁴

Defendant claimed that plaintiffs' amended complaint failed to state a plausible claim for relief in that it could not be reasonably inferred from the amended complaint that the Improvement Standard even existed.¹⁵⁵ Defendants explained that the "Improvement Standard," as set forth by plaintiffs, was inadequately defined and that there were alternative explanations for the complained conduct aside from a "covert policy."¹⁵⁶ For instance, defendant reasoned that the prior agency decisions relied upon by plaintiffs were simply "legal errors in the application of valid regulations," rather than a nationwide policy to deny these beneficiaries coverage.¹⁵⁷

Both parties cited various regulations, policies, and decisions that supported their respective positions that the "Improvement Standard" did or did not exist. In support of defendant's argument that there was no "Improvement Standard," defendant cited a number of regulations¹⁵⁸ and policies,¹⁵⁹ which forbid the utilization of an "Improvement

152. *Id.* at *51-52 (quoting 31 Foster Children v. Bush, 329 F.3d 1255, 1266 (11th Cir. 2003)).

153. *Jimmo*, 2011 U.S. Dist. LEXIS 123743, at *55.

154. *Id.*

155. *Id.* at *55-56.

156. *Id.* at *56.

157. *Id.* at *65.

158. *See Jimmo*, 2011 U.S. Dist. LEXIS 123743, at *56-60; *see, e.g.*, 42 C.F.R. § 409.44(a), (b)(3)(iii), (c) (2012).

159. *Jimmo*, 2011 U.S. Dist. LEXIS 123743, at *59; *see, e.g.*, Home Health Prospective Payment System Rate Update for Calendar Year 2011, 75 Fed. Reg. 70372, 70395 (Nov. 17, 2010); MEDICARE BENEFIT POLICY MANUAL, ch. 7, § 20.3,

Standard,” but instead mandate that coverage decisions be made based on the beneficiaries’ “unique medical conditions.”¹⁶⁰ In response, plaintiffs argued that these regulations and policies were being ignored.¹⁶¹ Plaintiffs argued that the existence of the “Improvement Standard” was supported by various Local Coverage Determinations (“LCDs”), provisions of the Medicare Benefit Policy Manual (“MBPM”), prior judicial decisions, and the written administrative decisions in the individual plaintiffs’ cases, all of which indicated that Medicare coverage was contingent on improvement of the beneficiary’s condition.¹⁶²

The court held that the individual-plaintiffs’ amended complaint stated a claim for relief under Fed. R. Civ. P. 8 and denied defendant’s motion to dismiss.¹⁶³ The court reasoned that it could not

Conclude as a matter of law that plaintiff’s Improvement Standard theory is factually implausible when it is supported by at least *some* evidence in each of the individual plaintiffs’ cases and where other plaintiffs have successfully demonstrated the use of illegal presumptions and rules of thumb much like plaintiffs allege here.¹⁶⁴

Jimmo v. Sebelius is a significant milestone in “Improvement Standard” litigation, as the settlement agreement which was subsequently reached in this case mandates changes to the Medicare system.¹⁶⁵ After surviving the motion to dismiss discussed above, *Jimmo* ultimately settled on October 16, 2012.¹⁶⁶ Briefly, these changes include modifications to Medicare coverage rules, the re-examination of

<http://cms.gov/Regulations-and-Guidance/Manuals/Downloads/bp102c07.pdf> (last visited Apr. 24, 2013).

160. *Jimmo*, 2011 U.S. Dist. LEXIS 123743, at *37-38.

161. *Id.* at *61.

162. *See id.* at *56-64 (citing various Local Coverage Determinations, including LCD 23604, LCD 28290, and LCD 340).

163. *Id.* at *67.

164. *Id.* at *66 (citing *Ashcroft v. Iqbal*, 129 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

165. *See generally* Settlement Agreement, *Jimmo v. Sebelius*, No. 5:11-CV-17-CR (D. Vt. Oct. 16, 2012), available at <http://www.medicareadvocacy.org/wp-content/uploads/2012/12/Jimmo-Settlement-Agreement-00011764.pdf>. *See also* *Improvement Standard*, MEDICARE ADVOCACY, <http://www.medicareadvocacy.org/medicare-info/improvement-standard-2/>, retrieved 1/25/13 (last visited Mar. 25, 2013); Robert Pear, *Settlement Eases Rules for Some Medicare Patients*, N.Y. TIMES, Oct. 22, 2012, http://www.nytimes.com/2012/10/23/us/politics/settlement-eases-rules-for-some-medicare-patients.html?_r=0 [hereinafter Pear, *Settlement Eases Rules*].

166. Settlement Agreement, *supra* note 165, at 8-9.; *see also* *Improvement Standard*, *supra* note 165.

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previously decided claims, and the education of those who make coverage determinations.¹⁶⁷

IV. FEDERAL LEGISLATION AND POLICY

A. Medicare Secondary Payer and “Future Medicals” Proposed Rule

On June 15, 2012, the Centers for Medicare and Medicaid Services (“CMS”) published an Advance Notice of Public Rulemaking (“ANPRM”), CMS-6047-ANPRM, to address the issue of future medical expenses with respect to Medicare Secondary Payer (“MSP”) claims.¹⁶⁸ In the ANPRM, CMS advised that it would be soliciting comments and feedback on the proposed rule until August 14, 2012.¹⁶⁹

As brief background, under the 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.”¹⁷⁰ 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.¹⁷¹ 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 reimburse Medicare for any such payments made for items and/or services if it is shown that such primary payer has or had the responsibility to make payment for the same.¹⁷²

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”¹⁷³ includes payment for injury-

167. Settlement Agreement, *supra* note 165, at 14.; *see also* Pear, *Settlement Eases Rules*, *supra* note 165.

168. Medicare Program & Medicare Secondary Payer and “Future Medicals,” 77 Fed. Reg. 35917, 35917-18 (proposed June 15, 2012) (to be codified at 42 C.F.R. pts. 405 & 411).

169. *Id.* at 35918.

170. 42 U.S.C. § 1395y (b)(2)(B)(i) (Supp. V 2011); *see also* ROY UMLAUF & THOMAS THORNTON, DRI: THE VOICE OF THE DEFENSE BAR, MEDICARE SECONDARY PAYER REPORTING AND SECTION 111 OF MMSEA: THE NUTS AND BOLTS 10-14 (2010).

171. 42 U.S.C. § 1395y(b)(2)(A)(ii).

172. *Id.* § 1395y(b)(2)(B)(ii).

173. 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.” *Id.* § 1395y(b)(2) (emphasis added). In addition, although a workers’ 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

related care which occurs after settlement or verdict.¹⁷⁴ The latter is encompassed in a Medicare Set Aside (“MSA”) which is created to “pay for future injury-related care which would otherwise be covered by Medicare.”¹⁷⁵ However, at present, there are no regulations which require the use of an MSA in the liability context and very little guidance has been provided from CMS regarding their use.¹⁷⁶ Although regulations note Medicare’s future payment interest,¹⁷⁷ with respect to liability MSAs (“LMSAs”), the only source of guidance from Medicare has been through non-binding documents¹⁷⁸ such as memorandums, handouts, or information through some courts that have attempted to articulate the LMSA process.¹⁷⁹

CMS hopes to alleviate this ambiguity with CMS-6047-ANPRM. Specifically, CMS has proposed this rule

[t]o clarify how [beneficiaries and their representatives] can meet their obligations to protect . . . [MSP] claims involving automobile and liability insurance (including self-insurance), no-fault insurance, and workers’ compensation when future medical care is claimed or the settlement, judgment, award, or other payment releases (or has the effect of releasing) claims for future medical care.¹⁸⁰

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 SALLY STALCUP, DEP’T OF HEALTH & HUMAN SERVS., CTRS. FOR MEDICARE & MEDICAID SERVS., DIV. OF FIN. MGMT. & FEE FOR SERV. OPERATIONS, REGION VI, *available at* <http://providiomedisolutions.com/Assets/CMSDallasRegionalOfficeSallyStalcupResponsetoQuestionsRegardingLiabilityMSAs.pdf> (last visited Mar. 25, 2013).

174. JOHN V. CATTIE, JR. & CESAR NOBLE, THE DRI CMTY., LIABILITY MEDICARE SET-SIDE ARRANGEMENTS: REQUIRED, RECOMMENDED OR RIDICULOUS? (2011).

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

176. STALCUP, *supra* note 173; GARRETSON RESOLUTION GRP., at 2, *supra* note 175.

177. See generally 42 U.S.C. § 1395y.

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

179. See generally *Big R Towing, Inc. v. Benoit*, No. 10-538, 2011 WL 43219 (W.D. La. Jan. 5, 2011). See *Schexnayder v. Scottsdale Ins.*, No. 6:09-CV-1390, 2011 U.S. Dist. LEXIS 83687, *6 (W.D. La. July 28, 2011).

180. Medicare Program & Medicare Secondary Payer and “Future Medicals,” 77 Fed. Reg. 35917, 35917-18 (proposed June 15, 2012) (to be codified at 42 C.F.R. pts. 405 & 411).

The proposed rule is as follows:

[i]f an individual or Medicare beneficiary obtains a “settlement” and has received, reasonably anticipates receiving, or should have reasonably anticipated receiving Medicare covered and otherwise reimbursable items and services after the date of “settlement,” he or she is required to satisfy Medicare’s interest with respect to “future medicals” related to his or her “settlement.”¹⁸¹

CMS-6047-ANPRM sets forth that Medicare’s interest with respect to future medical care would be considered satisfied upon the completion of one of the seven options provided in the proposed rule.¹⁸² Options One through Four would be used by Medicare beneficiaries and individuals who are not yet beneficiaries, whereas Options Five through Seven would be available to beneficiaries only.¹⁸³

In Option One, the “individual/beneficiary pays for all related future medical care until his/her settlement is exhausted and documents it accordingly.”¹⁸⁴ In Option Two, Medicare would not pursue “future medicals” if the individual/beneficiary’s case meets certain conditions concerning the amount of settlement, the type of injury, the timing of the injury with respect to the settlement, the injured individual’s Medicare status and the status of additional “settlements” and claims.¹⁸⁵ Option Three would involve the individual/beneficiary obtaining an attestation from his or her treating physician as to the “Date of Care Completion,” or the date the patient completed treatment related to his or her settlement.¹⁸⁶ The physician would also have to attest that the patient would not require any additional care related to his or her “settlement.”¹⁸⁷ In Option Four, the individual/beneficiary submits proposed MSA amounts for review by CMS and receives approval.¹⁸⁸

Option Five consists of three Medicare recovery options for the beneficiary who does not expect to receive additional settlements related to the incident and whose settlement is \$25,000 or less, \$5,000 or less, or \$300 or less.¹⁸⁹ Under this Option, the beneficiary can self-calculate a conditional payment amount (if the settlement is \$25,000 or less), pay 25% of the gross settlement amount (if the settlement is

181. *Id.* at 35919.

182. *Id.*

183. *Id.*

184. *Id.* at 35920.

185. 77 Fed. Reg. at 35920.

186. *Id.* at 35919-35920.

187. *Id.* at 35920.

188. *Id.*

189. *Id.*

\$5,000 or less) or be relieved of paying Medicare (if the settlement is not greater than \$300).¹⁹⁰ In Option Six, the beneficiary would make an upfront payment to Medicare,¹⁹¹ and in Option Seven the beneficiary obtains a compromise or waiver of recovery.¹⁹²

The proposed rule makes clear that parties need to consider Medicare's future interest in personal injury actions and offers a number of options in meeting that obligation.¹⁹³ It is a step in the right direction inasmuch as CMS is finally attempting to provide some guidance to attorneys and the individuals and entities that they represent as to how to address Medicare's future interest. However, much ambiguity as to the actual process of satisfying Medicare's future interest in the liability context remains, as even acknowledged by CMS in its Advanced Notice.¹⁹⁴ Hopefully, the finalized rule will shed more light on these critical issues.

CONCLUSION

Looking ahead to next year's *Survey* on New York State law, it will be interesting to see if there are any challenges at the Appellate Division or Court of Appeals level in the future to the controversial holding in *Muhammad v. Fitzpatrick*. Further, as the Medical Indemnity Fund regulations have been promulgated which provide more specificity as to how the Fund will operate, we should expect to see more cases interpreting these regulations. Hopefully, future cases will shed greater light as to the Fund's impact on the settlement process in obstetrical malpractice cases.

As for federal law, although the constitutionality of the Individual Mandate and the Medicaid Expansion have been decided, it is likely that additional litigation as to other provisions in PPACA will be forthcoming. In addition, a finalized rule from CMS regarding the

190. 77 Fed. Reg. at 35920.

191. *Id.*

192. *Id.* at 35921.

193. *Id.*

194. *Id.* at 35920. CMS states in its introduction to the proposed rule:

[w]e are soliciting comment on whether and how Medicare should implement . . . a similar process [as that in the Worker's Compensation context] in liability insurance situations, as well as comment on the proposed definitions and additional options outlined later in this section. We are further soliciting suggestions on options we have not included later in this section. We are most interested in the feasibility and usability of the outlined options and whether implementation of these options would provide affected parties with sufficient guidance.

77 Fed. Reg. at 35919. In addition, no specific "defined amounts" were listed in CMS's Option Two. CMS states "[w]e request comment on the appropriate defined amounts to use in Options 2a and 2b, as well as comment on the efficacy of this approach." *Id.* at 35920.

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MSP and “future medicals” can be expected as well as implementation of the settlement agreement in *Jimmo v. Sebelius* within the Medicare system.