HEALTH LAW

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INTRODUCTION

In this *Survey* year, the Second Circuit fortified challenges that individuals with disabilities face in surmising failure to accommodate

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claims under the Americans with Disabilities Act.[1] The New York State trial courts have been busy dealing with continued challenges to the statutory prohibition on disclosure of hospital incident reports[2] as well as statutory amendments to the New York State Medical Indemnity Fund (MIF) to improve and increase access to medical treatment for infants injured as the result of medical malpractice.[3] Additionally, the Court of Appeals delivered a major decision that all but finalized the ban on physician-assisted suicide (i.e., aid-in-dying) in New York State.[4] The First Department extended absolute privilege as a defense to a claim for defamation based on statements made in an agency proceeding as well.[5]

In the New York State Legislature, the statute of limitations for medical malpractice actions involving the alleged failure to diagnose cancer has been expanded following the close of the *Survey* year by measuring the time for bringing a malpractice claim from the moment of discovery (or with reasonable diligence could have been discovered), not the moment the alleged malpractice occurred.[6] Additionally, the New York State Legislature has developed additional regulations to promote the expansion and improvement of its medical marijuana program.[7]

At the federal level, the 21st Century Cures Act was passed toward the end of 2016 to improve the discovery, innovation, and delivery of medical treatments and provided clarification on implementation of HIPAA regulations.[8] The Helping Families in Mental Health Crisis Act was also passed as part of the Cures Act to ensure that individuals in need of mental health treatment are treated fairly by insurance companies and to seek guidance on HIPAA's regulations regarding the disclosure of a patient's mental health information to third parties.[9]

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1. *See* Stevens v. Rite Aid Corp., 851 F.3d 224, 230 (2d Cir. 2017).

2. *See* Phillips v. City of New York, 54 Misc. 3d 294, 297, 40 N.Y.S.3d 751, 752–53 (Sup. Ct. Bronx Cty. 2016).

3. *See* K.I. v. Vullo, 57 Misc. 3d 244, 245, 57 N.Y.S.3d 661, 662 (Sup. Ct. Kings Cty. 2017).

4. Myers v. Schneiderman, 30 N.Y.3d 1, 10, 85 N.E.3d 57, 60, 62 N.Y.S.3d 838, 841 (2017). Although the decision is outside the scope of the *Survey* year, it is a critical decision that, for the foreseeable future, has issued a hardline ban on physician-assisted suicide in New York State. *Id.* at 58, 85 N.E.3d at 94–95, N.Y.S.3d at 875–76.

5. *See* Stega v. N.Y. Downtown Hosp., 148 A.D.3d 21, 22–23, 44 N.Y.S.3d 417, 418 (1st Dep't 2017).

6. Act of Jan. 31, 2018, 2017 McKinney's Sess. Laws of N.Y., ch. 506, at 1105–07 (codified at N.Y. C.P.L.R. 203, 214-a).

7. N.Y. PUB. HEALTH LAW §§ 3360–69 (McKinney Supp. 2018); 10 N.Y.C.R.R. 1004.1–1004.24 (2017).

8. *See* 21st Century Cures Act, Pub. L. No. 114-225, 130 Stat. 1033, 1033 (2016).

9. *Id.* div. B (originally introduced as the Helping Families in Mental Health Crisis Act of 2016, H.R. 2646, 114th Cong.).

I. FEDERAL CASE LAW

A. Essential Job Requirements under the Americans with Disabilities Act

During this *Survey* year, the Second Circuit clarified what a court should consider in determining what an essential job requirement is for purposes of a failure to accommodate claim pursuant to the Americans with Disabilities Act (ADA). In *Stevens v. Rite Aid Corp.*, the plaintiff pharmacist claimed that the defendant employer wrongfully terminated him, retaliated against him, and failed to accommodate his disability pursuant to the ADA.[10] The plaintiff had been working for the defendant for thirty-four years handling medications and counseling customers.[11] Beginning in 2011, the defendant required its pharmacists to perform immunizations and included this function in its list of "essential duties and responsibilities" for pharmacists.[12] Upon notice of this, the plaintiff obtained a note from his treating physician that he suffered from trypanophobia.[13] The plaintiff's physician believed that the plaintiff could not administer immunizations via injections because he was at risk of becoming diaphoretic, becoming hypotensive or possibly even fainting.[14] In response, the defendant threatened that the plaintiff would lose his job unless he completed immunization training.[15] The plaintiff was subsequently terminated for refusing to perform immunizations.[16]

At trial, a jury awarded the plaintiff damages for all three claims; however, a post-trial order dismissed his failure-to-accommodate claim.[17] The defendant also moved for judgment as a matter of law on the other two claims, which were denied.[18] The plaintiff and the defendant appealed.[19]

"The ADA prohibits discrimination in employment against 'a qualified individual on the basis of disability.'"[20] "A 'qualified individual' is . . . one who, 'with or without reasonable accommodation, can perform the essential functions of the employment position . . . .'"[21]

10. Stevens v. Rite Aid Corp., 851 F.3d 224, 227 (2d Cir. 2017).
11. *Id.*
12. *Id.*
13. *Id.* Trypanophobia is a fear of needles. *See id.*
14. *Stevens*, 851 F.3d at 227.
15. *Id.*
16. *Id.* at 227–28.
17. *Id.* at 228.
18. *Id.*
19. *Stevens*, 851 F.3d at 228.
20. *Id.* (quoting 42 U.S.C. § 12112(a) (2012)).
21. *Id.* at 229 (quoting 42 U.S.C. § 12111(8) (2012)).

In other words, if an individual cannot perform an essential function of his job even if the employer were to provide reasonable accommodations, then the employer does not discriminate under the ADA in terminating that employee.[22]

The Second Circuit first examined whether administering immunizations was an essential job function.[23] The court explained that this is a fact-specific inquiry and that it considers "the employer's judgment, written job descriptions, the amount of time spent on the job performing the function, the mention of the function in a collective bargaining agreement, the work experience of past employees in the position, and the work experience of current employees in similar positions."[24] The court noted that it "must give considerable deference to an employer's judgment regarding what functions." it considers essential.[25] Despite this, no one factor is dispositive.[26]

The court found that immunization administration was an essential function of being a pharmacist for the defendant.[27] The defendant revised its job description to require immunization certification and licensure and included immunizations on its list of "essential duties and responsibilities" for its pharmacists.[28] While little time was spent administering immunizations at the time the plaintiff left his position, nothing showed that this was the practice after he left.[29] Thus, the court held that immunization administration was an essential job function.[30]

The court next looked at whether reasonable accommodations existed such that the plaintiff could perform this essential job function.[31] The court explained that a reasonable accommodation could include "job restructuring, part-time or modified work schedules, reassignment to a vacant position, acquisition or modification of equipment or devices, appropriate adjustment or modification of examinations, training materials or policies, the provision of qualified readers or interpreters, and other similar accommodations for individuals with disabilities."[32] "A reasonable accommodation can never involve the elimination of an

22. *Id.* (quoting Sista v. CDC Ixis N. Am., Inc., 445 F.3d 161, 169 (2d Cir. 2006)).

23. *See id.*

24. *Stevens*, 851 F.3d at 229 (internal quotation marks omitted) (quoting McMillan v. City of New York, 711 F.3d 120, 126 (2d Cir. 2013)) (citing 29 C.F.R. § 1630.2(n)(3) (2017)).

25. *Id.* (internal quotation marks omitted) (quoting Shannon v. N.Y.C. Transit Auth., 332 F.3d 95, 100 (2d Cir. 2003)).

26. *Id.* (quoting Stone v. City of Mount Vernon, 118 F.3d 92, 97 (2d Cir. 1997)).

27. *Id.*

28. *Id.*

29. *Stevens*, 851 F.3d at 229.

30. *Id.* at 230.

31. *Id.*

32. *Id.* (internal quotation marks omitted) (quoting 42 U.S.C. § 12111(9)(B) (2012)).

essential" job function.[33] Further, an employer is not obligated to offer medical treatment as a reasonable accommodation.[34]

The court found that the plaintiff pharmacist failed to show that a reasonable accommodation existed.[35] Because an employer is not obligated to provide medical treatment, the plaintiff pharmacist was not entitled to desensitization therapy.[36] Furthermore, because a nurse or another pharmacist performing these functions for the plaintiff is not an accommodation, the plaintiff pharmacist's suggestion to be transferred to a higher-staffed facility was inadequate.[37] Finally, while he was offered a technician position where he would not have to administer immunizations, the plaintiff pharmacist failed to offer any evidence that he requested or was open to the position at the time of his termination.[38]

The Court thus held that "no juror could reasonably conclude that [the plaintiff pharmacist] was 'qualified to perform the essential functions of his job, with or without reasonable accommodation.'"[39] As such, the court affirmed the dismissal of the failure to accommodate claim and reversed the denial of the motion for judgment as a matter of law on the wrongful termination and retaliation claims.[40]

This case is important because it upholds the deference that courts give to employers in enabling them to define what constitutes an essential job function.[41] Other federal circuit courts have taken a similar position. The Tenth Circuit, for example, has held that its "disability-discrimination caselaw [sic] explicitly incorporates the EEOC's regulations and counsels in favor of deference to an employer's judgment

33. *Id.* (internal quotation marks omitted) (quoting Shannon v. N.Y.C. Transit Auth., 332 F.3d 95, 100 (2d Cir. 2003)) (first citing Emerllahu v. Pactiv, LLC, No. 11-CV-6197, 2013 U.S. Dist. LEXIS 155380, at *9 n.2 (W.D.N.Y. Oct. 30, 2013); and then citing Desmond v. Yale-New Haven Hosp., 738 F. Supp. 2d 331, 351 (D. Conn. 2010)).

34. *Stevens*, 851 F.3d at 230.

35. *Id.* at 231.

36. *Id.* at 230 (first citing *Emerllahu*, 2013 U.S. Dist. LEXIS 155380 at *9 n.2; and then citing *Desmond*, 738 F. Supp. 2d at 351).

37. *Id.* at 231 (citing *Shannon*, 332 F.3d at 100).

38. *Id.*

39. *Stevens*, 851 F.3d at 231.

40. *Id.* at 231.

41. *See id.* at 229 (quoting *Shannon*, 332 F.3d at 100). In *Shannon*, the Second Circuit held that a color differentiation was an essential job function for a bus driver. *Shannon*, 332 F.3d at 103. The Second Circuit considered regulations that possibly permitted a colorblind driver to drive a bus, but found that even if applicable, such regulations would not bar the NYC Transit Authority from enforcing higher standards for its own drivers. *Id.* at 102 (citing Albertson's, Inc. v. Kirkingburg, 527 U.S. 555, 571 (1999)). The court explained that "[e]mployers formulate jobs to fit the needs of their enterprises, and cannot fill jobs without deciding what attributes are essential to those needs." *Id.* at 102–03. As such, the Court upheld the employer's motion for summary judgment dismissing the plaintiff's claims under the ADA. *Id.* at 105.

concerning essential functions."[42] The court refuses to "second guess the employer or require it to lower company standards," particularly where the "description is job-related, uniformly enforced, and consistent with business necessity."[43] While an employer cannot make every function essential, the court weighs "*heavily* an employer's judgment."[44]

Some courts, though, have been less deferential. In *Jacobs v. North Carolina Administrative Office of the Courts*, the Fourth Circuit held that working the front desk was not an essential function for a court clerk with social anxiety.[45] The plaintiff was hired as an office assistant and had been working microfilming and filing in the Clerks' Office.[46] After a month, she was promoted to deputy clerk and placed at the front desk, where she experienced difficulty working with customers due to her social anxiety.[47] She requested to be trained to fill a different role in the Clerk's Office, which was typically reserved for senior court clerks.[48] Her employer denied her request and terminated her.[49]

In determining whether working the front desk was an essential function of a court clerk, the court explained that an employer's written job description, "written . . . before advertising or interviewing applicants for the job," should be considered evidence of whether the function is essential.[50] The court examined the job's description, which included "providing customer service."[51] However, the court also found that the defendant employed thirty deputy clerks, only four of which worked at the front counter.[52] Depending on seniority, a deputy clerk could be trained for other roles.[53] Some deputy clerks, though, never had to work the front counter; however, most were trained to work behind the front counter such that many employees were available to perform that function.[54] The court held that the plaintiff had established a genuine

42. Adair v. City of Muskogee, 823 F.3d 1297, 1307 (10th Cir. 2016) (internal quotation marks omitted) (quoting Hawkins v. Schwan's Home Serv., 778 F.3d 877, 884–85 (10th Cir. 2015)).

43. *Id.* at 1308 (quoting Mason v. Avaya Commc'ns, 357 F.3d 1114, 1119 (10th Cir. 2004)).

44. *Id.* (first quoting *Hawkins*, 778 F.3d at 889; and then quoting Hennagir v. Utah Dep't of Corr., 587 F.3d 1255, 1262 (10th Cir. 2009)).

45. 780 F.3d 562, 581 (4th Cir. 2015).

46. *Id.* at 566.

47. *Id.*

48. *Id.* at 566–67.

49. *Id.* at 567.

50. *Jacobs*, 780 F.3d at 579 (quoting 42 U.S.C. § 12111(8) (2012)).

51. *Id.* at 580.

52. *Id.*

53. *Id.*

54. *Id.*

issue of material fact regarding whether working the front counter was an essential job function of a court clerk.[55]

The Fourth Circuit seems to have given less deference to the employer's judgment in *Jacobs* than the Second Circuit did in *Stevens*. While prior Second Circuit decisions certainly gave deference to an employer's judgment, *Stevens* seems to go even further, particularly considering that the job function was implemented long after the plaintiff was hired to work at the defendant's pharmacy, which goes beyond the deference suggested in the ADA statute (i.e., the written job description at the time of hiring the employee).[56] Allowing a company to change its policy and subsequently terminate long-time employees that cannot perform new functions could have significant implications.

II. NEW YORK CASE LAW

A. Developments in the New York State Medical Indemnity Fund

The Kings County Supreme Court recently heard an Article 78 application to reverse the determination of a third-party administrator of the Medical Indemnity Fund (MIF) and compel the third-party administrator to accept the infant petitioner for enrollment in the MIF.[57] The court granted the infant petitioner's application and directed acceptance to the MIF.[58]

1. Statutory Amendments to the MIF

By way of background, the MIF, which was created on April 1, 2011 and is governed by the Public Health Law, provides a "funding source for future health care costs associated with birth related neurological injuries in order to reduce premium costs for medical malpractice insurance coverage."[59] More specifically, a "qualified plaintiff" for purposes of the

55. *Jacobs*, 780 F.3d at 580.

56. *Compare* Stevens v. Rite Aid Corp., 851 F.3d 224, 227 (2d Cir. 2017) (mentioning the pharmacist plaintiff had worked at Rite Aid for thirty-four years prior to the revised job description), *with* 42 U.S.C. § 12111(8) (2012) ("[C]onsideration shall be given to the employer's judgment as to what functions of a job are essential, and if an employer has prepared a written description before advertising or interviewing applicants for the job, this description shall be considered evidence of the essential functions of the job.").

57. K.I. v. Vullo, 57 Misc. 3d 244, 245, 57 N.Y.S.3d 661, 662 (Sup. Ct. Kings Cty. 2017).

58. *Id.* at 252, 57 N.Y.S.3d at 667.

59. *Id.* at 247, 57 N.Y.S.3d at 664 (quoting N.Y. PUB. HEALTH LAW § 2999-g (McKinney 2015)); Legislative Memorandum of Sen. Hannon, *reprinted in* 2016 McKinney's Sess. Laws of N.Y., ch. 517, at 1653 ("This bill would ensure that the future health care costs for infants who sustained birth-related neurological injuries and received a court-approved settlement or judgment are properly paid for by the Medical Indemnify Fund.").

MIF is anyone a jury or court has found to have sustained a birth-related neurological injury as a result of medical malpractice or has sustained a birth-related neurological injury and settled a lawsuit for the alleged malpractice.[60] A "birth-related neurological injury" refers to an injury to the brain or spinal cord of a live infant that was caused by the deprivation of oxygen or mechanical injury "occurring in labor, delivery, or resuscitation, or by other medical services provided or not provided during delivery admission, that rendered the infant with a permanent and substantial motor impairment or with a developmental disability . . . or both."[61]

Effective February 14, 2017, the New York State Legislature expanded the coverage under the MIF by providing access to habilitation, respite, medical transportation, and any other services and supplies necessary to meet health care needs including those that provide a therapeutic benefit.[62] In its supporting memorandum, the Assembly noted that the

> Medical Indemnity Fund (MIF) was designed to ensure that children with birth-related neurological injuries are able to have their medical needs met, and access services that they need to improve their quality of life. In furtherance of that goal, the bill that created chapter 517 of the laws of 2016 as well as this bill make changes to the MIF to allow children to better access such services.[63]

On a more technical level, and as more relevant to the below discussion of *K.I. v. Vullo*, the Legislature made amendments to clarify issues with third-party administrators' determinations regarding eligibility for the MIF under Public Health Law § 2999-h.[64] The impetus for the more technical amendments arose out of a 2016 supreme court case from Kings County, *K.O. v Lawsky*.[65] In *K.O.*, the plaintiff and the medical malpractice defendants brought an Article 78 petition against the Superintendent of New York State Department of Financial Services and as Administrator of the New York State Medical Indemnity Fund, challenging the third-party MIF administrator's denial of enrollment to

60. *K.I.*, 57 Misc. 3d at 247, 57 N.Y.S.3d at 664 (citing N.Y. PUB. HEALTH LAW § 2999-h(4) (McKinney 2015 & Supp. 2018)).

61. *Id.* at 248, 57 N.Y.S.3d at 664 (quoting PUB. HEALTH § 2999-h(1)).

62. Act of Feb. 1, 2017, 2017 McKinney's Sess. Laws of N.Y., ch. 4, at 2–3 (codified at N.Y. PUB. HEALTH LAW §§ 2999-h, 2999-j (McKinney Supp. 2018) (repealing N.Y. Pub. Health Law § 2999-k (McKinney Supp. 2018)).

63. Legislative Memorandum of Assemb. Abinanti, *reprinted in* 2017 McKinney's Sess. Law News, ch. 4, at A-20.

64. *See K.I.*, 57 Misc. 3d at 249, 57 N.Y.S.3d at 665 (quoting PUB. HEALTH § 2999-h(1)).

65. *See* Legislative Memorandum of Sen. Hannon, *supra* note 59, at 1654 ("Section 3 of this bill also makes technical amendments regarding eligibility for the Fund to address issues raised in *Matter of K.O. v. Lawsky* . . . .").

the infant petitioner as arbitrary and capricious.[66] Factually, there was no dispute that the infant was delivered at home, that the infant was rushed to the hospital after birth, and that the infant sustained neurological injuries during the birth process.[67] The case settled and the court approved the Infant Compromise Order, which contained the necessary language qualifying the infant for enrollment in the MIF.[68] The plaintiffs submitted an application to the MIF Administrator and were notified that the infant did not qualify for the MIF because the delivery occurred at home and not during the course of a hospital admission.[69] The court determined that, given the legislative history of the Public Health Law surrounding the MIF, the critical factor was the delivery of the neurologically impaired infant, not the location of the delivery itself.[70] That is, the fact that the delivery occurred at home and not in a hospital was irrelevant.[71] Additionally, the court determined that the regulations promulgated by the New York State Department of Health anticipate that it is the court's role to determine the eligibility of an infant for enrollment in the MIF upon settling the matter.[72] Therefore, the court held that the infant qualified for enrollment in the MIF and that the MIF third-party administrator acted arbitrarily and capriciously in denying enrollment to the subject infant.[73] Accordingly, the court deemed the infant admitted into the MIF.[74]

Therefore, the Legislature was compelled to amend the regulations governing eligibility of the MIF to improve families' access to funds necessary for their infants' future health care expenses.[75] The technical amendments, which were also effective February 14, 2017, included expanding the definition of a birth-related neurological injury (quoted above) with the addition of a comma after "resuscitation."[76] Although a seemingly insignificant amendment at first glance, it was added to

66. K.O. v. Lawsky, 50 Misc. 3d 742, 743, 18 N.Y.S.3d 840, 841 (Sup. Ct. Kings Cty. 2015).

67. *Id.* at 745, 18 N.Y.S.3d at 843.

68. *Id.*

69. *Id.* at 745–46, 18 N.Y.S.3d at 843.

70. *Id.* at 748, 18 N.Y.S.3d at 844.

71. *See K.O.*, 50 Misc. 3d at 748, 18 N.Y.S.3d at 844.

72. *See id.* (quoting Joyner-Pack v. New York, 38 Misc. 3d 903, 909–10, 957 N.Y.S.2d 810, 814 (Ct. Cl. 2012)).

73. *Id.* at 748, 18 N.Y.S.3d at 845.

74. *Id.*

75. *See* Legislative Memorandum of Sen. Hannon, *supra* note 59, at 1654 (specifically addressing the desire to expand child access to the fund, which was emphasized by Judge Steinhardt in her opinion in *K.O.*).

76. *See* K.I. v. Vullo, 57 Misc. 3d 244, 249, 57 N.Y.S.3d 661, 665 (Sup. Ct. Kings Cty. 2017) (quoting N.Y. PUB. HEALTH LAW § 2999-h(1) (McKinney Supp. 2018)).

prevent challenges regarding the timing of the neurological injury.[77] Put differently, there is no requirement that the birth-related neurological injury occur at the time of birth or even during the birth admission. Rather, "[t]he determinative factor is that the injury occurs during the labor, delivery or resuscitation."[78] Furthermore, according to the United States Department of Health and Human Services, labor occurs in three stages and is not limited to only the moments leading up to the birth.[79]

2. K.I. v. Vullo

In *K.I. v. Vullo*, the infant petitioner, K.I., was born via emergency cesarean section on December 12, 2008.[80] During birth, the mother, Ms. Azam, experienced a placental abruption,[81] a serious condition where the placenta peels away from the uterus before delivery, depriving the child of oxygen and nutrition.[82] As a result, the child was diagnosed with Hypoxic-Ischemic Encephalopathy (HIE),[83] a brain injury caused by birth complications that restricts proper blood-flow to the infant's brain.[84] Accordingly, the plaintiff brought a medical malpractice action on behalf of her infant child and alleged that the hospital, among other things, failed to: (1) timely perform a cesarean section; (2) properly train and instruct the medical personnel; (3) recognize and diagnose placental abruption; (4) recognize the mother's underlying conditions placing her at risk for placental abruption; and (5) timely admit the mother to the hospital and treat her prior to the onset of labor.[85] The plaintiff maintained similar allegations against the physician.[86] The plaintiff further claimed that, as a result of the aforementioned failures, the infant sustained brain damage

77. *See id.*

78. *Id.* at 250, 57 N.Y.S.3d at 665.

79. *See id.* at 250, 57 N.Y.S.3d at 666 (quoting *Pregnancy—Labor and Birth*, DEPT. HEALTH & HUM. SERVS., https://www.womenshealth.gov/pregnancy/childbirth-and-beyond/labor-and-birth (last updated Feb. 9, 2018)).

80. *Id.* at 245, 57 N.Y.S.3d at 663.

81. *K.I.*, 57 Misc. 3d at 246, 57 N.Y.S.3d at 663.

82. *See* Yinka Oyelese & Cande V. Ananth, *Placental Abruption*, 108 OBSTETRICS & GYNECOLOGY 1005, 1005–16 (2006) (providing a highly technical explanation of the medical causes and effects of placental abruption, followed by an exploration of treatment options); *Placental Abruption*, MAYO CLINIC (Jan. 12, 2018), https://www.mayoclinic.org/diseases-conditions/placental-abruption/basics/definition/CON-20024292 (giving a broad overview of the symptoms, causes, complications, and treatment of placental abruption).

83. *K.I.*, 57 Misc. 3d at 246, 57 N.Y.S.3d at 663.

84. *See* Kimberly A. Allen & Debra H. Brandon, *Hypoxic Ischemic Encephalopathy: Pathophysiology and Experimental Treatments*, 11 NEWBORN & INFANT NURSING REV. 125–33 (2011) (comprehensively explaining the medical condition and its ramifications for children while examining experimental treatments for future application).

85. *K.I.*, 57 Misc. 3d at 245–46, 57 N.Y.S.3d at 663.

86. *Id.* at 246, 57 N.Y.S.3d at 663.

due to HIE, including intractable seizures, spastic quadriplegia, and hypotonia.[87] At eight years old, the infant still had no head control and required complete support to be placed in and to maintain a sitting position.[88]

The case settled in 2015 and, in the Order of Compromise dated January 7, 2016, the trial court determined that the provisions of Public Health Law § 2999 were met, which permits the contracting of the administration of a recovery under the MIF to a third-party, private entity, and that the infant petitioner had sustained a birth-related neurological injury.[89] Therefore, the court determined that the infant qualified for enrollment in the MIF.[90]

Ultimately, the third-party MIF administrator denied enrollment to the infant after determining that the case fell outside the provisions of the statute, i.e., that the alleged medical malpractice "was not birth-related and did not take place in the course of labor or delivery."[91] The mother of the infant brought the instant Article 78 petition to challenge the denial.[92]

The court ultimately explained that it was irrelevant where the malpractice occurred as long as the injury itself occurred during labor, birth, or birth admission.[93] In arriving at its decision, the court placed particular emphasis on recent revisions to the MIF statute and the impetus behind those revisions.[94] More specifically, the court rejected respondents' argument that the infant was injured during the prenatal stage of pregnancy, by noting that it was a contradiction of the U.S. Department of Health and Human Services' definition of labor, which is the process by which the fetus and placenta leave the uterus and occurs in three stages (first contractions, dilation through birth, and delivery of the placenta).[95] The court also determined that respondent's

87. *Id.*

88. *Id.*

89. *Id.* (citing N.Y. PUB. HEALTH LAW § 2999-h(4) (McKinney Supp. 2018)).

90. *K.I.*, 57 Misc. 3d at 246, 57 N.Y.S.3d at 663.

91. *Id.* at 247, 57 N.Y.S.3d at 663–64.

92. *See id.* at 245, 57 N.Y.S.3d at 662.

93. *Id.* at 250, 57 N.Y.S.3d at 665 ("[T]he Court finds that there is no requirement that the alleged malpractice take place precisely at the time of birth. The plain meaning of the statutory language clearly indicates that the pertinent provision of the Public Health Law requires that the *injury* take place in the course of labor, at the time of birth, or during the birth admission.").

94. *See id.* at 248–50, 57 N.Y.S.3d at 664–65 (quoting Legislative Memorandum of Sen. Hannon, *supra* note 59, at 1654).

95. *See K.I.*, 57 Misc. 3d at 250–51, 57 N.Y.S.3d at 666 (quoting Nat'l Inst. of Health, *About Labor and Delivery*, DEP'T HEALTH AND HUM. SERV. (Sept. 1, 2017), https://www.nichd.nih.gov/health/topics/labor-delivery/topicinfo).

understanding that the injury to the infant occurred during the prenatal stage of labor had no medical foundation; i.e., the infant was born mere hours after the mother experienced vaginal bleeding.[96] Additionally, the court rejected the mother's affidavit indicating that the infant's hypoxia occurred prior to delivery inasmuch as the mother was not an expert and, in any event, that opinion was not consistent with the medical records, which only presumed placental abruption at the time of the cesarean section.[97] The court also noted that the mother's affidavit was not provided in support of any medical issue on the case.[98] Rather, the mother made the affidavit in support of the Order to Compromise, the purpose of which is to approve the reasonableness of the settlement for the infant, not to make any medical determinations at that point.[99] As an aside, the court also noted that the mother's affidavit was based on what someone else said and thus would have generated a hearsay objection at trial.[100]

Therefore, the court, in considering the aforementioned legislative intent and rejecting the third-party party administrator's arguments opposing the enrollment of the infant in the MIF, granted the petitioner's application and compelled acceptance of the infant into the MIF.[101]

3. Conclusion

In light of the foregoing legislative changes and the court's decision in *K.I.*, New York has clarified its intent in providing for the future health care costs of neurologically-impaired infants that were injured as the result of medical malpractice during birth. That is, New York has definitively stated that the location of birth is of no moment; rather, it is the nature and timing of the birth-related injury that matters.[102] In *K.I.*, New York also signaled its intent to include as many infants and children as possible in the MIF by adopting a broader definition of how to determine whether an individual has suffered a birth-related injury.[103]

B. Hospital Incident Reports and Exemption from Disclosure

In *Phillips v. City of New York*, the Bronx County Supreme Court further clarified the extent to which hospital incident reports are protected from disclosure.[104] The court determined that a hospital incident report

96. *Id.* at 251, 57 N.Y.S.3d at 666.
97. *See id.*
98. *Id.*
99. *Id.* at 251–52, 57 N.Y.S.3d at 666–67.
100. *See K.I.*, 57 Misc. 3d at 252, 57 N.Y.S.3d at 667.
101. *Id.*
102. *See id.* at 250, 57 N.Y.S.3d at 665.
103. *See id.* at 249, 57 N.Y.S.3d at 665.
104. *See* 54 Misc. 3d 294, 296, 40 N.Y.S.3d 751, 752 (Sup. Ct. Bronx Cty. 2016).

documenting a patient's assault of a hospital employee was protected from disclosure pursuant to Mental Hygiene Law § 29.29, Education Law § 6527, and Public Health Law § 2805-m.[105]

By way of background, obtaining disclosure of quality assurance, utilization review, or physician credentialing material, even if relevant to the civil action for which the materials are sought, is virtually impossible unless the disclosure is being made to the New York State Department of Health or to another hospital for purposes of credentialing a physician.[106] There is one clear exception, of which many practitioners are aware. Statements made by a party to a hospital's quality assurance committee, the subject of which is relevant to the action or proceeding at issue, are subject to disclosure.[107] However, the rest of the incident report remains privileged; i.e., the party's statements do not eliminate the privilege for the rest of the incident report.[108] Otherwise: (1) reports of a quality assurance or utilization review committee, (2) reports generated as part of a medical, dental, or podiatric malpractice review program, (3) documentation produced as part of granting or renewing privileges to a physician, dentist, or podiatrist, (4) reports of adverse events occurring at the hospital, and (5) incident reports concerning mental health patients at health facilities, are not subject to disclosure under CPLR Article 31 and no individual who is a member of such a review committee may be required to testify about the discussions that transpired at such a meeting.[109]

In light of that background, we turn to *Phillips*. In *Phillips v. City of New York*, the plaintiff brought an action seeking damages for injuries sustained while working as a special education teacher at Bronx Lebanon Hospital in a unit that permitted student-patients with special needs to attend classes.[110] A student-patient allegedly assaulted the plaintiff at the hospital.[111] During the course of discovery, the plaintiff moved for an order compelling Bronx Lebanon Hospital (a nonparty) to comply with a subpoena duces tecum previously ordered by the court "to produce documents responsive to the subpoena for an in camera inspection."[112] After the court-ordered subpoena was served on the hospital, the hospital

105. *Id.*

106. N.Y. EDUC. LAW § 6527(3) (McKinney 2016 & Supp. 2018); N.Y. PUB. HEALTH LAW § 2805-m(1)–(2) (McKinney 2012 & Supp. 2018).

107. EDUC. § 6527(3).

108. *See id.*

109. *Id.*; *see* N.Y. PUB. HEALTH LAW §§ 2805-j(1)(a), (f), 2805-k(1), 2805-*l* (1)(a), 2805-m(1)–(2) (McKinney 2012); N.Y. MENTAL HYG. LAW § 29.29(1)(ii) (McKinney 2011).

110. 54 Misc. 3d at 295, 40 N.Y.S.3d at 751.

111. *Id.*

112. *Id.*

provided the plaintiff with the majority of documents requested, except for the completed "OMH Incident Reporting Form," which the hospital provided with a privilege log for an in camera inspection to determine whether the hospital's claim of privilege was proper under Mental Hygiene Law § 29.29, Education Law § 6527, Public Health Law § 2805-m, and 14 NYCRR § 524.9(e).[113]

The court determined that the hospital's incident report was exempted from disclosure pursuant to Education Law § 6527(3) and Mental Hygiene Law § 29.29.[114] Initially, the court noted that Education Law § 6527(3) expressly exempts disclosure of incident reports prepared pursuant to Mental Hygiene Law § 29.29.[115] Incident reports are those "reports of accidents and injuries affecting patient health and welfare," including reports of "any allegations of 'violent behavior exhibited by either patients or employees.'"[116] Although the plaintiff argued that the burden of proof to exempt a document from disclosure under Education Law § 6527(3) is on the organization seeking the protection, the court disagreed.[117] The court reviewed *Katherine F. v. New York* and determined that the language of Education Law § 6527(3) was unequivocal in referencing and exempting reports created pursuant to Mental Hygiene Law § 29.29, which includes incident reports on patient safety issues such as violent behavior on the part of a patient or facility employee.[118] Therefore, when Education Law § 6527(3) and Mental

113. *See id.* at 295, 40 N.Y.S.3d at 751–52.

114. *See id.* at 297, 40 N.Y.S.3d at 753.

115. *See Phillips*, 54 Misc. 3d at 296, 40 N.Y.S.3d at 752 (quoting Katherine F. v. New York, 94 N.Y.2d 200, 204, 723 N.E.2d 1016, 1017, 702 N.Y.S.2d 231, 232 (1999)).

116. *Id.* (internal quotation marks omitted) (quoting *Katherine F.*, 94 N.Y.2d at 204, 723 N.E.2d at 1017, 702 N.Y.S.2d at 232).

117. *See id.*

118. *See id.* In *Katherine F.*, the Court of Appeals upheld the appellate division's determination that the defendant psychiatric hospital's incident reports regarding a hospital employee's sexual abuse and assault of her child who was a patient at the hospital were exempted from disclosure under Education Law § 6527 (3). *Katherine F.*, 94 N.Y.2d at 203, 205–06, 723 N.E.2d at 1017–18, 702 N.Y.S.2d at 232–33. More specifically, the Court of Appeals determined that the incident reports the hospital produced were done in accordance with Mental Hygiene Law § 29.29, which requires psychiatric hospitals to appoint a "patient care and safety team" to conduct investigations and reporting of "any incidents of violent behavior exhibited by a hospital employee." *Id.* at 205, 723 N.E.2d at 1018, 702 N.Y.S.2d at 233 (quoting N.Y. MENTAL HYG. LAW § 29.29(1)(ii) (McKinney 2011)). Furthermore, the Court of Appeals determined that such incident reports were unequivocally part of the psychiatric hospital's quality assurance function, inasmuch as any incident reports must be transmitted to the Commissioner of the Office of Mental Health, who then forwards the reports to the State Commission on Quality of Care for the Mentally Disabled. *Id.* at 205, 723 N.E.2d at 1018, 702 N.Y.S.2d at 233 (citing MENTAL HYG. § 29.29(4)–(5)). Therefore, the Court of Appeals determined that an investigation report prepared by a physician for the Director of Quality Assurance, two incident reports prepared by hospital personnel, and an incident report prepared by the State Office of Mental Health's Bureau of Safety and Security

Hygiene Law § 29.29 are read together, the court concluded that the incident report Bronx Lebanon Hospital generated with regard to the patient's assault on the plaintiff, was exempt from disclosure.[119]

The plaintiff further argued that she was entitled to disclosure of the report to the extent that the report contained statements by the plaintiff herself and because she is a party to the action.[120] The court rejected that argument, noting that the disclosure applied only to the "testimony" of an individual, not the incident report itself.[121] The court also rejected the plaintiff's argument that the need for the incident report outweighed the privilege inasmuch as there was no concern that the plaintiff failed to remember the details of the incident herself and therefore, the court determined that there was no need to override the privilege and exempted the incident report from disclosure.[122]

In light of the foregoing, we are reminded of the strong statutory protections afforded to hospitals and medical centers in protecting internal quality assurance documents from disclosure. Although *Phillips* hints that perhaps the outcome would have been different if the plaintiff had not remembered the details of the incident herself, the statutory protections provided to hospitals and medical centers should not be overridden lightly.[123] As a matter of public policy, we want our hospitals and medical centers to improve the quality of their facilities for members of the public without fear of reprisal for doing so.[124] Put differently, we want hospitals and medical centers to remedy wrongs that may occur and such facilities should not have to be concerned with whether their internal quality reviews for purposes of improving patient care will be subject to disclosure and used to show evidence of negligence in a court of law.

C. Update on Legalization of Aid-in-Dying

In our last *Survey* article, we discussed the First Department's decision in *Myers v. Schneiderman*,[125] where the appellate division interpreted that the Penal Law prohibited a physician from actively aiding a patient in dying and upheld the constitutionality of prosecuting

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Services were clearly exempt from disclosure under Education Law § 6527 (3), which expressly includes reports prepared pursuant to Mental Hygiene Law § 29.29. *Id.* at 206, 723 N.E.2d at 1018, 702 N.Y.S.2d at 233.

119. *See Phillips*, 54 Misc. 3d at 296, 40 N.Y.S.3d at 752.

120. *Id.* at 297, 40 N.Y.S.2d at 752–53.

121. *Id.* at 297, 40 N.Y.S.2d at 753.

122. *See id.*

123. *See id.*

124. *See* Katherine F. v. New York, 94 N.Y.2d 200, 205, 723 N.E.2d 1016, 1018, 702 N.Y.S.2d 231, 233 (1999).

125. *See* Samuel J.M. Donnelly & Mary Ann Donnelly, *2015–16 Survey of New York Law: Health Law*, 67 SYRACUSE L. REV. 989, 998–1003 (2017).

physicians who provide aid-in-dying under the Penal Law.[126] The plaintiffs in *Myers* appealed to the Court of Appeals, which rendered its decision on September 7, 2017.[127] The Court of Appeals, in a unanimous per curiam opinion, affirmed the appellate division's decision.[128]

First, the Court of Appeals determined that the language of Penal Law §§ 120.30 and 125.15(3), which govern assisting a person in committing suicide, "apply to anyone who assists an attempted or completed suicide"[129] without exception, which had already been clarified by the Court of Appeals in *People v. Duffy*.[130]

Second, the Court of Appeals rejected the plaintiffs' claims that assisted suicide statutes, as applied to aid-in-dying, violate an individual's constitutional equal protection and due process rights.[131] More specifically, the Court of Appeals determined that an individual's equal protection rights afforded in New York State are coextensive with those guaranteed under the federal Constitution as outlined in *Vacco v. Quill*,[132] where the U.S. Supreme Court determined that New York's ban on assisted suicide was constitutional because assisting a suicide is different from a patient refusing lifesaving medical treatment for him or herself.[133] Therefore, the Court of Appeals saw no reason to depart from that distinction in *Myers*.[134] On the ground of due process, the Court of Appeals rejected the plaintiffs' claim that the assisted suicide statutes unconstitutionally burdened the plaintiffs' fundamental right of self-determination to control the course of their medical treatment, which includes aid-in-dying.[135] Although the Court of Appeals acknowledged that New York's Due Process Clause sometimes provides greater constitutional protections than its federal counterpart, the right to obtain assistance to end one's life is not, and has never been, part of New York's

126. *See* 140 A.D.3d 51, 65, 31 N.Y.S.3d 45, 55–56 (1st Dep't 2016), *aff'd*, 30 N.Y.3d 1, 85 N.E.3d 57, 62 N.Y.S.3d 838 (2017).

127. Myers v. Schneiderman, 30 N.Y.3d 1, 11, 85 N.E.3d 57, 61, 62 N.Y.S.3d 838, 842 (2017). Although we recognize that the Court of Appeals' decision is beyond the scope of this *Survey* year, we felt it necessary to provide a brief update on what appears to be end of the aid-in-dying discussion in New York before the next *Survey* year.

128. *Id.* at 10, 17, 85 N.E.3d at 60, 65, 62 N.Y.S.3d at 841, 846.

129. *See id.* at 12, 85 N.E.3d at 62, 62 N.Y.S.3d at 843.

130. *See id.* at 12–13, 85 N.E.3d at 62, 62 N.Y.S.3d at 843 (citing People v. Duffy, 79 N.Y.2d 611, 615, 595 N.E.2d 814, 817, 584 N.Y.S.2d 739, 742 (1992)).

131. *See id.* at 13, 85 N.E.3d at 62, 62 N.Y.S.3d at 843.

132. *Myers*, 30 N.Y.3d at 13, 85 N.E.3d at 62, 62 N.Y.S.3d at 843 (first citing People v. Aviles, 28 N.Y.3d 497, 502, 68 N.E.3d 1208, 1211, 46 N.Y.S.3d 478, 481 (2016); and then citing Vacco v. Quill, 521 U.S. 793, 797 (1997)).

133. *See Vacco*, 521 U.S. at 800–01.

134. *Myers*, 30 N.Y.3d at 13, 85 N.E.3d at 62, 62 N.Y.S.3d at 843.

135. *See id.* at 13–14, 85 N.E.3d at 63, 62 N.Y.S.3d at 844.

broader due process protections.[136] Instead, the Court of Appeals reiterated its long-held distinction between refusing life-sustaining treatment and assisted suicide: "In the case of the terminally ill, refusing treatment involves declining life-sustaining techniques that intervene to delay death. Aid-in-dying, by contrast, involves a physician actively prescribing lethal drugs for the purpose of directly causing the patient's death."[137]

In that light, the Court of Appeals determined that the right to die was not a fundamental one and therefore, "the assisted suicide statutes need only be rationally related to a legitimate government interest."[138] The Court determined that the State had a legitimate government interest in preserving life and preventing suicide, which is a public health problem, and in protecting against the risks of misuse of a prescription dose of a lethal medication.[139] The Court of Appeals further referred to the U.S. Supreme Court's decision in *Vacco* for a list of legitimate State interests in prohibiting assisted suicide, which include "prohibiting intentional killing and preserving life; preventing suicide; maintaining physicians' role as their patients' healers; protecting vulnerable people from indifference, prejudice, and psychological and financial pressure to end their lives; and avoiding a possible slide toward euthanasia."[140] Therefore, the Court of Appeals concluded that the State Legislature had a legitimate government interest in criminalizing assisted suicide.[141]

Although Judge Rivera concurred in the per curiam opinion, she determined that the State's interests in banning assisted suicide "are not absolute or unconditional."[142] Rather, she would carve out an exception for mentally-competent, terminally-ill patients approaching the "final stage of the dying process that is agonizingly painful and debilitating."[143] Judge Rivera further explained that the State cannot prevent the inevitable for a terminally ill patient and that, in those cases, the State's interest in protecting against misuse of a lethal dose of prescription medication or in preventing suicide does not outweigh the patient's "right to self-

136. *See id.* at 14, 85 N.E.3d at 63, 62 N.Y.S.3d at 844 (citing *Aviles*, 28 N.Y.3d at 505, 68 N.E.3d at 1213–14, 46 N.Y.S.3d at 483).

137. *Id.* at 15, 85 N.E.3d at 63, 62 N.Y.S.3d at 844.

138. *Id.* at 15, 85 N.E.3d at 64, 62 N.Y.S.3d at 845 (citing People v. Knox, 12 N.Y.3d 60, 67, 903 N.E.2d 1149, 1152, 875 N.Y.S.2d 828, 832 (2009)).

139. *Myers*, 30 N.Y.3d at 16, 85 N.E.3d at 64, 62 N.Y.S.3d at 845 (first citing Bezio v. Dorsey, 21 N.Y.3d 93, 104, 989 N.E.2d 942, 950, 967 N.Y.S.2d 660, 668 (2013); and then citing Washington v. Glucksberg, 521 U.S. 702, 729 (1997)).

140. *Id.* (internal quotation marks omitted) (quoting Vacco v. Quill, 521 U.S. 793, 808–09 (1997)).

141. *Id.* at 17, 85 N.E.3d at 65, 62 N.Y.S.3d at 846.

142. *Id.* at 18, 85 N.E.3d at 66, 62 N.Y.S.3d at 847 (Rivera, J., concurring).

143. *Id.*

determination or the freedom to choose a death that comports with the individual's values and sense of dignity."[144] Indeed, Judge Rivera noted that the State's interest diminishes for the patient who does not have a choice as to whether to live or die, but only as to how he or she will die.[145] Judge Rivera also opined that the State could choose not to do anything for a terminally ill patient and to let death take its natural course, but the State had not done that by virtue of allowing a patient to refuse life-sustaining treatment.[146] Furthermore, physicians do not passively participate in a patient's refusal of life-sustaining treatment; i.e., there is nothing passive about turning off a ventilator or withholding nutrition.[147] The same is true for physicians who provide a lethal dose of medication for the patient to administer him or herself.[148] Finally, Judge Rivera noted that the test is not the physician's intent or role in assisting the patient that is balanced against the State's interests in determining whether assisted suicide is constitutionally permitted; rather, it is the patient's own right to autonomy and personal integrity that is balanced against the State's interests that is the deciding factor in determining the constitutionality of assisted suicide.[149]

In his concurrence, Judge Fahey's concerns with legalizing assisted suicide included that it could lead to unanticipated consequences, such as putting the State on a slippery slope toward legalizing nonvoluntary euthanasia (i.e., euthanasia of an infant or mentally incompetent individual), and that it would expand to include persons not terminally ill.[150] In Judge Garcia's concurrence, he opined that, to the extent that the plaintiffs asserted a '"more particularized' challenge to the assisted suicide statutes"; i.e., based on individual patients' circumstances, he would reject those claims.[151] In other words, Judge Garcia opined that, even when applied to a particular patient, the challenges to the State's ban on assisted suicide do not survive rational basis review.[152] Judge Garcia

144. *Myers*, 30 N.Y.3d at 18, 85 N.E.3d at 66, 62 N.Y.S.3d at 847 (Rivera, J., concurring).

145. *Id.* at 24, 85 N.E.3d at 70, 62 N.Y.S.3d at 851 (quoting Washington v. Glucksberg, 521 U.S. 702, 746 (1997) (Stevens, J., concurring)) (citing Wilkinson v. Skinner, 34 N.Y.2d 53, 58, 312 N.E.2d 158, 161, 356 N.Y.S.2d 15, 121–22 (1974)).

146. *See id.* (citing Fosmire v. Nicoleau, 75 N.Y.2d 218, 227, 551 N.E.2d 77, 81–82, 551 N.Y.S.2d 876, 880–81 (1990)).

147. *See id.*

148. *Id.* at 26, 85 N.E.3d at 72, 62 N.Y.S.3d at 853 (quoting Timothy E. Quill et al., *Palliative Options of Last Resort*, 278 J. AM. MED. ASS'N 2099, 2102 (1997)).

149. *Myers*, 30 N.Y.3d at 28, 85 N.E.3d at 73, 62 N.Y.S.3d at 854 (quoting Rivers v. Katz, 67 N.Y.2d 485, 498, 495 N.E.2d 337, 344, 504 N.Y.S.2d 74, 81 (1986)).

150. *Id.* at 35, 37, 85 N.E.3d at 78–80, 62 N.Y.S.3d at 859–61 (Fahey, J., concurring) (citing L.W. SUMMER, ASSISTED DEATH: A STUDY IN ETHICS AND LAW 17 (1st ed. 2011)).

151. *Id.* at 48, 85 N.E.3d at 87, 62 N.Y.S.3d at 868 (Garcia, J., concurring) (quoting Washington v. Glucksberg, 521 U.S. 702, 750 (1997) (Stevens, J., concurring)).

152. *Id.* at 56, 85 N.E.3d at 93, 62 N.Y.S.3d at 874. Judge Garcia's opinion is based, in

further noted that the State's interests in preserving life and promoting "sound medical ethics" do not diminish just because a patient is terminally ill and facing a painful death, that suicidal thoughts can be managed medically and with counseling, and that the risk of misuse of a lethal dose of a prescription medicine persists in the final stages of life inasmuch as many patients ultimately do not take the drug and may do so accidentally if provided.[153] Therefore, Judge Garcia opined that New York's Due Process Clause does not include a fundamental right to physician-assisted suicide.[154] Finally, Judge Garcia expressly noted that, although a successful constitutional challenge to New York's ban on physician-assisted suicide is not foreclosed, "it is difficult to conceive of such a case" where such a challenge would be successful in light of the Court of Appeals' holding in *Myers* that "heightened scrutiny is unwarranted."[155]

In light of the foregoing, it is generally clear that New York has rendered what is for all intents and purposes, a final decision banning physician-assisted suicide in New York State. Although a case involving a mentally-competent, terminally-ill patient facing an imminent and painful death might sway some of the Court to carve out an exception to permit physician-assisted suicide (e.g., Judge Rivera), the Court of Appeals nevertheless agrees that only a rational basis level of review is warranted and that it is a mighty hard obstacle for a patient to overcome to challenge New York's ban on assisted suicide.

D. Extension of Absolute Privilege as a Defense to Defamation

The First Department recently clarified what constitutes privileged communications in defense to a claim of defamation. In *Stega v. New York Downtown Hospital*, the plaintiff research scientist was the chair of the defendant hospital's Institutional Review Board (IRB).[156] The IRB is a board of individuals designated by the defendant to "review, approve[,] and oversee its biomedical research involving human subjects."[157] The defendant was testing a compound for the treatment of cancer.[158] The

part, on the alleged door left open by Justice Stevens in *Washington v. Glucksberg*; namely that the Court was upholding New York's "general public policy against assisted suicide," but that the potential harms surrounding assisted suicide "will not always outweigh the individual liberty interest of a particular patient." *Glucksberg*, 521 U.S. at 749–50 (Stevens, J., concurring).

153. *Myers*, 30 N.Y.3d at 56–57, 85 N.E.3d at 93–94, 62 N.Y.S.3d at 874–75.

154. *Id.* at 58, 85 N.E.3d at 94, 62 N.Y.S.3d at 875.

155. *Id.* at 58, 85 N.E.3d at 94–95, 62 N.Y.S.3d at 875–76 (quoting *Glucksberg*, 521 U.S. at 735, n.24 (majority opinion)).

156. 148 A.D.3d 21, 23, 44 N.Y.S.3d 417, 418 (1st Dep't 2017).

157. *Id.*

158. *Id.*

drug's manufacturer retained an oncologist to create research protocol and perform a clinical trial for the drug.[159] However, because the oncologist was unable to develop research protocol, he requested that the plaintiff do it.[160]

The plaintiff was successful and received compensation from the drug company.[161] The oncologist subsequently applied for approval of the study from the IRB, which was granted, and began his clinical trial.[162] However, he ran into financial problems such that he and the drug company requested that the plaintiff take over the trial.[163] The oncologist left the study without developing alternative treatment plans for the patients.[164] The defendant, pursuant to the supervision of the plaintiff, treated the patients.[165] When the drug company asked the defendant to take over the study, the plaintiff disclosed that the drug manufacturer had paid her.[166]

"[The plaintiff] was placed on administrative leave pending an investigation of her conduct," and was subsequently terminated.[167] The plaintiff filed a formal complaint with the Food and Drug Administration (FDA) due to concerns that the patients in research protocols by the IRB "would not be properly supervised."[168] The FDA commenced its investigation, including an onsite inspection of the defendant.[169]

During the course of its investigations, the chief medical officer of the hospital allegedly told the FDA that the plaintiff was removed because she had '"channeled' funds from [the] research study sponsor [in]to her own research group and that she had [told the oncologist] that she could use her position on the IRB to get a patient into the study."[170] The representative also claimed that while the plaintiff was the chairperson, all IRB approvals were "tainted."[171] The plaintiff subsequently brought suit for defamation against the defendant hospital as well as the chief medical officer.[172]

159. *Id.*
160. *Id.* at 23, 44 N.Y.S.3d at 418–19.
161. *Stega*, 148 A.D.3d at 23, 44 N.Y.S.3d at 419.
162. *Id.* at 23–24, 44 N.Y.S.3d at 419.
163. *Id.* at 24, 44 N.Y.S.3d at 419.
164. *Id.*
165. *Id.*
166. *Stega*, 148 A.D.3d at 24, 44 N.Y.S.3d at 419.
167. *Id.* at 24–25, 44 N.Y.S.3d at 419–20.
168. *Id.* at 25, 44 N.Y.S.3d at 420.
169. *Id.*
170. *Id.*
171. *Stega*, 148 A.D.3d at 25, 44 N.Y.S.3d at 420.
172. *Id.*

The defendant hospital moved to dismiss on the grounds that the representative's statements were absolutely privileged.[173] The motion court denied the motion and found that the statements were protected by a common interest qualified privilege since the FDA investigation did not have the indicia of a quasi-judicial proceeding.[174] The defendants appealed.[175]

Generally, an absolute privilege extends to "communications made by individuals participating in [public functions], such as executive, legislative, judicial[,] or quasi-judicial proceedings . . . ."[176] The purpose is to "ensure that [an individual's] own personal interests," such as being subjected to a civil lawsuit, do not adversely impact the performance of the individual's public function.[177]

The First Department explained that courts have extended the absolute privilege to apply to a wide variety of hearings held by administrative agencies since they are "in substance judicial."[178] As agencies continue to take on a more prominent role, courts have recognized that "certain attributes of the judicial process have equal relevance to those administrative bodies that utilize a quasi-judicial process in the determination of individual rights, privileges[,] or obligations."[179] The First Department explained that the trend has thus been to extend the privilege to statements made during the *investigatory process* of an agency where the statements are "material and pertinent to the questions involved."[180]

"The FDA is an administrative agency of the federal government."[181] It is responsible for overseeing the operation of IRBs in conducting new drug protocols.[182] In the event the FDA, in the course of its investigation, finds the IRB is noncompliant with governing

173. *Id.*

174. *Id.*

175. *Id.*

176. *Stega*, 148 A.D.3d at 25–26, 44 N.Y.S.3d at 420 (internal quotation marks omitted) (quoting Rosenberg v. MetLife, Inc., 8 N.Y.3d 359, 365, 866 N.E.2d 439, 442–43, 834 N.Y.S.2d 494, 497–98 (2007)).

177. *Id.* at 26, 44 N.Y.S.3d at 420 (internal quotation marks omitted) (quoting *Rosenberg*, 8 N.Y.3d at 365, 866 N.E.2d at 442–43, 834 N.Y.S.2d at 497–98).

178. *Id.* at 26, 44 N.Y.S.3d at 421 (quoting Allan & Allan Arts v. Rosenblum, 201 A.D.2d 136, 139–40, 615 N.Y.S.2d 410, 412 (2d Dep't 1994)).

179. *Id.* at 26, 44 N.Y.S.3d at 420–21 (first quoting *Allan & Allan Arts*, 201 A.D.2d at 139, 615 N.Y.S.2d at 412).

180. *Id.* at 26–27, 32–33, 44 N.Y.S.3d at 421, 425–26 (first citing Herzfeld & Stern v. Beck, 175 A.D.2d 689, 691, 572 N.Y.S.2d 683, 685 (1st Dep't 1991); and then citing Cicconi v. McGinn, Smith & Co., 27 A.D.3d 59, 62, 808 N.Y.S.2d 604, 606 (1st Dep't 2005)).

181. *Stega*, 148 A.D.3d at 28, 44 N.Y.S.3d at 422.

182. *Id.*

regulations, the FDA can disqualify the IRB or its parent institution.[183] The FDA will then institute proceedings for a regulatory hearing, which is subject to judicial review.[184] The First Department explained that given the possibility for an adversarial hearing before the FDA and judicial review, this is the type of quasi-judicial process for which an absolute privilege should apply.[185] The court thus held that "statements made to an investigator in the course of the initial investigation by the FDA into the hospital's IRB are protected by an absolute privilege."[186] Finding that "there is a strong public interest in ensuring that those with information about research protocols for newly developed drugs are encouraged to speak fully and candidly, without any need for self-censorship," the First Department reversed the denial of the defendant's motion to dismiss.[187]

The dissent argued that any hearing following the FDA's investigation would not be an avenue for the plaintiff to challenge the defendant's alleged defamatory allegations; instead, the hearing would be between the IRB and the FDA.[188] As such, the FDA's investigatory process lacked the "safeguards" the Court of Appeals in the seminal case *Toker v. Pollak*[189] had envisioned in refusing to extend the absolute privilege to certain agency proceedings.[190] The plaintiff was not the subject of the investigation and had been afforded no due process protections.[191] She thus had no forum to challenge the statements.[192]

As such, the situation in this case was in stark contrast to prior cases holding that statements made during an investigatory proceeding were absolutely privileged. In *Rosenberg v. Metlife, Inc.*, for instance, the

183. *Id.*

184. *Id.* (first citing 21 C.F.R. § 56.121(a) (2017); and then citing 21 C.F.R. § 10.45(a) (2017)).

185. *Id.* at 28–29, 44 N.Y.S.3d at 422 (quoting Rosenberg v. Metlife, Inc., 8 N.Y.3d 359, 366, 866 N.E.2d 439, 443, 834 N.Y.S.2d 494, 498 (2007)) (first citing 21 C.F.R. § 56.121(a); and then citing 21 C.F.R. § 10.45).

186. *Stega*, 148 A.D.3d at 28–29, 44 N.Y.S.3d at 422.

187. *Id.* at 29–30, 44 N.Y.S.3d at 423–24.

188. *Id.* at 34–36, 44 N.Y.S.3d at 427 (Kapnick, J., dissenting) (first citing Herzfeld & Stern v. Beck, 175 A.D.2d 689, 691, 572 N.Y.S.2d 683, 685 (1st Dep't 1991); then citing *Rosenberg*, 8 N.Y.3d at 367, 866 N.E.2d at 444, 843 N.Y.S.2d at 499; and then citing 21 C.F.R. § 10.45).

189. 44 N.Y.2d 211, 222, 376 N.E.2d 163, 168, 405 N.Y.S.2d 1, 7 (1978) (first citing Bradley v. Hartford Acc. & Ind. Co., 30 Cal. App. 3d 818, 823 (1973); and then citing McAfee v. Feller, 452 S.W.2d 56, 57–58 (1970)) (holding that because there was no quasi-judicial hearing at which the subject of the defamatory statements could have challenged the statements, and the hearing would not have been subject to judicial review, the comments to the Department of Investigation were not protected by an absolute privilege).

190. *Id.*; *Stega*, 148 A.D.3d at 35, 44 N.Y.S.3d at 427 (Kapnick, J., dissenting).

191. *Stega*, 148 A.D.3d at 35, 44 N.Y.S.3d at 427 (Kapnick, J., dissenting) (citing 21 C.F.R. § 10.45).

192. *Id.* at 35, 44 N.Y.S.3d at 427.

Court of Appeals looked at "whether statements made by an employer on a National Association of Securities Dealers (NASD) employee termination notice (Form U-5)" were subject to an absolute privilege.[193] The Court found that NASD performs regulatory functions like the Security and Exchange Commission (SEC).[194] During its investigations of violations of the SEC's laws, NASD can hold "disciplinary proceedings against registered representatives for securities violations" before a hearing panel.[195] These determinations are subject to judicial review.[196] Impliedly, the former employee can appear before a panel at a hearing as the investigation ensues, the decision from which the former employee can appeal. The Court found that "[t]he Form U-5's compulsory nature and its role in the . . . quasi-judicial process," coupled with the public interest in the accuracy of the form, should be protected by an absolute privilege.[197]

The First Department's broad interpretation of a quasi-judicial proceeding fortifies absolute privilege as a defense to defamation claims. Whereas prior case law seemed to suggest that the subject of the defamatory statement must have the benefit of a hearing and judicial review of that outcome in order for the proceeding to be considered quasi-judicial, the First Department seemed to broaden the scope of the privilege to encompass scenarios where as long as there is an administrative hearing of some sort, regardless of whether the subject is entitled to participation, statements during the investigatory process are protected pursuant to an absolute privilege. As agencies continue to take on a more significant role in society, particularly in the healthcare industry, it is probable that the privilege will continue to expand.

III. NEW YORK STATE LEGISLATION

Within the last *Survey* year, New York State has had two major legislative developments, one involving the modification of the statute of limitations to bring a medical malpractice matter to run from the time of discovery, not the time of the alleged malpractice, and the other involving New York's adoption of the principles of the federal 21st Century Cures Act, which is discussed above.

193. 8 N.Y.3d 359, 361–62, 866 N.E.2d 439, 440, 834 N.Y.S.2d 494, 495 (2007).

194. *Id.* at 367, 866 N.E.2d at 444, 834 N.Y.S.2d at 499 (quoting DL Capital Grp., LLC v. Nasdaq Stock Mkt., Inc., 409 F.3d 93, 95 (2d Cir. 2005)).

195. *Id.*

196. *Id.* (citing 15 U.S.C. §§ 78s(d), (e), 78y(a)(1) (2012)).

197. *Id.* at 368, 866 N.E.2d at 444, 834 N.Y.S.2d at 499.

A. Lavern's Law

Named for Brooklyn woman Lavern Wilkinson, Lavern's Law amends the statute of limitations for commencing a medical malpractice action to run from the discovery of the initial alleged malpractice (or the time when the malpractice should have been discovered), and not from the time the initial alleged malpractice occurred.[198] The concept is not novel and, in fact, New York is one of only six states to not have a discovery rule in place by which a medical malpractice statute of limitations is measured.[199] The other states include Arkansas, Idaho, Maine, Minnesota, and South Dakota.[200]

Ms. Wilkinson's case involved the alleged failure to diagnose lung cancer.[201] In 2010, she presented to Kings County with chest pain, and an X-ray was taken, which the resident physician in the emergency room read as being unremarkable.[202] Ms. Wilkinson was sent home and started to have trouble breathing, which the hospital physicians attributed to asthma.[203] However, in 2012, a physician looked at the 2010 chest X-ray again and saw what the physician should have seen the first time; i.e., a small mass that was likely curable at the time, instead of "full-blown lung cancer" that had metastasized to other organs.[204] Upon discovery of the mass, Ms. Wilkinson tried to sue the hospital—which was city-owned—for malpractice, but it was too late, as she failed to bring the lawsuit against the municipal entity within fifteen months of when the alleged medical malpractice occurred in 2010.[205] Ms. Wilkinson ultimately died in March 2013 at forty-one years of age.[206]

Ms. Wilkinson's case resulted in state legislators devising a new law, colloquially known as Lavern's Law (Senate Bill S6800), that would measure the time to bring a medical malpractice lawsuit from the time the allegedly-injured individual discovered the malpractice, or should have discovered it, not from the time of the malpractice itself.[207] That version

198. Act of Jan. 31, 2018, 2017 McKinney's Sess. Laws of N.Y., ch. 506, at 1105–07 (codified at N.Y. C.P.L.R. 203, 214-a); *Reset the Clock for Malpractice Suits*, N.Y. TIMES (Aug. 18, 2017), https://www.nytimes.com/2017/08/18/opinion/new-york-laverns-law-malpractice.html.

199. *Reset the Clock for Malpractice Suits*, *supra* note 198.

200. *Id.*

201. *Id.*

202. *Id.*

203. *Id.*

204. *Reset the Clock for Malpractice Suits*, *supra* note 198.

205. *Id.*

206. *Id.* (explaining how the City had previously provided Ms. Wilkinson with a settlement of $625,000 prior to dying).

207. N.Y. Senate Bill No. 6800, 240th Sess. (2017) (N.Y. C.P.L.R. 203, 214-a); *Reset the Clock for Malpractice Suits*, *supra* note 197; *see* Kenneth Lovett, *Pared Down Lavern's Law*

of the law was significantly narrowed to claims of failure to diagnose cancer in order to ensure that it would pass both the State Assembly and State Senate and get to Governor Cuomo's desk.[208]

On June 21, 2017, the New York State Senate passed Lavern's Law, leaving only the need for Governor Cuomo's approval for the amendment to the statute of limitations to become law.[209] As described generally above, the goal of Lavern's Law was to

> amend the statute of limitations for medical, dental or podiatric malpractice to include a discovery of injury rule for failure to diagnose cancer or a malignant tumor, allowing the current two and half year statute of limitations to run from the date an injured patient discovers, or should have discovered, that their injury was caused by malpractice.[210]

Specifically, Lavern's Law proposed to modify Civil Practice Law and Rules (CPLR) 203(g) by adding a new paragraph indicating that, for purposes of commencing a medical, dental or podiatric malpractice action against the State or other municipal entity, the time period for bringing such an action does not begin to run until the later of either (1) when the allegedly injured party "knows or reasonably should have known of the negligent failure to diagnose cancer or a malignant tumor" and "knows or reasonably should have known" that the failure to diagnose caused the injury; or (2) "the date of the last treatment" for the injury, illness, or condition where there is "continuous treatment [of] the same injury, illness or condition [that] gave rise to the accrual of [the] action."[211] Notably, the legislation will not affect the one-year discovery rule for commencing a malpractice action where an individual discovers the presence of a foreign object in his or her body (e.g., retained lap sponge from surgery).[212]

The legislation also proposes to modify CPLR 214-a by measuring the two-and-a-half year statute of limitations from the later of either (1) when the allegedly injured party "knows or reasonably should have known of the . . . negligent failure to diagnose" cancer or a malignant

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Passes in Albany, N.Y. DAILY NEWS (June 21, 2017), http://www.nydailynews.com/news/politics/pared-down-lavern-law-passes-albany-article-1.3266296.

208. N.Y. Assembly Bill No. 8516, 240th Sess. (2017); N.Y. Senate Bill No. 6800; Lovett, *supra* note 207.

209. N.Y. Senate Bill No. 6800 (N.Y. C.P.L.R. 203, 214-a); *see Reset the Clock for Malpractice Suits*, *supra* note 198.

210. Legislative Memorandum of Sen. DeFrancisco, *reprinted in* 2017 McKinney's Session Laws of N.Y., ch. 506, at 1733.

211. Act of Jan. 31, 2018, 2017 McKinney's Sess. Laws of N.Y., ch. 506, at 1106 (codified at N.Y. C.P.L.R. 203).

212. *Id.*

tumor and "knows or reasonably should have known" that the failure to diagnose caused the injury; or (2) "the date of the last treatment" for the injury, illness, or condition where there is "continuous treatment [of] the same injury, illness[,] or condition giving rise to the accrual of [the] action.[213]

However, the discovery period will not exist in perpetuity. Under the proposed modifications to both CPLR 203(g) and CPLR 214-a, no action may be commenced after seven years from "the act, omission[,] or failure complained of," or from the last treatment where continuous treatment is involved.[214] Rather, an allegedly injured individual for failure to timely diagnose cancer will have no more than seven years from the date of the alleged malpractice to bring a medical malpractice action regardless of whether the individual discovers the injury after the seven years.[215] This seven-year maximum holds true and supersedes the provision in Lavern's Law that will give an allegedly-injured individual two-and-a-half years from the effective date of the act to commence a malpractice action if the action would have been timely under the new discovery rule prior to enactment of the act.[216]

Notably, the original version of Lavern's Law called for the discovery rule to be implemented across all medical malpractice cases, not just instances of alleged failure to diagnose cancer and/or a malignant tumor.[217] The original version would have also permitted a one-year window to revive cases that were time-barred under the current statute of limitations.[218] However, the version of Lavern's Law that passed by the State Senate on June 21, 2017 did not include the aforementioned propositions.[219] New York State Senator John DeFrancisco indicated that to get Lavern's Law passed, concessions had to be made, which included the removal of the aforementioned provisions from the original version of the law.[220]

Lavern's Law was signed into law by Governor Cuomo on January 31, 2018.[221] Indeed, it will be interesting to watch whether this is the end of the road for Lavern's Law or whether state legislators will continue to push to broaden the law to include all medical malpractice actions. It

213. Act of Jan. 31, 2018, 2017 McKinney's Sess. Laws of N.Y., ch. 506, at 1106–07 (codified at N.Y. C.P.L.R. 214-a).

214. *Id.*

215. *See id.*

216. *Id.*

217. N.Y. Assembly Bill No. 1056, 236th Sess. (2013); Lovett, *supra* note 207.

218. N.Y. Assembly Bill No. 1056.

219. N.Y. Senate Bill No. 6800; Lovett, *supra* note 207.

220. Lovett, *supra* note 207.

221. N.Y. Senate Bill No. 6800.

certainly seems that way in light of Assemblywoman Helene Weinstein's comments that the current version of Lavern's Law is a "good first step" toward "encompass[ing] all victims of medical malpractice."[222] Although Lavern's Law seems like a "win" for allegedly injured individuals, Governor Cuomo will undoubtedly continue receiving pressure from both sides on further expansion of the statute of limitations to include all medical malpractice actions. Prior to Governor Cuomo approving Lavern's Law, medical societies and hospitals voiced their concerns that insurance premiums would rise and that some physicians would leave the state, which could negatively impact patients' access to medical care in New York State.[223] A spokesperson for the Lawsuit Reform Alliance of New York also indicated that the passing of Lavern's Law could turn what is already a crisis concerning medical care in New York into a catastrophe, although he did not elaborate on that point.[224] Whether there is any impact on insurance premiums or whether there has been any adverse effect on healthcare in New York State remains to be seen, but New York State should be cautious about broadening the statute of limitations for medical malpractice claims any further to avoid what could be strong opposition from physicians and hospitals statewide.

B. Changes in New York Medical Marijuana Regulations[225]

Throughout the year, and as recently as August of 2017, the New York State Department of Health (NYSDOH) announced new sets of regulations aimed at improving the state's medical marijuana program for patients, practitioners, and registered manufacturing and dispensary organizations.[226] By way of background, in July 2014 Governor Cuomo signed the Compassionate Care Act into law, creating a Medical Marijuana Program that regulates the manufacture, sale, and use of medical marijuana.[227] After a lengthy eighteen month phase-in period, the

222. *Id.*

223. *Id.*; *Reset the Clock on Malpractice*, *supra* note 198.

224. Lovett, *supra* note 207.

225. Although we recognize that some of the new medical marijuana regulations spill over into the new survey year, we thought it best to include them here given the significant uptick in the number of patients qualifying for New York State's medical marijuana program. *See* Press Release, N.Y. State Dep't of Health, New York State Department of Health Announces New Regulations to Improve State's Medical Marijuana Program for Patients, Practitioners, and Registered Organizations (Aug. 10, 2017), https://www.health.ny.gov/press/releases/2017/2017-08-10_new_mmp_regulations.htm.

226. *Id.*

227. Press Release, N.Y. Governor's Office, Governor Cuomo Signs Bill to Establish Comprehensive Medical Marijuana Program (July 7, 2014), https://www.governor.ny.gov/news/governor-cuomo-signs-bill-establish-comprehensive-medical-marijuana-program [hereinafter Medical Marijuana Signing Press Release].

Program officially launched on January 7, 2016.[228] However, the State's progressive Act did not alter the laws regarding recreational use of marijuana, which remains illegal in New York State.[229]

At its most basic level, the Program allows healthcare practitioners to certify qualifying patients for medical marijuana use in nonsmoking forms including pills, oils, and vapors.[230] To qualify, a patient must suffer from a severe or life-threatening condition (e.g., cancer, HIV or AIDS, ALS, etc.) that is coupled with a complicating condition such as chronic pain, seizures, or severe nausea.[231] The governing regulations outline eleven life-threatening conditions and five complicating conditions.[232] Further, qualified patients must be a resident of New York State and obtain a registry identification card from the NYSDOH that must be carried with them whenever they are in possession of medical marijuana.[233] While there is a wealth of other regulations governing the Program, the underlying premise is simple—give eligible patients access to medical marijuana for legitimate healthcare purposes.

Unfortunately, the original iteration of the Program did not adequately achieve this goal. In practice, there were several deficiencies that prevented the Program from running smoothly and efficiently.[234] For

228. N.Y. PUB. HEALTH LAW § 3369-b (McKinney Supp. 2018); Press Release, N.Y. State Dep't of Health, NYS Department of Health Announces January 7 Launch of Medical Marijuana Program (Jan. 5, 2016), https://www.health.ny.gov/press/releases/2016/2016-01-05_launch_of_medical_marijuana_program.htm.

229. *See* Medical Marijuana Signing Press Release, *supra* note 227 (specifically noting that recreational marijuana is still illegal).

230. N.Y. PUB. HEALTH LAW § 3360 (McKinney Supp. 2018); Samuel J.M. Donnelly & Mary Ann Donnelly, *2014–15 Survey of New York Law: Health Law*, 65 SYRACUSE L. REV. 785, 796–97 (2015) (noting that the term "certification" is used rather than "prescription" in order to avoid conflict with federal law regarding Schedule 1 narcotics); *see* Medical Marijuana Signing Press Release, *supra* note 227.

231. *See* 10 N.Y.C.R.R. § 1004.2 (2017); *Frequently Asked Questions*, N.Y. ST. DEP'T HEALTH, https://www.health.ny.gov/regulations/medical_marijuana/faq.htm (last updated Apr. 2018) (providing a broad overview of New York's Medical Marijuana Program, including a brief history of the program and information on how to register for the program and obtain marijuana legally).

232. PUB. HEALTH § 3360; 10 N.Y.C.R.R. § 1004.2 (the eleven life threatening conditions include: cancer, HIV/AIDS, ALS, MS, Parkinson's, spinal cord issues with intractable spasticity, epilepsy, inflammatory bowel disease, neuropathies, Huntington's disease, and any severely debilitating condition that degrades patient health and has intolerable side effects lasting longer than three months; while the five complicating conditions include: cachexia or wasting syndrome, chronic pain, severe nausea, seizures, severe muscle spasms, and other conditions added by the commissioner).

233. *See* N.Y. PUB. HEALTH LAW § 3363 (McKinney Supp. 2018); *Medical Marijuana*, COMPASSIONATE CARE NY, http://www.compassionatecareny.org/medical-marijuana/ (last visited Apr. 8, 2018).

234. *See* COMPASSIONATE CARE NY, THE NEW YORK MEDICAL MARIJUANA PROGRAM: 2016 BILL SUMMARIES (2016) [hereinafter BILL SUMMARIES], http://www.compassionatecareny.org/wp-content/uploads/CCNY-2016-Bills_Fact-

one, the Program's strict regulations significantly inhibited patients' ability to acquire medical marijuana, creating low patient demand and high production costs that in turn made medical marijuana too expensive for the majority of patients to afford.[235] In addition, there were too few registered medical practitioners with the ability to certify patients for the usage of medical marijuana.[236] Forms of medical marijuana were restricted, manufacturing was limited to a select group of companies, doctors were not knowledgeable about the Program, and many felt that too few medical conditions were covered.[237]

In response to these issues, New York's Legislature and the NYSDOH proposed and implemented several legislative and regulatory changes. On November 30, 2016, nurse practitioners gained the power to certify qualifying patients.[238] In December 2016, manufacturing caps were lifted that allowed more state-approved companies to grow and sell medical marijuana, increasing variety and driving down consumer costs.[239] In March 2017, chronic pain was added as a complicating condition and physician's assistants also gained the authority to certify patients.[240] These alterations not only increased the number of patients eligible for medical marijuana, but also increased the number of healthcare providers licensed to prescribe it. The effects were immediately noticeable—as of August 2017, the Medical Marijuana Program served 26,561 certified patients, with 1,155 registered participating practitioners.[241] Of those patients, 11,569 had received

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Sheet_Updated-May-13.pdf (summarizing a number of new proposed bills aimed at remedying various issues and inefficiencies with the program and its administration).

235. *Id.*

236. *Id.*

237. *Id.*

238. *See* 10 N.Y.C.R.R. §§ 1004.1(a)(2), 1004.2 (2017); Press Release, N.Y. State Dep't of Health, NYSDOH Announces Expansion of Medical Marijuana Program (Nov. 22, 2016), https://www.health.ny.gov/press/releases/2016/2016-11-22_medical_marijuana_program_expansion.htm.

239. N.Y. PUB. HEALTH LAW § 3364 (McKinney Supp. 2018); *see* Press Release, N.Y. State Dep't of Health, NYSDOH Announces Ability for Wholesaling of Medical Marijuana Products and Removes Cap on Number of Products Available to Patients (Dec. 8, 2016), https://www.health.ny.gov/press/releases/2016/2016-12-08_wholesaling_of_medical_marijuana_products.htm (clarifying that the change would be made through DOH guidance to subjects rather than through the administrative notice and comment process).

240. *See* 10 N.Y.C.R.R. §§ 1004.1, 1004.2; Press Release, N.Y. State Dep't of Health, New York State Department of Health Announces Latest Enhancements to Improve Patient Access to the Medical Marijuana Program (Mar. 16, 2017), https://www.health.ny.gov/press/releases/2017/2017-03-16_medical_marijuana_enhancements.htm.

241. *See* Jon Campbell, *Medical Marijuana: Lozenges, Lotions Coming to New York*, USA TODAY (Aug. 10, 2017), https://www.usatoday.com/story/news/politics/politics-on-the-hudson/2017/08/10/medical-marijuana-lozenges-lotions-coming-new-york/104463066/;

certification only after the newest regulations took force.[242] All in all, the number of patients participating in the program rose by a staggering seventy-seven percent since the Program's initial launch.[243] Finally, as of June 2017, a second four-hour course had been added through the Medical Cannabis Institute to assist registered practitioners in completing their continuing medical education credits.[244]

While the aforementioned regulations are in place, there are a bevy of proposals still awaiting legislative approval or working their way through the administrative process. On August 10, 2017, the NYSDOH announced a new set of regulations aimed at continually expanding the state's current Program, reducing costs, and providing an "improved experience" for both medical marijuana patients and the organizations manufacturing and dispensing it.[245] If enacted, the newest regulations will (1) expand and permit the sale of additional medical marijuana products that are currently not available to patients; (2) improve the way in which medical marijuana is dispensed; (3) allow prospective practitioners to complete their training in a shorter amount of time; and (4) allow hospital-bound patients to self-administer medical marijuana (within limits).[246]

With regard to medical marijuana products, the newest set of regulations will allow dispensing organizations to manufacture and distribute additional forms of medical marijuana to qualified patients, including topical lotions, ointments, patches, solid and semi-solid products, chewable and effervescent tablets, lozenges, and other nonsmokeable forms of ground marijuana plant material.[247] This marks a broad expansion given the fact that presently-certified patients only have

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Press Release, N.Y. State Dep't of Health, New York State Department of Health Announces New Regulation to Improve State's Medical Marijuana Program for Patients, Practitioners, and Registered Organizations (Aug. 10, 2017), https://www.health.ny.gov/press/releases/2017/2017-08-10_new_mmp_regulatins.htm [hereinafter NYSDOH August Improvements Press Release].

242. NYSDOH August Improvements Press Release, *supra* note 241.

243. *See id.*

244. *See* Press Release, N.Y. State Dep't of Health, New York State Department of Health Announces Enhancements to Medical Marijuana Program (June 22, 2017), https://www.health.ny.gov/press/releases/2017/2017-06-22_medical_marijuana_program_enhancements.htm.

245. BILL SUMMARIES, *supra* note 234; *see* NYSDOH August Improvements Press Release, *supra* note 241 (proposing to amend N.Y. PUB. HEALTH LAW § 3369-a; 10 N.Y.C.R.R. § 1004.2 (2017); N.Y. PUB. HEALTH LAW § 502; and 10 N.Y.C.R.R. § 55-2 (2017)).

246. *See* N.Y. PUB. HEALTH LAW § 3369 (McKinney Supp. 2018); 10 N.Y.C.R.R. § 1004.1(a).

247. *See* NYSDOH August Improvements Press Release, *supra* note 241.

access to the use of nonsmokeable forms of medical marijuana.[248] The proposed regulations would also allow new companies to manufacture and sell medical marijuana, hopefully increasing supply and sparking competition that might drive down prices.[249] Registration requires application to the NYSDOH, the submission of detailed plans of their infrastructural business plans, and payment of a $10,000 nonrefundable application fee and a $200,000 registration fee to the State.[250] Additionally, the selected organizations are required to contract with a New York State independent laboratory to test medical marijuana products prior to dispensing.[251] While these requirements are somewhat arduous, the State can ensure that patients are receiving quality medical marijuana from responsible and well-functioning companies while simultaneously generating revenue that the State can reinvest into the Program.[252]

All things considered, New York's Medical Marijuana Program is expanding quite rapidly. In just under two years since its official launch, the Program boasts over 25,000 patients, has already generated positive revenue for the State, and has undergone several legislative and administrative changes in a political climate where consensus is not easily found. How this Program evolves in coming years will be quite intriguing, and when, if at all, New York will eventually make the jump to legalizing recreational marijuana.

IV. FEDERAL LEGISLATION

Just prior to the end of President Obama's second term as President of the United States, he signed two pieces of legislation into law as part of an overall health care reform package in December 2016—the 21st Century Cures Act,[253] which incorporates components of the Helping

248. N.Y. PUB. HEALTH LAW § 3362(2)(a) (McKinney Supp. 2018).

249. *See* BILL SUMMARIES, *supra* note 234; Press Release, N.Y. State Dep't of Health, State Health Department Now Accepting Medical Marijuana Registered Organization Applications (Apr. 17, 2015), https://www.health.ny.gov/press/releases/2015?2015-04-27_mm_application.htm [hereinafter Medical Marijuana Application Press Release].

250. 10 N.Y.C.R.R. §§ 1004.5, 1004.6 (2017); Medical Marijuana Application Press Release, *supra* note 247.

251. 10 N.Y.C.R.R. §§ 1004.10(a)(4), 1004.14 (2017); *see* NYSDOH August Improvements Press Release, *supra* note 241.

252. *See* Josefa Velasquez, *Medical Marijuana Revenue Much Lower than Expected*, POLITICO (May 3, 2017), https://www.politico.com/states/new-york/albany/story/2017/05/03/medical-marijuana-revenue-falls-even-lower-than-expected-111770 (noting that while $585,000 was far less than the $4,000,000 projected revenue from the 7% excise tax on medical marijuana, this was prior to the regulatory expansion that greatly increased medical marijuana availability).

253. 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016); *We Did It! Mental Health Reform Is Headed to the President's Desk*, NAMI (Dec. 7, 2016),

Families in Mental Health Crisis Act that originally died in the United States Senate.[254]

A. The 21st Century Cures Act

In December 2016, Congress passed the 21st Century Cures Act (the "Cures Act") in an attempt to continue the "discovery, development, and delivery" cycle of medical treatments and innovation.[255] The Energy and Commerce Committee has weighed in on the Cures Act, stating that

> [i]n the [twenty-first] [c]entury, the pace of health care innovation is rapidly accelerating. . . . Health research is moving quickly, but the federal drug and device approval apparatus is in many ways the relic of another era. We have dedicated scientists and bold leaders at agencies like the NIH and the FDA, but when our laws don't keep pace with innovation, we all lose.[256]

Indeed, as a multifaceted act covering a wide variety of issues with biomedical research in the [twenty-first] century, we cover the following highlights here in this Survey.

The Cures Act reauthorized funding for the National Institutes of Health (NIH) for the 2016–2020 Fiscal Years.[257] Beyond refunding the NIH, the Cures Act established an innovation fund at the NIH for the 2017–2026 fiscal years;[258] the goal of which is to "spur scientific innovation" through "high-risk high-reward research," namely for "unmet medical needs."[259] High-risk, high-reward research involves innovative, creative, cutting edge methods of pursuing solutions to the thousands of diseases that have no cures.[260] In other words, without taking a risk on the research, the gain will not be great and the director of the NIH has the power to establish the percentage of funding that an individual institute will be required to spend on a particular area of research.[261] That is, the NIH will not fund traditional research that provides only incremental advances to medical research.[262]

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https://www.nami.org/About-NAMI/NAMI-News/2016/We-Did-It-Mental-Health-Reform-Is-Headed-to-the-P.

254. 21st Century Cures Act div. B (to be codified at scattered sections of 42 U.S.C.) (originally introduced as the Helping Families in Mental Health Crisis Act of 2016, H.R. 2646, 114th Cong.).

255. 21st Century Cures Act tit. II, III, IV.

256. *21st Century Cures*, ENERGY & COM. COMMITTEE, https://energycommerce.house.gov/cures (last visited Apr. 8, 2018).

257. 21st Century Cures Act sec. 2001 (to be codified at 42 U.S.C. § 282a(a)(1)).

258. *Id.* sec. 1001(b) (to be codified at 42 U.S.C. § 201).

259. H.R. REP. NO. 114-190, at85, 107–08 (2015).

260. *See id.*

261. *Id.* at 108.

262. *See id.* at 108.

Although the Cures Act authorizes funding for high-risk, high-reward research, it is not funding without strings attached. The Cures Act requires increased accountability on the part of the NIH as it pertains to the potential duplication of biomedical research.[263] To that end, the Cures Act gives the director of the NIH power to appoint directors of various national research institutes for five-year terms and there is no limit on the number of terms a director can serve.[264] The Cures Act would also require the NIH to review all "R-series" grants by directors of national research institutes and centers, but the directors would have to consider whether the research aligns with the NIH strategic plan and whether the research is duplicative of research being conducted by other programs or projects.[265]

Perhaps most importantly, the Cures Act provides new guidance for protection of patient records and information involved in the NIH research under the Health Insurance Portability and Accountability Act (HIPAA). Previously, HIPAA permitted covered entities to use a patient's protected health information for purposes of treatment, payment for services, and health care operations.[266] Essentially then, the House of Representatives in forming the Cures Act expanded the definition of health care operations and public health activities to include disclosure of, and remote access to, protected health information without prior patient authorization for research purposes.[267]

Indeed, under section 2063, the Cures Act would permit a researcher to access patients' protected health information remotely for the limited purposes of research as long as appropriate safeguards are in place and the researcher may not be otherwise permitted to copy or retain the information after the approved research has been concluded.[268] In fact, the Cures Act expressly calls on the Secretary of Health and Human Services to treat disclosures of a patient's protected health information for research purposes similarly to disclosures of protected health information for public health purposes.[269] Finally, the Cures Act permits a patient to fill out an authorization for future disclosure of protected health information for research purposes as long as it expressly explains the purposes of the disclosure of patient health information and is subject

263. *See id.* at 106.

264. 21st Century Cures Act, Pub. L. No. 114-255, sec. 2033(a), § (a)(2)(b)–(c), 130 Stat. 1033, 1057 (2016) (to be codified at 42 U.S.C. § 284).

265. *Id.* sec. 2033(a), § (b).

266. 45 C.F.R. § 164.506(a) (2017).

267. 21st Century Cures Act sec. 2063 (to be codified at 42 U.S.C. § 1320d-2); H.R. REP. NO. 114-190, at 113.

268. *Id.*

269. *Id.* 2063(a).

to revocation at a specific time or upon completion of the research.[270]

Additionally, the Cures Act requires the creation of working groups to report on how the disclosure of protected health information for research purposes is working, including the ability of patients to set preferences for how his or her protected health information was used during research, timing of authorizations, procedure for revoking authorizations, barriers to research related to the restrictions on disclosure, and use of protected health information.[271] Part of the working groups' duties also include assessing the expectations regarding the use of protected health information for research and the impact of using protected health information from special groups of patients in research (e.g., children and disabled individuals).[272]

The Cures Act also provides a framework for utilizing evidence from patients' clinical experience, i.e., "real world evidence," in evaluating the effectiveness of drugs. For purposes of this discussion, "real world evidence" "means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials," including from observational studies, registries, claims and patient-centered outcome research activities.[273] In particular, the Secretary of Health and Human Services, no later than two years after enactment, is required to set forth a framework for implementing the integration of real world evidence into the data collected to support the approval of a new indication for a drug.[274] The framework must include (1) current sources of data from real world evidence, i.e., patients' clinical experience, (2) gaps in current data collection, (3) current standards and methodologies for collection and analysis of data, and (4) priority areas and potential pilot opportunities.[275] The Secretary of Health and Human Services must also consult with the applicable "regulated industry, academia, medical professional organizations, representatives of patient advocacy organizations, consumer organizations, disease research foundations, and any other interested parties" in establishing that framework to integrate clinical experience data with other data collected in support of approving a new indication of a drug.[276] The framework must then be implemented within two years of enactment of the Cures Act.[277] In implementing the framework, the Secretary of Health and

270. *Id.* 2063(b)(2)–(3).
271. *Id.* 2063(c)(3)(A).
272. 21st Century Cures Act sec. 2063(c)(3)(B).
273. *Id.* sec. 3022, § 505F(b), (c) (to be codified at 21 U.S.C. § 355f).
274. *Id.* sec. 3022, § 505F(c)(1).
275. *Id.* sec. 3022, § 505F(c)(2)(A)–(D).
276. *Id.* sec. 3022, § 505F(c)(3)(A).
277. 21st Century Cures Act sec. 3022, § 505F(d).

Human Services must also use the framework to provide "guidance for industry" on the circumstances under which drug sponsors and the Secretary of Health and Human Services can rely on real world evidence and the standards and methodologies for collecting and analyzing evidence from clinical experience.[278] The Secretary of Health and Human Services can also use real world evidence for purposes not specified above as long as there is a sufficient basis for nonspecified use.[279]

In terms of innovation, the Cures Act also expanded antimicrobial resistance monitoring programs and, in conjunction with State and local public health departments, will work to implement antimicrobial stewardship programs.[280] The purpose of these antimicrobial stewardship programs is to identify patterns of bacterial and fungal resistance in humans to various antimicrobial drugs, prevent the spreading of infections that are resistant to antimicrobial drugs and promote antimicrobial stewardship.[281] Ultimately, the goal is to develop new antibacterial and antifungal medications to combat these drug-resistant bacteria and fungi in limited populations before being released to all members of the general public.[282]

Although the Cures Act was passed with bipartisan support under the Obama administration, we anxiously await the guidance from the Department of Health and Human Services on numerous issues related to the disclosure of patients' protected health information for purposes of cutting edge biomedical research. Therefore, despite the advances that the Cures Act makes in providing funding for high-risk, high-reward research, those advances may be thwarted if the current presidential administration's budget passes with the aforementioned cuts as part of it.

B. Helping Families in Mental Health Crisis Act

The Helping Families in Mental Health Crisis Act (the "Crisis Act"), authored and proposed by Representative Timothy Murphy, is an amendment to the Public Health Services Act[283] and is designed to ensure access to psychiatric and mental health services and to ensure that those individuals with mental health issues and substance use disorders are "treated fairly" by insurance companies.[284] The Crisis Act also seeks

278. *Id.* sec. 3022, § 505F(e)(1)(A)–(B).

279. *Id.* sec. 3022, § 505F(f)(1).

280. 21st Century Cures Act sec. 3041(a), § (g) (to be codified at 42 U.S.C. § 247d-5).

281. *Id.* sec. 3041(i) (1)-(3).

282. *Id.* sec. 3042.

283. H.R. REP. NO. 114-667, at 39, 42 (2016).

284. 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033, 1202 (2016) (to be codified at scattered sections of 42 U.S.C.); *Mental-Health Bill Made into Fed Law*, OBSERVER REP. (Dec. 13, 2016), http://www.observer-

clarification of HIPAA privacy provisions as it relates to disclosure of protected health information for individuals with mental health issues.[285]

The impetus for the Crisis Act was the gravity of nationwide untreated serious mental illness.[286] Indeed, several legislators have remarked on the broken nature of the nation's mental health care system, the lack of access to required mental health services, and the fact that many individuals cannot afford the mental health care they need.[287] More generally, Senator John Cornyn from Texas remarked that the Crisis Act "is about finding ways to help the mentally ill individual get help while keeping the community safe at the same time."[288]

In brief, the Crisis Act is about helping the federal agencies make structural changes such that the provision of mental health services across the nation is more efficient and better coordinated for patients.[289] To that end, the Crisis Act creates a new committee, the Interdepartmental Serious Mental Illness Coordinating Committee, to link leaders of several agencies involved in providing mental health care (e.g., the Department of Veteran Affairs, the Department of Justice and Substance Abuse, and Mental Health Services Administration),[290] creates the new position of the Assistant Secretary for Mental Health and Substance Use in the Department of Health and Human Services to administer the new developments in access to mental health services,[291] and establishes the National Mental Health and Substance Use Policy Laboratory to determine areas where expansion of treatment services is required.[292] Perhaps most critically, the Interdepartmental Serious Mental Illness Coordinating Committee is required within five years of the enactment of the Crisis Act to provide:

a summary of advances in serious mental illness and serious emotional disturbance research related to the prevention of, diagnosis of, intervention in, and treatment and recovery of, serious mental illnesses, serious emotional disturbances, and advances in access to services and support for individuals with a serious mental illness or serious emotional disturbance;

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reporter.com/20161213/murphyx2019s_mental-health_bill_signed_by_president.

285. 21st Century Cures Act sec. 11003 (to be codified at 42 U.S.C. § 1320d-2).

286. *See* H.R. REP. NO. 114-667, at 40.

287. Liz Szabo, *Mental Health Care Gets a Boost from 21st Century Cures Act*, NPR (Dec. 7, 2016), http://www/npr.org/sections/health-shots/2016/12/07/504725936/mental-health-care-gets-a-boost-from-21st-century-cures-act.

288. *Id.*

289. *See id.*

290. 21st Century Cures Act sec. 6031(a)(1), (e).

291. *Id.* sec. 6001(a), § (c)(1) (to be codified at 42 U.S.C. § 290aa(c)).

292. *Id.* sec. 7001, § 501A(a) (to be codified at 42 U.S.C. § 290aa).

1. an evaluation of the effect on public health of Federal programs related to serious mental illness or serious emotional disturbance, including measurements of public health outcomes such as—
   (A) rates of suicide, suicide attempts, prevalence of serious mental illness, serious emotional disturbances, and substance use disorders, overdose, overdose deaths, emergency hospitalizations, emergency room boarding, preventable emergency room visits, involvement with the criminal justice system, crime, homelessness, and unemployment;
   (B) increased rates of employment and enrollment in educational and vocational programs;
   (C) quality of mental and substance use disorder treatment services; and
   (D) any other criteria as may be determined by the Secretary;
2. a plan to improve outcomes for individuals with serious mental illness or serious emotional disturbances, including reducing incarceration for such individuals, reducing homelessness, and increasing employment; and
3. specific recommendations for actions that agencies can take to better coordinate the administration of mental health services for people with serious mental illness or serious emotional disturbances.[293]

Finally, the Interdepartmental Serious Mental Illness Coordinating Committee will also include a host of members from the community, including: (1) at least two individuals who have lived experience with a serious mental illness or serious emotional disturbance; at least (2) one individual who is a parent or guardian of an individual with a serious mental illness or emotional disturbance; (3) one individual who is from a leading research, advocacy, or service organization for individuals with mental illness; (4) two psychiatrists, psychologists, clinical social workers, or psychiatric nurses, nurse practitioners, or physician assistants; (5) one mental health professional licensed in treating children and adolescents with serious emotional disturbances; (6) one mental health professional with research and/or clinical mental health experience with minorities and medically-underserved populations; (7) one state-certified mental health peer specialist; (8) one judge with experience in adjudicating cases in mental health court; (9) one law enforcement or

293. *Id.* sec. 6031(c)(1)–(3). Notably, subsection (3) quoted above was not integrated into the final version of the Crisis Act that was integrated into the Cures Act. Rather, it was included in the failed bill that proposed the Crisis Act as a standalone piece of legislation.

corrections officer with experience in handling individuals in mental health crisis or with a serious mental illness or emotional disturbance; and (10) one homeless services provider with experience with patients with serious mental illness or emotional disturbance or in mental health crisis.[294]

The Crisis Act directs the Assistant Secretary for Mental Health and Substance Use, who is appointed by the President, to oversee all mental health and substance use programs and to develop a strategy for evaluating programs under the Assistant Secretary's purview and those programs under the purview of other offices with the Department of Health and Human Services.[295] It is also the duty of the Assistant Secretary to provide recommendations to the Secretary of Health and Human Services regarding the improvement of the quality of prevention and treatment programs for individuals with mental and substance use disorders.[296] The Crisis Act also establishes a National Mental Health and Substance Use Policy Laboratory for the identification, coordination, and facilitation of policy changes "likely to have a significant effect on mental health, mental illness, recovery supports, and the prevention and treatment of substance use disorder services."[297]

In terms of the proposed improvements to treatment, the Crisis Act provides grants for community based health systems across the states that provide mental health and substance use services to patients.[298] The service would be available twenty-four hours each day, seven days per week.[299] A community-based health system must (1) identify a state agency to be responsible for administration of the program under the grant; (2) "provide for an organized community-based system of care for individuals with mental illness, and describe available services and resources in a comprehensive system of care"; (3) outline the manner in which the state and local authorities will provide services in a way that maximizes the efficiency, effectiveness, and quality of programs; (4) describe how the state will promote evidence-based practices, including those available for patients with early onset mental illness, how the state will provide comprehensive individual treatment, and how the state will integrate physical and mental health services; (5) outline case management services; (6) describe how to engage both mentally ill adults and children with their caregivers in making health care decisions; and

294. *Id.* sec. 6031(e)(2).
295. 21st Century Cures Act sec. 6001(a), § (c)(1).
296. *Id.* sec. 6021(a).
297. *Id.* sec. 7001, § 501A(b)(2).
298. *Id.* sec. 8001 (to be codified at 42 U.S.C. § 300x(b)).
299. Szabo, *supra* note 287.

(7) include descriptions of how the system will reduce hospital stays and incidents of suicide, available recovery support services for mentally ill adults and children, and how the state will integrate mental health and primary care together.[300] The community-based system of care outlined above that is to be provided for adults with mental illnesses includes health and mental health services, rehabilitation services, employment services, housing services, educational services, substance abuse services, medical and dental care, as well as other support services to ensure that the individuals are able to function outside of inpatient or residential treatment.[301]

Additionally, states are not permitted to spend less than ten percent of the amount the state receives for implementing the community-based system of care for adults who suffer from psychotic disorders.[302] Indeed, research from the NIH "shows that people who receive this kind of care stay in treatment longer; have greater improvement in their symptoms, personal relationships and quality of life; and are more involved in work or school compared to people who receive standard care."[303] Therefore, through the above grants, the federal government is attempting to ensure that patients with serious mental illnesses have the best chance of functioning in the community (i.e., outside institutional treatment).

In addition to the above community-based treatment, the House of Representatives passed, as part of its bill, a five million dollar grant program for states for assertive community treatment, which provides a team of mental health professionals to patients twenty-four hours each day, seven days per week, as well as access to additional assisted outpatient treatment where an individual might not otherwise seek help.[304] The assertive community treatment program also requires the Assistant Secretary for Mental Health and Substance Abuse to provide a report as to the cost savings and improvement in public health outcomes, including mortality, suicide, substance abuse, and hospitalization, as well as the rates of patient involvement with the criminal justice system and homelessness, and the patient's (and family's) satisfaction with program participation.[305]

Likewise, the Crisis Act provides for similar access to mental health or psychiatric treatment for children and adolescents through pediatric primary care providers and a mental health team consisting of case

300. 21st Century Cures Act sec. 8001(b)(5)(A).
301. *Id.*
302. *Id.* sec. 8001(c)(1) (to be codified at 42 U.S.C. § 300x-9).
303. Szabo, *supra* note 287.
304. H.R. REP. NO. 114-667, at 150 (2016); 21st Century Cures Act sec. 9015, § 502M(e).
305. 21st Century Cures Act sec. 9015, § 502M(d).

coordinators, child and adolescent psychologists, social workers, or mental health counselors.[306]

The Crisis Act also strengthens the network of national suicide hotlines. Namely, the Assistant Secretary must coordinate a network of suicide crisis centers across the nation that will operate day and night; maintain a suicide prevention hotline to link the caller to appropriate emergency, mental health, and social services personnel; and work with the Secretary for Veterans Affairs to ensure that veterans have access to specialized suicide crisis services.[307] Grants will also be awarded to community-based primary care, behavioral health care, emergency department, or state mental health[308] entities "to implement suicide prevention and intervention programs for individuals who are [twenty-five] years of age or older."[309] The goal in providing these grants is to raise suicide awareness, to establish a process for referring patients for appropriate counseling services, and to improve clinical care and outcomes for individuals at risk of committing suicide.[310]

With respect to changes to HIPAA, the Crisis Act requires the Secretary of Health and Human Services to develop and disseminate model programs and materials to train health care providers, lawyers, patients, and their families regarding the circumstances under which a patient's protected health information may be disclosed without permission.[311] Prior to the Crisis Act, there were no protections for disclosure of a patient's mental health information under the federal HIPAA regulations.[312] As a reminder, at present, HIPAA permits, but does not require, the following disclosures without an authorization from the patient for disclosure: (1) to the individual; (2) for treatment, payment, and health care operations; (3) where an individual is incapacitated or in an emergency, or where informal verbal consent is obtained; (4) where disclosure is incident to an otherwise permitted use and disclosure; (5) for public interest and benefit activities; and (6) as part of a Limited Data Set for purposes of research, public health, and health care operations.[313] A disclosure is considered to be for public interest and

306. *Id.* sec. 10002, § 330M(b)(2).

307. *Id.* sec. 9005, § 520E-3.

308. *Id.* sec. 9009, § 520L(a)(2).

309. *Id.* sec. 9009, § 520L(a)(1).

310. 21st Century Cures Act sec. 9009, § 520L(a)(1), (3).

311. *Id.* sec. 11004(a)(1).

312. Elizabeth Snell, *Considering HIPAA Privacy with Mental Health Data*, HEALTHIT SECURITY (Jan. 31, 2017), https://healthitsecurity.com/news/considering-hipaa-privacy-rule-with-mental-health-data.

313. 45 C.F.R. § 164.502(a)(1)(i)–(vi) (2017); *Summary of the HIPAA Privacy Rule*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html (last visited Apr. 8, 2018) [hereinafter *Summary of HIPAA*].

benefit activities where the disclosure is required by law; public health activities warrant the disclosure (e.g., disease control); the patient is a victim of abuse, neglect or domestic violence; health oversight activities (e.g., oversight of the health care system); for judicial and administrative proceedings; for law enforcement purposes; regarding decedents to coroners, funeral directors and medical examiners; for cadaver donation; for research purposes; serious threats to health or safety; essential government functions; and workers' compensation.[314]

Although the Crisis Act includes various other minutiae, the above provides the highlights of the act as incorporated into the Cures Act and demonstrates the gravity of the mental health crisis in the United States and the failure of the healthcare system to provide mental health treatment. However, even though Congress passed the Crisis Act as part of the Cures Act, Congress will still have to approve the proposed grants and appropriations and therefore, should Congress decline to approve the recommendations in the act, the above measures could have been all for naught.[315] Indeed, we will have to watch the upcoming congressional budgets to determine whether the states will have access to the increased federal funding to provide better access to mental health treatment. Furthermore, on a more micro level, issues with disclosure of mental health information will be something to watch as the Secretary for Health and Human Services reveals its guidance on the issue as it may prove more difficult for defense litigants to gain access to a plaintiff's mental health information even where relevant to the litigation.

CONCLUSION

Looking ahead, the decisions surrounding the MIF amendments and the disclosure of hospital incident reports, and the continued push of Lavern's Law through the New York State Legislature, will have the most immediate effect on medical malpractice practitioners across the State and must be watched closely. Additionally, the Court of Appeals has signaled its reluctance to open the door to legalizing physician-assisted suicide (i.e., aid-in-dying) in New York, sending what appears to be largely a death knell for future challenges to the State's ban on the practice. Furthermore, we anticipate a greater expansion of absolute privilege for statements made in the course of administrative proceedings and await potential challenges to the gross deference afforded to an employer in ADA failure to accommodate claims. Finally, the Helping Families in Mental Health Crisis Act will hopefully provide federal support to assist patients suffering from mental illnesses with improved

314. 45 C.F.R. § 164.512 (2017); *Summary of HIPAA*, *supra* note 313.

315. *See* Szabo, *supra* note 287.

access to the care they need.