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Health Law Journal

A publication of the Health Law Section
of the New York State Bar Association

Inside

NEW YORK STATE BAR ASSOCIATION

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Third Edition

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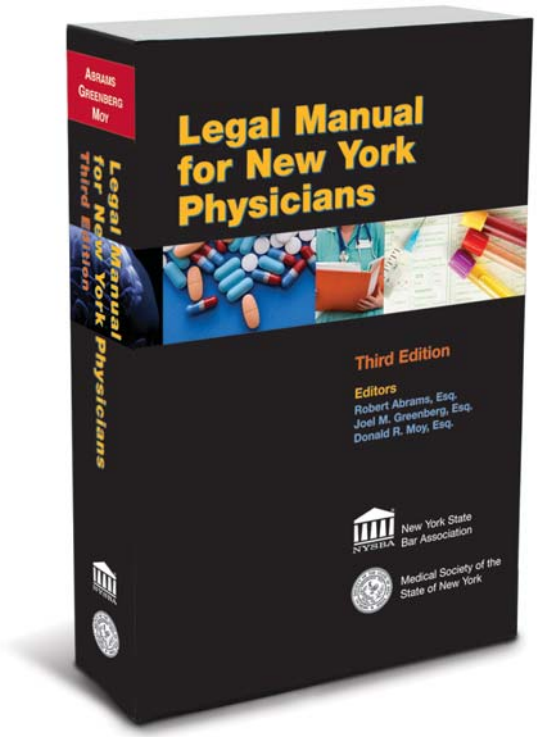

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NYSBA

HEALTH LAW JOURNAL

Fall 2013

Vol. 18, No. 3

THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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A Message from the Section Chair

I am honored to have been elected to serve as the Chair of the Health Law Section for 2013-2014. There are 1,282 members of the Health Law Section. Though our Section is fewer in number than some others, the members are particularly active and engaged in the legal issues of the day in our area of practice.

I know that I speak for the entire Section in expressing sincere appreciation to Ellen V. Weissman for her strong leadership of the Section for 2012-2013. Ellen served for several years as the superb Chair of the Payment and Reimbursement Committee. Ellen's name prefaces "best" "leading" or "super" in each of the respective lawyer rating surveys. She brought the same level of performance to chairing the Section in a pivotal health law year.

"The only constant in life is change" could be applied to health law. Although Heraclitus was not musing about our area of practice, his observation is pertinent. There is always something new and challenging, whether it be the recommendations of the Berger Commission and Medicaid Redesign Task Force or the range of CMS Initiatives (ACOs, RACs). The hospital landscape continues to resemble the battlefield of a war of attrition. Several venerable and popular hospitals in urban, suburban and rural areas of our State have closed or reduced inpatient or outpatient services or are clinging to life. Reimbursement cutbacks, however styled, and unfunded mandates are relentless. Organizational models for efficient health care delivery are being designed and implemented at a rapid fire pace. The seismic shock of the Affordable Care Act will reverberate in the health care and legal systems for years to come. The environment is fraught with pressures of all kinds. In short, our clients face more challenges than ever before. It has never been more important for those who practice law in our field to be informed. Participation in Section activities is among the ways we can learn and be poised to give our clients the best advice possible.

Meetings

Fall Meeting

The Fall Meeting was held on Friday, October 25, at the New York State Bar Association headquarters in Albany. Program Chair Raul A. Tabora Jr., assisted by Daniel Meier, prepared a timely and practical CLE—Affordable Care Act & Readiness for 2014 and Beyond—Public Benefit Exchange: Impact on Insurers, Providers, and Medicaid Program. Raul assembled experts for each segment of the program. I am grateful to Raul for once again taking charge of developing an excellent CLE program.

Annual Meeting

The NYSBA Annual Meeting week will be January 27 to February 1 at the New York Hilton Midtown. The Health Law Section's Annual Meeting Day is Wednesday, January 29. Margaret (Margie) J. Davino is the Program Chair for the Annual Meeting. Margie was a terrific Program Co-Chair of the 2013 Annual Meeting. It is no surprise that Margie's 2014 Annual Meeting preparation is careful and well under way. The title of the program is "Hot Topics for NY Healthcare Lawyers." The agenda will cover the latest developments across the range of New York State health law subjects. With Margie at the helm, our Section's Annual Meeting promises to be interesting, informative and successful.

A challenging year lies ahead. The Annual Meeting program will help you prepare for it.

Committees

The best way to be active in the Section is to join and participate in a Committee. The Committees have been designed to address each area of health law. The benefits of joining one or more Section committees are many. First, one becomes better informed about the law in a particular area. Second, Committee participation allows advance notice and opportunity to keep abreast of new and prospective legal developments. Third, the Committees weigh in on proposed and current New York legislation and regulations. Thanks to the work of the former Section Chairs and the Editor of the *Health Law Journal* Robert N. Swidler, the Section has become a respected voice in the legislative and regulatory arena. Finally, but not least in importance, participation on a Committee and involvement in Section activities is a way to meet attorneys in your field, many of whom will become valued colleagues and friends.

Health Law Journal

With the *Journal*'s Editor Robert Swidler, I would like to invite you to write an article for the *Health Law Journal*. The *Journal* is one of the finest, if not the best, of its kind. The caliber of the *Journal* is recognized in the NYSBA and by other health law groups in the country. Please consider writing an article alone or with a colleague. It is a way to educate your colleagues, bring your expertise and insights to the attention of your peers, and further the aims of the NYSBA and our cherished profession.

* * *

Lastly, I want to thank you, the members of the Section, for your participation in Section activities, Committee meetings, and for contributing to the development and success of the programs offered. Please join me in welcoming and encouraging lawyers new to the bar, health law practice, or to the Section. We want the Section to be relevant and useful to all of you. This is your Section. If you have any suggestions of any kind, whether for new committees or programs or any way that the Section may be more helpful to the members, please let us know. The email addresses for the Executive Committee members are listed on p. 63 and on the NYSBA Health Law Section website. We look forward to hearing from you.

Kathleen M. Burke
Chair
NYSBA Health Law Section

In the New York State Courts

By Leonard M. Rosenberg

Court of Appeals Holds that Under Mental Hygiene Law § 22.09(d) a Hospital Lacks Authority to Involuntarily Detain an Individual Impaired or Intoxicated by Alcohol When That Individual Voluntarily Comes in for Treatment

Kowalski v. St. Francis Hospital and Health Centers, 2013 WL 3197637 (June 26, 2013). On December 20, 2006, at approximately 11:20 a.m., Plaintiff entered the emergency room of defendant St. Francis Hospital in an extremely intoxicated condition. Plaintiff had been brought to St. Francis by a friend. At the time of Plaintiff's arrival to St. Francis, Plaintiff had a blood-alcohol content of .369%, red eyes, disjointed speech, smelled of alcohol, and was seeking admission to St. Francis' "Turning Point" detoxification facility. This was Plaintiff's second visit to St. Francis in approximately one month's time. Plaintiff had previously been admitted to St. Francis for suicidal thoughts and had to be placed on a "one-to-one" watch, but was subsequently discharged two days later after showing signs of improvement. The records from Plaintiff's prior admission were not consulted in relation to this visit.

Four hours after Plaintiff's arrival during this latest admission, while awaiting transportation to the Turning Point facility, Plaintiff informed a nurse that Plaintiff was going to leave St. Francis prior to any formal discharge. The nurse reported this news to Plaintiff's examining physician, Dr. Chandra Chintapalli, and asked whether the police should be called. Dr. Chintapalli indicated that the nurse should notify St. Francis security, but not the police. When the nurse returned to check on Plaintiff, Plaintiff had left the facility. Plaintiff had exited St. Francis unescorted and was struck by a vehicle one to two hours later while trying to cross a nearby road at approximately 5:20 p.m.

Plaintiff survived the crash and then filed suit against St. Francis, Dr. Chintapalli, and Dr. Chintapalli's professional corporation, Emergency Physician Services of New York, P.C. (collectively, the "Defendants") for negligence and medical malpractice. Thereafter, Defendants filed a motion for summary judgment.

Supreme Court, Dutchess County, denied Defendants' motion for summary judgment. The Appellate Division, Second Department, reversed, granting the Defendants' motion for summary judgment, holding that under Mental Hygiene Law ("MHL") § 22.09(d), the Defendants lacked the authority to confine Plaintiff in the situation where Plaintiff had voluntarily sought treatment for alcoholism. The Court of Appeals affirmed the ruling of the Appellate Division, also relying on MHL § 22.09(d).

The Court of Appeals held that MHL § 22.09(d) does not provide for the involuntary retention of an intoxicated person who voluntarily comes into or is brought into a hospital or facility for treatment. The Court of Appeals highlighted that there is a distinction between voluntary treatment and involuntary treatment and that MHL § 22.09(e) provides for the retention of an individual who is brought into a hospital or facility over his/her objection, but that MHL 22.09(e) was inapplicable given the facts in this case.

Moreover, the Court rejected Plaintiff's argument that the duty to restrain Plaintiff flowed from St. Francis' and Dr. Chintapalli's common law duty of care. The Court held that "there can be no duty to do that which the law forbids." Such a duty did not attach, and was not breached by the hospital's failure to examine the records from Plaintiff's prior hospitalization, or when Dr. Chintapalli instructed the nurse not to call the police. "A patient cannot be confined simply because he was having suicidal thoughts a month ago. And the doctor had no duty to call the police; the police could not, on the facts known to Dr. Chintapalli when [P]laintiff left the hospital, have forced [P]laintiff to return." The Court further denied the notion that any deviation from St. Francis' own treatment protocols as asserted in the dissent would alter the result.

Appellate Division Rules That NYC's "Soda Ban" Is Unconstitutional

New York Statewide Coalition of Hispanic Chambers of Commerce, et al. v. New York City Dep't of Health and Mental Hygiene, et al., 970 N.Y.S.2d 200 (1st Dep't 2013). Petitioners, a coalition of interest groups, brought an article 78 and declaratory judgment proceeding against the New York City Department of Health and Mental Hygiene ("DOHMH") and the New York City Board of Health (the "Board") challenging the constitutionality of an amendment to the New York City Health Code known as the "Sugary Drinks Portion Cap Rule" or "Soda Ban," which prohibits food service establishments from serving sugary drinks over sixteen ounces. Affirming the decision of the Supreme Court, the Appellate Division, First Department (Renwick J.), held that Board exceeded the bounds of its lawfully delegated authority when it promulgated the Rule.

To address rising obesity rates, New York City Mayor Michael Bloomberg proposed an amendment to Article 81 of the New York City Health Code, which would require restaurants, movie theaters and other food-service establishments to cap the size of cups and containers used to offer, provide and sell sugary beverages at 16 ounces. The DOHMH, an administrative agency charged with

regulating and supervising all matters affecting health, including enforcing provisions of the New York City Health Code, submitted the proposal to the Board of Health. On September 13, 2012, the Board adopted the Portion Cap Rule without substantive changes. As adopted, the Rule targeted non-diet soft drinks, sweetened teas, sweetened black coffee, hot chocolate, and energy and sport drinks, but excluded alcoholic beverages, milkshakes, fruit smoothies, mixed coffee drinks, and 100% fruit juices. The ban also excluded grocery stores, convenience stores, gas stations and other similar businesses. On October 12, 2012, before the Rule went into effect, petitioners commenced this action seeking to invalidate the Rule on the grounds that it "usurped the role of the City Council and imposed social policy by executive fiat." The Supreme Court agreed, finding that the Board exceeded its authority and violated the separation of powers doctrine, and declared the Rule invalid.

In affirming the decision of Supreme Court, the Court agreed that the starting point for determining whether the regulation violates the separation of powers doctrine is the Court of Appeals' landmark decision in *Boreali v. Axelrod*, which illustrates when the "difficult-to demarcate line between administrative rulemaking and legislative policymaking has been transgressed." *Boreali* outlined four factors which the Court determined were "indicators of the usurpation of the legislature." The Court analyzed each factor at length.

As for the first factor—whether the Board exceeded its authority by engaging in the balancing of competing concerns of public health and economic costs—the Court concluded that the Board did not act solely with a view toward public health considerations when it adopted exemptions for certain drinks and food service establishments but instead acted on its own ideas of sound public policy. The Court determined that the decision to regulate a particular food is inherently a policy decision that necessarily reflects a balance between health concerns, an individual consumer's choice of diet, and business financial interests in providing the targeted sugary drinks. As such, the Court concluded that the "Soda Ban" is one particularly suited for the legislature as it involves "difficult social problems, which must be resolved by making choices among competing ends."

Applying the second factor—whether the Board exceeded its authority by writing on a "clean slate" rather than "interstitial rule making" or using its regulatory power to fill in the details of a legislative mandate—the Court concluded that the Board's actions went beyond filling in the details of a broad legislative scheme. The Court rejected the Board's argument that the City Charter's grant of broad authority to regulate "all matters affecting the health of the City" authorized the Board's action. In the Court's view, the City Charter's Enabling Act was intended by the legislature to provide the agency with the discretion to engage in interstitial rule making designed to protect the public from "inherently harmful and inimical matters" affecting the health of the City. Because the Board does not claim that soda consumption can be classified as such a health hazard, the Court concluded that the Board's action in curtailing its consumption was not the kind of interstitial rule making intended by the legislature. As such, the Court found that the Board exceeded its authority by writing on a "clean slate," creating its own comprehensive set of rules without the benefit of legislative guidance.

With regard for the third factor—whether the Board attempted to "take it upon itself" to impose a solution when the legislature was unable to agree on the goals and methods that should govern in resolving the issue—the Court concluded that the Board exceeded its authority in attempting to impose a solution to excessive sugary beverage consumption, an issue which the legislature has repeatedly tried but failed to reach an agreement on how to resolve.

Turning to the final factor—whether the Board overstepped its bounds because the development of the Rule did not require expertise in the field of health—the Court concluded that the Board did not exercise any special expertise or technical competence to develop the Portion Cap Rule. The Court found that the deleterious effects (i.e., obesity) associated with excessive soda consumption are well-known and the Board did not rely on any scientific or health expertise in creating the Rule. Moreover, given that "the rule was drafted, written and proposed by the Office of the Mayor and submitted to the Board, which enacted it without substantive changes," the Court determined that no technical competence was necessary to flesh out the details of the legislative policies embodied in the Rule. Based on its analysis of these four factors, the Court agreed with the Supreme Court that the Board of Health overstepped the boundaries of its lawfully delegated authority when it promulgated the Portion Cap Rule.

U.S. Supreme Court Rules That Naturally Occurring DNA Segments Are Not Patentable, But That Laboratory-Created cDNA Segments, Created from the Naturally Occurring DNA Segments, Are Eligible for Patent Protection

Association for Molecular Pathology, et al. v. Myriad Genetics, Inc., et al., 133 S. Ct. 2107 (2013). Tackling the often-murky intersection between non-patentable nature and patentable science, the United States Supreme Court recently ruled that, regardless of how difficult the process of isolating particular human genes may be, the discoverer of those genes is not entitled to a patent for the particular DNA sequence it located, but may be able to patent certain laboratory-created segments of DNA that are based upon the original gene, but that do not otherwise occur naturally.

Myriad Genetics, Inc. identified, among the human genome's approximately 22,000 genes along 23 chromosomes, the exact location and sequence of the BRCA1 and BRCA2

genes, mutations of which can dramatically increase the risk of breast and ovarian cancer. This discovery allowed Myriad to determine the genes' typical nucleotide sequence, which, in turn, enabled it to develop medical tests useful for detecting mutations in these genes in a particular patient. Myriad also synthetically created BRCA "complimentary DNA," also known as cDNA. cDNA contains the same protein-coding information found in a segment of natural DNA, but omits portions within the DNA segment that do not code for proteins. The creation and study of cDNA can lead to medical breakthroughs in treatment for genetic mutations, like the mutations of the BRCA1 and BRCA2 genes that cause breast and ovarian cancer. It is important to note that the Myriad patents in issue were "composition" and not "method" patents, as the laboratory methods used by Myriad to isolate the BRCA1 and BRCA2 genes and to create BRCA cDNA are "well understood, widely used, and fairly uniform," as would be used by any genetic scientist.

Myriad's patents, if valid, would "give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes (or any strand of 15 or more nucleotides within the genes) by breaking the covalent bonds that connect the DNA to the rest of the individual's genome. The patents would also give Myriad the exclusive right to synthetically create BRCA cDNA. In Myriad's view, manipulating BRCA DNA in either of these fashions triggers its 'right to exclude others from making' its patented composition of matter under the Patent Act." Myriad sent letters to alleged infringers and filed suit against others engaged in genetic testing of individuals' BRCA1 and BRCA2 genes, resulting in settlements and the voluntary discontinuance of testing by several other providers. Some years later, petitioner, along with patients, advocacy groups, and other physicians, filed this lawsuit seeking a declaration that Myriad's patents are invalid. The District Court granted summary judgment in favor of the petitioners on all claims, concluding that Myriad's patents on the BRCA DNA and cDNA were invalid because they covered "products of nature." Following appeals and remand, the Federal Circuit eventually held that both isolated BRCA DNA and BRCA cDNA were patent eligible under 35 U.S.C.A. § 101. The Federal Circuit judges were divided in their views as to why isolated BRCA DNA was eligible for patent protection, however, with some holding, for example, that the isolation of the DNA sequence alone is an inventive act entitled to protection, and others holding that the isolated DNA segment is a new molecule that is not, in their view, "naturally occurring."

In this appeal, the Supreme Court again recognized patent protection must strike "a delicate balance between creating 'incentives that lead to creation, invention, and discovery' and 'imped[ing] the flow of information that might permit, indeed spur, invention.'" Myriad's arguments relied heavily on the Court's decision in *Diamond v. Chakrabarty*, 447 U.S. 303, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (1980), wherein scientists added four plasmids to a bacterium, which in turn enabled the bacterium to break down various components of crude oil. The *Chakrabarty* decision held that the modified bacterium was patentable because the bacterium was "a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'" In contrast in this case, however, the Court held that "Myriad did not create anything." While it did find an important gene, the Court further held that "separating that gene from its surrounding genetic material is not an act of invention." The Court analogized Myriad's claims to those presented to it in the *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 68 S.Ct. 440, 92 L.Ed. 588 (1948) matter, in which the Court held that a combination of otherwise naturally occurring bacteria was not patent eligible as a new composition of matter, because it fell within the law of nature exception in Patent Law §101.

The Court further found that Myriad's patents with regard to its discovery of the BRCA1 and BRCA2 genes are not expressed in terms of chemical composition, and do not rely on the new molecule created from the isolation of a particular section of DNA. Instead, Myriad's claims focus on the genetic information encoded in the BRCA1 and BRCA2 genes. The Court recognized that if the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid Myriad's patent claims on entire genes by simply isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. By necessity, then, the Myriad patents seek patent protection for the information contained in the genetic sequence, not the specific chemical composition of a particular molecule.

The Court did, however, hold that Myriad's creation of BRCA cDNA from the BRCA genes that it located was eligible for patent protection. The Court held that "the lab technician unquestionably creates something new when cDNA is made." Indeed, noted the Court, cDNA retains the naturally occurring portions of DNA, but is chemically distinct from the DNA from which it was derived. As a result, cDNA is not a "product of nature" and is patent eligible, except perhaps in limited cases where a short strand of cDNA may be indistinguishable from natural DNA, which was not the case with Myriad's BRCA cDNA.

Court Applies "Missing Witness" Rule to Treatment Over Objection Proceeding; Denies Psychiatric Facility's Request for a Treatment Order Where Patient's Treating Psychiatrist Was Available But Did Not Testify

In the Matter of Adam K. v. Iverson, 970 N.Y.S.2d 297 (2d Dep't 2013). On August 31, 2011, Creedmoor Psychiatric Center ("Creedmoor"), through its

director Kathleen Iverson ("Petitioner"), brought an application pursuant to Mental Hygiene Law ("MHL") § 7.09(b) and 14 NYCRR 527.8(c)(4) for an order permitting the administration of antipsychotic medication over the objection of Adam K. ("Patient"), an involuntarily committed sixty-three year old male, who resided at the Queens, New York facility.

Prior to seeking the order, Petitioner complied with the statutory framework established by 14 NYCRR 527.8(c)(4)(ii) and had Patient examined by two physicians, Patient's treating psychiatrist, Dr. Mathew, and a reviewing psychiatrist, Dr. Reddy. Both doctors averred that Patient not only suffered from a mental illness and had refused medication, but that Patient lacked the capacity to make a reasoned decision regarding Patient's own treatment, and that a court order compelling medications was in Patient's best interest.

At the treatment over objection hearing, Patient, who did not attend the hearing, was represented by the Mental Hygiene Legal Services ("Respondent"). At the hearing, Petitioner called Dr. Brodsky, a Creedmoor psychiatrist, as its sole witness. The parties further stipulated to the admission of Patient's clinical record, which included reports prepared by Dr. Mathew.

Although Dr. Brodsky had reviewed Patient's records and met with Patient on a prior occasion, the Court inquired why Dr. Brodsky appeared in Dr. Mathew's stead. After Dr. Brodsky testified that Dr. Mathew was available to appear, but that Petitioner elected not to call him in order to preserve the patient-psychiatrist relationship, the Court, sua sponte, held that Petitioner's failure to call Dr. Mathew justified application of the "missing witness" rule. Upon continued testimony, Dr. Brodsky asserted that Patient lacked capacity and that court ordered medication was in Patient's best interest. However, on cross-examination, Dr. Brodsky was questioned about Dr. Mathew's evaluation, which indicated that Patient only had a "partial to fair" response to medication. Dr. Brodsky countered that such a response was actually a "good response," but conceded that her experience with Patient was limited.

The Court held that Dr. Mathew was available and under Petitioner's control, and that Petitioner had not satisfactorily accounted for Dr. Mathew's non-appearance. Accordingly, the Court applied the "missing witness" rule and drew an adverse inference against Petitioner. The Court then denied Petitioner's application, holding that while Petitioner demonstrated that Patient lacked capacity by clear and convincing evidence, Petitioner did not prove by the same standard that the proposed treatment was narrowly tailored to give substantial effect to Patient's liberty interest as is Petitioner's burden. On appeal, the Second Department considered if (i) the "missing witness" rule was properly applied where, as is here, Petitioner did not call Patient's treating psychiatrist, and whether (ii) Petitioner had failed to establish that the proposed treatment was narrowly tailored.

The Court held that the "missing witness" rule is properly invoked where an "uncalled witness possessing information on a material issue would be expected to provide noncumulative testimony in favor of the opposing party and is under the control of and available to that party." Application of the rule permits the "trier of fact to draw the strongest possible adverse inference" as to any evidence which the missing witness would be in a position to controvert. At the same time, the Court cautioned that the "missing witness" rule may be avoided where a party can demonstrate that the missing witness is not under the party's control or is unavailable, or where the testimony to be provided is not material, would otherwise be in the party's favor, or is cumulative.

The Court upheld the trial court's determination that Dr. Mathew was under Petitioner's control and was available despite Petitioner's assertion that Dr. Mathew be deemed unavailable by virtue of a policy in favor of the patient psychiatrist relationship. The Second Department rejected this argument, finding that Petitioner had failed to identify the basis for such, and that this purported policy was contradicted by Petitioner's calling treating psychiatrists in earlier treatment hearings. Moreover, the Court reasoned that even if it accorded weight to Petitioner's policy, Dr. Mathew's examination would not have interfered with the relationship as Patient did not attend the hearing and was already on notice of Dr. Mathew's findings. The Court noted that under different facts, a facility may be able to show a lack of control and/or availability of a treating psychiatrist.

After ruling that Dr. Mathew was available to appear, the Court held that Dr. Mathew's testimony touched upon material issues and disputed Petitioner's claims that MHL and 14 NYCRR 527.8 inured against application of the "missing witness" rule. In particular, Petitioner argued that application of the "missing witness" rule was in error since a treating psychiatrist would be expected to provide testimony in favor of a psychiatric facility and also because there is no statute that requires that a treating psychiatrist testify at a hearing. However, the Second Department rejected both arguments, finding that the rule was properly applied.

Similarly, the Court rejected Petitioner's assertion that the concurring physician evaluations provided for under 14 NYCRR 527.8(c)(4)(ii) render a treating psychiatrist's testimony cumulative. Rather, a distinction exists between a statutory requirement that calls for independent medical opinions, and testimony that examines the basis for those judgments. As such, the Court ruled that governing statutes do not provide "sufficient assurance of cumulative testimony as to preclude the application of the 'missing witness' rule" in treatment cases.

Under Narrow Scope of Judicial Review Provided by Section 10(a)(4) of the Federal Arbitration Action, U.S. Supreme Court Upholds Arbitrator's Finding That General Arbitration Provision Provides for Class Arbitration

Oxford Health Plans LLC v. Sutter, 133 S. Ct. 2064, 2065, 186 L. Ed. 2d 113 (2013). Physician brought a class action lawsuit against Oxford for allegedly failing to fully and promptly pay him and other physicians under a fee-for-services contract. After a motion made by Oxford, the claim was compelled to arbitration based on a binding arbitration provision in the parties' contract. The parties then agreed that the arbitrator should determine whether the parties' contract authorized class arbitration.

In interpreting the parties' binding arbitration clause, which stated that "[n]o civil action concerning any dispute arising under this Agreement shall be instituted before any court, and all such disputes shall be submitted to final and binding arbitration…," the arbitrator found that the contract, on its face, expressed "the parties' intent that class arbitration can be maintained." Oxford filed a motion in federal court to vacate the arbitrator's decision, which was subsequently denied by the District Court. The Court of Appeals for the Third Circuit affirmed the denial, and the class arbitration proceeded.

While the class arbitration was ongoing, the United States Supreme Court issued a decision in *Stolt-Nielsen S.A. v. AnimalFeeds Int'l Corp*., 559 U.S. 662 (2010), that parties "may not be compelled…to submit to class arbitration unless there is a contractual basis for concluding that the party agreed to do so." In *Stolt-Nielsen*, the Supreme Court vacated an arbitrator's approval of class proceedings because, in that case, the parties stipulated that they had never reached an agreement on class arbitration. Thus, there was no contractual basis for concluding that the parties had agreed to class procedures.

Relying on the *Stolt-Nielsen* decision, Oxford asked the arbitrator to reconsider his approval of class arbitration. The arbitrator affirmed his prior decision, stating that *Stolt-Nielsen* had no bearing on the present matter because, unlike the parties in *Stolt-Nielsen*, the parties here had an agreement authorizing class arbitration. Oxford renewed the motion to vacate in federal court, which was again denied by the District Court. The Court of Appeals for the Third Circuit affirmed, stating that the power of review under § 10(a)(4) is limited in scope to simply whether or not the arbitrator's decision was based on a good faith attempt to interpret a contract, and that any decision based on contract interpretation is not subject to vacatur even where "serious errors of law or fact" were made.

Based on a circuit split as to whether § 10(a)(4) permits vacatur under similar circumstances, the United States Supreme Court granted certiorari and affirmed the Court of Appeals. The Supreme Court stated that, under § 10(a)(4), an arbitral award may be vacated only where an arbitrator exceeds his powers, which is a difficult burden to meet because "parties bargained for the arbitrator's construction of their agreement." Thus, any arbitral decision "arguably construing or applying the contract must stand, regardless of a court's view of its (de)merits."

Here, the parties agreed that the arbitrator was to determine whether the contract provision provided for class procedures, and twice the arbitrator determined that the contract did. This is unlike the unusual circumstances in *Stolt-Nielsen*—where the parties stipulated that they never reached an agreement with respect to class arbitration and, thus, the arbitrator had no contractual provision to interpret.

New York City's Notification of Hospital's Involvement in False Claim Action on Electronic Database Deemed Arbitrary and Unreasonable

New York and Presbyterian Hospital v. City of New York Mayor's Office of Contract Services, 39 Misc.3d 1214(A), 2013 N.Y. Slip Op. 50611(U). The New York and Presbyterian Hospital (the "Hospital") commenced an Article 78 Proceeding in Supreme Court, New York County, against the City of New York Mayor's Office of Contract Services (the "City") for an order and judgment declaring that the City engaged in an "abuse of discretion" by publishing a "Caution Notification" on its Vendor Information Exchange System (the "System"), concerning the Hospital's involvement in a Qui Tam, False Claims Action filed by a hospital employee. The System is an automated database maintained by the City to provide background information regarding prospective vendors seeking city contracts, and to assist contracting officers in determining whether a vendor has a "satisfactory record of business integrity." (New York City Procurement Policy Board Rules, 9 RCNY § 2-08(b)(2)(vi)).

The lawsuit alleged that a physician affiliated with the Hospital (and other hospital facilities) was engaged in unlawful Medicaid billing practices, and that the Hospital was complicit in those practices. The United States intervened, and filed a settlement agreement.

After learning of the settlement, the City posted a notification on the System stating that the Hospital was a party to the lawsuit and that it was "aware of [the physician's] fraudulent practices, failed to stop these practices, and caused his claims to be submitted to Medicare."

The Hospital argued that the City acted beyond its authority in posting the caution notification on the System because the Hospital's alleged conduct did not fall within one of the enumerated categories of information to be disclosed pursuant to the Administrative Code, and because

the Hospital was not given an opportunity to comment on the notification before it was posted. The Hospital also argued that the City failed to review the settlement agreement prior to issuing its post and that that a such a review would have revealed that: (a) the stipulation was not an admission of liability by the Hospital; (b) the entire settlement payment was made by another hospital facility; and (c) the plaintiff represented that he had no knowledge of any violations of law committed by the Hospital. The Hospital claimed that, without a complete retraction of the post, it would be forced to disprove allegations that had already been withdrawn, with prejudice, by the federal government.

The Court agreed with the Hospital's position. Initially, the Court pointed to the well-settled doctrine that a court "may not substitute its judgment for that of the board or body it reviews unless the decision on review is arbitrary and unreasonable and constitutes an abuse of discretion." The Court noted that while New York City regulations governing vendor responsibility include "a satisfactory record of business integrity" (See NY City Procurement Policy Board Rules, 9 RCNY § 2-08(b)(2)(vi)), the City was basing its System notification on "allegations on a complaint that was settled with no admission of wrongdoing by, or penalty to the Hospital, and which the United States agreed to dismiss with prejudice." That being the case, the Court held that maintenance of the System notification was arbitrary and unreasonable, and issued an order directing the City to remove any notice concerning the Hospital in connection with the Qui Tam action.

Fourth Department Holds That the New York State Office of Medicaid Inspector General Must Consider Underpayments to Providers When Determining Amount of Overpayment to Providers During Audits

Bulmahn v. New York State Office of Medicaid Inspector General, 106 A.D.3d 1504 (4th Dep't 2013). Petitioner, the owner of Niagara Pharmacy, sought to annul a determination of the Administrative Law Judge ("ALJ") following a fair hearing that upheld a Medicaid overpayment calculation by the New York State Office of Medicaid Inspector General ("OMIG"). The ALJ ruled that OMIG, in extrapolating the overpayment amount, need not consider any underpayments.

The Court first affirmed the general principle that medical assistance programs like Medicaid and Medicare may use an extrapolation method to calculate overpayments when the number of claims is "voluminous." The extrapolation method will be presumed to be valid, absent expert testimony and evidence to the contrary. Here, the Court found that petitioner submitted expert testimony sufficient to rebut the presumption. Specifically, the expert testified that Respondents' failure to consider the underpayment resulted in an inaccurate calculation in the overpayment amount. The ALJ ruled that OMIG "is not charged with auditing to detect and correct underpayments to providers." The Court, however, held that OMIG's failure to consider the underpayment was "irrational and unreasonable" because excluding the underpayments would not constitute "an accurate determination of the total overpayment made." Accordingly, the Court remitted the matter to OMIG for further proceedings.

Federal District Court Holds That a Physician's Conclusory Allegations Failed to State a Claim for Discrimination or Antitrust Violations

Bhanusali v. Orange Regional Medical Center, No. 10-cv-6694, 2013 WL 4828657 (S.D.N.Y. Aug. 12, 2013). Plaintiff Govindlal Bhanusali, M.D. ("Dr. Bhanusali") is an orthopedic surgeon with privileges to practice at the defendant hospital, Orange Regional Medical Center ("ORMC"). He and his medical practice brought suit against ORMC, several individuals working at ORMC, and a medical practice at which some of those individuals were employed, claiming that he was subject to a "sham peer review" at ORMC, which led to a temporary suspension of his medical staff privileges, as well as numerous restrictions on his privileges, rendering it economically and professionally impossible for Dr. Bhanusali to perform as an orthopedic surgeon. Plaintiff asserted numerous claims of discrimination based upon age, national origin, and race, including conspiracy to violate civil rights in violation of 42 U.S.C. § 1985, and antitrust claims under Section 1 of the Sherman Act and New York General Business Law § 340.

The Court dismissed the plaintiff's discrimination claims because he had not alleged sufficient facts to plausibly support an inference of discrimination. As an initial matter, the Court dismissed out of hand the premise that discrimination could be inferred simply because the individual defendants were younger than Dr. Bhanusali, and were white.

The Court then held that the plaintiffs had failed to show that comparative white and/or younger physicians who were subject to the same performance evaluations as Dr. Bhanusali, and engaged in comparable conduct, were treated more favorably on account of their age and race. The Court was unconvinced by the plaintiffs' conclusory assertions that white and/or younger physicians had engaged in conduct that led to lawsuits or adverse outcomes for patients, but went without peer review or discipline, because for the most part, the plaintiffs failed to identify the individuals involved or the nature of their alleged misconduct. Moreover, the few specific incidents that the plaintiffs did identify were not comparable. Those physicians had been involved in fewer incidents than Dr. Bhanusali, and plaintiff failed to establish that they had a comparable level of expertise. Plaintiff also failed to clearly describe the alleged incidents that led to his suspension.

The Court found even less convincing unconvincing the plaintiffs' examples of other nonwhite and/or

older physicians who had allegedly been treated less favorably than the white and/or younger physicians. For one nonwhite doctor, the plaintiffs failed to describe the type of doctor, what procedures were under review, how many incidents occurred, or anything about the allegedly discriminating white physicians. For another, the plaintiffs had made only conclusory allegations, and the allegations were remote in time to the treatment of Dr. Bhanusali, and therefore not instructive.

Based upon the plaintiffs' failure to provide any plausible comparators, the Court held that the plaintiffs had not alleged sufficient facts to support the inference that the defendants discriminated against Dr. Bhanusali on the basis of his race, national origin, or age, and therefore the Court dismissed all of the plaintiffs' discrimination claims, as well as his conspiracy claim under Section 1985.

Turning to the plaintiffs' antitrust claims, the Court first addressed the weight afforded to the decision of New York's Public Health and Health Planning Council ("PHHPC") in favor of ORMC. Dr. Bhanusali was required to bring his claim to the PHHPC before commencing a lawsuit, pursuant to the doctrine of primary jurisdiction, because the PHHPC possesses medical expertise that assists courts in resolving factual questions. However, even though the PHHPC had found for ORMC, the Court declined to rely upon the PHHPC's findings as a basis for granting the motions to dismiss, holding that the PHHPC's decision was helpful as a guide, but was not binding. Accordingly, the Court reviewed the plaintiffs' antitrust claims on independent grounds.

First, the Court held that Section 340 of New York's General Business Law does not apply to physicians. The plaintiffs did not dispute this argument, and therefore their § 340 claim was dismissed.

Second, the Court held that the plaintiffs had failed to allege an actionable antitrust injury, because they did not allege facts sufficient to show that the defendants' actions had caused an adverse effect on the competitive market. The plaintiffs alleged merely that they had been harmed, and that the removal of Dr. Bhanusali from the identified market (which was sizable) had reduced patient choice. They had provided no factual basis for these conclusory allegations, such as evidence about patient choice within the relevant market, or whether patients could no longer receive the types of services provided by Dr. Bhanusali, and therefore they had failed to state an antitrust claim.

Court Finds Penalty of Conditioning Medical Resident's License Upon Her Participation in a Medical or Psychiatric Examination Commensurate with Determination That Resident Practiced with Medical Incompetence on Multiple Occasions

Mehulic v. State Board for Professional Medical Conduct, 307 A.D.3d 1066, 967 N.Y.S.2d 183 (3d Dep't, June 6, 2013). Petitioner, a medical resident, commenced an Article 78 proceeding challenging a determination by the Administrative Review Board for Professional Medical Conduct ("ARB") that she practiced with incompetence on more than one occasion, and the Board's decision to place limitations on any future medical license Petitioner may obtain in New York.

Petitioner, a second-year resident, was charged with multiple counts of professional misconduct. A Hearing Committee sustained one specification of practicing the profession with incompetence on more than one occasion. The ARB upheld that determination. In addition, the Board conditioned issuance of a medical license to Petitioner on (i) her participation in a medical or psychiatric examination pursuant to Public Health Law § 230(7)(a), (ii) compliance with any order that results from such examination, (iii) and a three-year period of probation should such license be issued.

Petitioner alleged that (i) there is no rational basis for the hearing committee's determination that she practiced with incompetence on more than one occasion, (ii) she was denied the right to due process and a fair hearing and (iii) the penalty imposed is an abuse of discretion.

The Court found that the Board's determination that Petitioner practiced medicine with incompetence on multiple occasions was factually supported with a rational basis. Although Petitioner offered a different version of the events, the Court deferred to the credibility determinations of the Hearing Committee, which "discounted the Petitioner's testimony, noting that Petitioner testified in a paranoid and unfocused manner, blamed others, and believed that there was a conspiracy against her."

The Court also held that the administrative law judge did not err in beginning the pre-hearing conference without Petitioner, or in conducting the first day of the hearing in Petitioner's absence because Petitioner was given the required notice and opportunity to be heard. Finally, the Court held that conditioning petitioner's license upon her participation in a medical or psychiatric examination, compliance with any order that results from such examination, and a three-year period of probation should a license be issued was not a disproportionate response to Petitioner's misconduct.

Compiled by Leonard Rosenberg, Esq. Mr. Rosenberg is a shareholder in the firm of Garfunkel Wild, P.C., a full service health care firm representing hospitals, health care systems, physician group practices, individual practitioners, nursing homes and other health-related businesses and organizations. Mr. Rosenberg is Chair of the firm's litigation group, and his practice includes advising clients concerning general health care law issues and litigation, including medical staff and peer review issues, employment law, disability discrimination, defamation, contract, administrative and regulatory issues, professional discipline, and directors' and officers' liability claims.

In the New York State Agencies

By Francis J. Serbaroli

Quality Assurance Requirements for Medical Use of Radioactive Materials and Radiation Therapy

Notice of Adoption. The Department of Health adopted the amendment to Part 16 of Title 10 NYCRR to update and enhance the safety and quality assurance standards concerning use of ionizing radiation and radioactive materials. Filing date: April 23, 2013. Effective date: May 8, 2013. *See* N.Y. Register May 8, 2013.

Family-Based Treatment Provisions

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending Parts 587, 593 and 594 of Title 14 NYCRR to repeal provisions with respect to Family-Based Treatment programs ceased on March 31, 2013. *See* N.Y. Register May 8, 2013.

Operation of Residential Treatment Facilities for Children and Youth

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending Part 584 of Title 14 NYCRR to add fire safety and smoking provisions, update information regarding facility construction and design, and correct minor errors. *See* N.Y. Register May 8, 2013.

Certified Home Health Agency (CHHA) and Licensed Home Care Services Agency (LHCSA) Requirements

Notice of Adoption. The Department of Health amended Parts 763 and 766 of Title 10 NYCRR to expand access to palliative care and eliminate physicians from the LHCSA quality improvement committee. Filing date: April 30, 2013. Effective date: May 15, 2013. *See* N.Y. Register May 15, 2013.

Limits on Administrative Expenses and Executive Compensation

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services added Part 812 to Title 14 NYCRR to ensure state funds paid by this agency to providers are not used for excessive compensation or unnecessary administrative cost. Filing date: May 14, 2013. Effective date: July 1, 2013. *See* N.Y. Register May 29, 2013.

Adverse Event Reporting Via NYPORTS System

Notice of Adoption. The Department of Health amended sections 405.8 and 751.10 of Title 10

NYCRR to update current provisions to conform with current practice. Filing date: May 14, 2013. Effective date: May 29, 2013. *See* N.Y. Register May 29, 2013.

Limits on Executive Compensation and Administrative Expenses in Agency Procurements

Notice of Adoption. The Department of Health amended Part 1002 to Title 10 NYCRR to ensure State funds and State-authorized payments are expended in the most efficient manner and appropriate use of funds. Filing date: May 14, 2013. Effective date: July 1, 2013. *See* N.Y. Register May 29, 2013.

Limits on Administrative Expenses and Executive Compensation

Notice of Adoption. The Office of Mental Health amended Part 513 to Title 14 NYCRR to implement Executive Order No. 38 to limit administrative expenses and executive compensation of providers of services. Filing date: May 14, 2013. Effective date: July 1, 2013. *See* N.Y. Register May 29, 2013.

Transfer of Involuntary Patients to Authorized Secure Facilities

Notice of Adoption. The Office of Mental Health amended Part 57 of Title 14 NYCRR to allow for the transfer of an involuntary patient from an OMH hospital to one of its regional forensic units. Filing date: May 13, 2013. Effective date: May 29, 2013. *See* N.Y. Register May 29, 2013.

Limits on Administrative Expenses and Executive Compensation

Notice of Adoption. The Office for People With Developmental Disabilities amended Part 645 to 14 NYCRR to curb abuses in executive compensation and administrative expenses and ensure that taxpayer dollars are used to help persons in need. Filing date: May 14, 2013. Effective date: July 1, 2013. *See* N.Y. Register May 29, 2013.

Electronic Prescriptions and Records for Hypodermic Needles and Hypodermic Syringes

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 80.131 and 80.133 of Title 10 NYCRR to allow a practitioner to issue an electronic prescription for hypodermic needles and syringes. *See* N.Y. Register June 5, 2013.

Operation of Residential Treatment Facilities for Children and Youth

Notice of Proposed Rulemaking. The Office of Mental Health proposed amending section 584.5 of Title 14 NYCRR to provide for the temporary increase in capacity of certain facilities for an additional three years. *See* N.Y. Register June 5, 2013.

Expand Medicaid Coverage of Enteral Formula

Notice of Emergency Rulemaking. The Department of Health amended section 505.5 of Title 18 NYCRR to expand Medicaid coverage of enteral formula for individuals with HIV infection, AIDS or HIV-related illness or other diseases. Filing date: June 7, 2013. Effective date: June 7, 2013. *See* N.Y. Register June 26, 2013.

Medicaid Managed Care Programs

Notice of Emergency Rulemaking. The Department of Health repealed Subparts 360-10 and 360-11 and sections 300.12 and 360-6.7 and added new Subpart 360-10 to Title 18 NYCRR to repeal old and outdated regulations and to consolidate all managed care regulations to make them consistent with statute. Filing date: June 14, 2013. Effective date: June 14, 2013. *See* N.Y. Register July 3, 2013.

Personal Care Services Program (PCSP) and Consumer Directed Personal Assistance Program (CDPAP)

Notice of Emergency Rulemaking. The Department of Health amended sections 505.14 and 505.28 of Title 18 NYCRR to establish definitions, criteria and requirements associated with the provision of continuous PC and continuous CDPA services. Filing date: June 19, 2013. Effective date: June 19, 2013. *See* N.Y. Register July 10, 2013.

Children's Camps

Notice of Emergency Rulemaking. The Department of Health amended Subpart 7-2 of Title 10 NYCRR to include camps for children with developmental disabilities as a type of facility within the oversight of the Justice Center. Filing date: June 25, 2013. Effective date: June 30, 2013. *See* N.Y. Register July 10, 2013.

Criminal History Information Reviews

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services added Part 805 to Title 14 NYCRR to enhance protections for service recipients in the OASAS System. Filing date: June 28, 2013. Effective date: June 30, 2013. *See* N.Y. Register July 17, 2013.

Patient Rights

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 815 and added new Part 815 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 28, 2013. Effective date: June 30, 2013. *See* N.Y. Register July 17, 2013.

Establishment, Incorporation and Certification of Providers of Substance Use Disorder Services

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 810 and added new Part 810 to Title 14 NYCRR to state the requirements or the establishment, incorporation and certification of providers of Substance Use Disorder Services. Filing date: June 28, 2013. Effective date: June 30, 2013. *See* N.Y. Register July 17, 2013.

Patient Rights

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 836 and added new Part 836 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 28, 2013. Effective date: June 30, 2013. *See* N.Y. Register July 17, 2013.

Credentialing of Addictions Professionals

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 853; and added new Part 853 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: June 28, 2013. Effective date: June 30, 2013. *See* N.Y. Register July 17, 2013.

Standards for Adult Homes and Adult Care Facilities Standards for Enriched Housing

Notice of Emergency Rulemaking. The Department of Health amended Parts 487 and 488 of Title 18 NYCRR to revise Parts 487 and 488 in regards to the establishment of the Justice Center for Protection of People with Special Needs. Filing date: June 27, 2013. Effective date: June 30, 2013. *See* N.Y. Register July 17, 2013.

Implementation of the Protection of People with Special Needs Act and Reforms to Incident Management

Notice of Emergency Rulemaking. The Office of Mental Health amended of Parts 501 and 550; repealed Part 524; and added new Part 524 to Title 14 NYCRR to enhance protections for people with mental illness served in the OMH system. Filing date: June 28, 2013. Effective date: June 30, 2013. *See* N.Y. Register July 17, 2013.

Medical Assistance Rates of Payment for Residential Treatment Facilities for Children and Youth

Notice of Emergency/Proposed Rulemaking. The Office of Mental Health amended Part 578 of Title 14 NYCRR to remove the trend factor from the 2013-14 Medicaid rate calculation and adjust the occupancy rates. Filing date: June 28, 2013. Effective date: June 28, 2013. *See* N.Y. Register July 17, 2013.

Implementation of the Protection of People with Special Needs Act and Reforms to Incident Management

Notice of Emergency Rulemaking. The Office for People With Developmental Disabilities amended Parts 624, 633 and 687 and added new Part 625 to Title 14 NYCRR to enhance protections for people with developmental disabilities served in the OPWDD system. Filing date: June 28, 2013. Effective date: June 30, 2013. *See* N.Y. Register July 17, 2013.

Reimbursement of Prevocational Services Delivered in Sheltered Workshops

Notice of Emergency/Proposed Rulemaking. The Office for People With Developmental Disabilities amended section 635-10.5 of Title 14 NYCRR to establish limits on the reimbursement of prevocational services delivered in sheltered workshops. Filing date: July 1, 2013. Effective date: July 1, 2013. *See* N.Y. Register July 17, 2013.

Prevention of Influenza Transmission by Health Care and Residential Facility and Agency Personnel

Notice of Adoption. The Department of Health amended sections 2.59, 405.3, 415.19, 751.6, 763.13, 766.11 and 793.5 of Title 10 NYCRR to require hospital, diagnostic and treatment center, nursing home, home care and hospice personnel to wear a surgical or procedure mask if not vaccinated for Influenza. Filing date: July 11, 2013. Effective date: July 31, 2013. *See* N.Y. Register July 31, 2013.

Unauthorized Providers of Health Services

Notice of Adoption and Revised Emergency Rulemaking. The Department of Financial Services amended Part 65 of Title 11 NYCRR to establish standards and procedures for the investigation and suspension or removal of a health service provider's authorization. Filing date: July 22, 2013. Effective date: July 22, 2013. *See* N.Y. Register August 7, 2013.

Reduction to Statewide Base Price

Notice of Emergency Rulemaking. The Department of Health amended section 86-1.16 of Title 10 NYCRR to continue a reduction to the statewide base price for inpatient services. Filing date: July 22, 2013. Effective date: July 22, 2013. *See* N.Y. Register August 7, 2013.

Statewide Pricing Methodology for Nursing Homes

Notice of Emergency Rulemaking. The Department of Health added section 86-2.40 to Title 10 NYCRR to establish a new Medicaid reimbursement methodology for Nursing Homes. Filing date: July 23, 2013. Effective date: July 23, 2013. *See* N.Y. Register August 7, 2013.

Death Certificates

Notice of Proposed Rulemaking. The Department of Health proposed amending section 35.4 of Title 10 NYCRR to issue a death certificate to any applicant upon the request of a sibling of the deceased. *See* N.Y. Register August 7, 2013.

Provider Requirements for Insurance Reimbursement of Applied Behavior Analysis

Notice of Emergency Rulemaking. The Department of Financial Services added Part 440 (Regulation 201) to Title 11 NYCRR to establish standards of professionalism, supervision, and relevant experience for providers of Applied Behavior Analysis. Filing date: July 25, 2013. Effective date: July 25, 2013. *See* N.Y. Register August 14, 2013.

Episodic Pricing for Certified Home Health Agencies (CHHAs)

Notice of Emergency Rulemaking. The Department of Health amended section 86-1.44 of Title 10 NYCRR to exempt services to a special needs population from the episodic payment system for CHHAs. Filing date: July 24, 2013. Effective date: July 24, 2013. *See* N.Y. Register August 14, 2013.

Physician Assistants and Specialist Assistants

Notice of Proposed Rulemaking. The Department of Health proposed amending section 94.2 of Title 10 NYCRR to change restriction of the number of physician assistants under the supervision of a physician in a private practice from 2 to 4. *See* N.Y. Register August 14, 2013.

Tanning Facilities

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 72-1 of Title 10 NYCRR to further clarify the authority of local jurisdictions to enact and enforce local regulations governing tanning facilities. *See* N.Y. Register August 14, 2013.

Prescription Monitoring Program

Notice of Adoption. The Department of Health amended Part 80 of Title 10 NYCRR to include reporting requirements to the prescription monitoring program registry by pharmacies and dispensing practitioners. Filing date: August 6, 2013. Effective date: August 27, 2013. *See* N.Y. Register August 21, 2013.

Adult Day Health Care Programs and Managed Long Term Care

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 425 of Title 10 NYCRR to create a hybrid model of adult day health care. *See* N.Y. Register August 28, 2013.

Statewide Planning and Research Cooperative System (SPARCS)

Notice of Proposed Rulemaking. The Department of Health proposed amending section 400.18 of Title 10 NYCRR to delete obsolete language, realign to current practice, add new provisions, including mandated outpatient clinic data collection. *See* N.Y. Register August 28, 2013.

Definitions Pertaining to This Chapter

Notice of Adoption. The Office of Mental Health, the Office for People With Developmental Disabilities, and the Office of Alcoholism and Substance Abuse Services repealed Part 72 of Title 14 NYCRR to remove an outdated Part in Title 14 NYCRR. Filing date: August 7, 2013. Effective date: August 28, 2013. *See* N.Y. Register August 28, 2013.

Amendments to Person-Centered Behavioral Intervention

Notice of Adoption. The Office for People With Developmental Disabilities amended section 633.16 of Title 14 NYCRR to expand minimum qualifications of parties authorized to develop and monitor behavior support plans and make technical changes. Filing Date: August 12, 2013. Effective date: August 28, 2013. *See* N.Y. Register August 28, 2013.

Minimum Standards for the New York State Partnership for Long-Term Care Program

Notice of Proposed Rulemaking. The Department of Financial Services proposed amending Part 39 (Regulation 144) of Title 11 NYCRR to amend the minimum daily benefit amounts for 2014 through 2023 for the New York State Partnership for Long-Term Care Program. *See* N.Y. Register September 4, 2013.

Administration of Vitamin K to Newborn Infants

Notice of Proposed Rulemaking. The Department of Health proposed amending section 12.3 of Title 10 NYCRR to require Vitamin K administration to newborn infants be consistent with 2012 American Academy of Pediatrics' Policy Statement. *See* N.Y. Register September 4, 2013.

School Immunization Requirements

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 66-1 of Title 10 NYCRR to amend and update NYS school entry immunization requirements. *See* N.Y. Register September 4, 2013.

Capital Projects for Federally Qualified Health Centers (FQHCs)

Notice of Emergency Rulemaking. The Department of Health amended section 86-4.16 of Title 10 NYCRR to state that Capital Projects with a total budget of less than $3 million shall be exempt from Certificate of Need (CON) requirements. Filing date: August 28, 2013. Effective date: August 28, 2013. *See* N.Y. Register September 18, 2013.

NYS Medical Indemnity Fund

Notice of Emergency Rulemaking. The Department of Health amended Part 69 of Title 10 NYCRR to provide the structure within which the NYS Medical Indemnity Fund will operate. Filing date: August 30, 2013. Effective date: August 30, 2013. *See* N.Y. Register September 18, 2013.

Presumptive Eligibility for Family Planning Benefit Program

Notice of Emergency Rulemaking. The Department of Health amended section 360-3.7 of Title 18 NYCRR to set criteria for the Presumptive Eligibility for Family Planning Benefit Program. Filing date: September 3, 2013. Effective date: September 3, 2013. *See* N.Y. Register September 18, 2013.

Certificate of Public Advantage

Notice of Proposed Rulemaking. The Department of Health proposed adding Subpart 83-1 to Title 10 NYCRR to allow the health care industry to obtain reasonable protections from antitrust liability through an active state oversight program. *See* N.Y. Register September 18, 2013.

Compiled by Francis J. Serbaroli. Mr. Serbaroli is a shareholder in the Health & FDA Business Group of Greenberg Traurig's New York office. He is the former Vice Chairman of the New York State Public Health Council, writes the "Health Law" column for the *New York Law Journal*, and is the former Chair of the Health Law Section. The assistance of Caroline B. Brancatella, Associate, of Greenberg Traurig's Health & FDA Business Group in compiling this summary is gratefully acknowledged.

New York State Fraud, Abuse and Compliance Developments

Edited By Melissa M. Zambri

New York State Department of Health OMIG Audit Decisions

Compiled by Eugene M. Laks

None to report.

New York State Attorney General Press Releases

Compiled by Charles Z. Feldman

Albany Nurse's Aide Who Hit an Elderly Patient in the Face with Urine-Soaked Underwear Arrested for Physical and Mental Abuse—September 20, 2013—An Albany nurse's aide faces an endangering the welfare of a vulnerable elderly person charge and other allegations after she grabbed an elderly patient by the left wrist, twisted her arm behind her head and then hit the woman in the face with her own hand and a pair of urine-soaked briefs.

Three Queens EMTs Arrested for Stealing Funds from Volunteer Ambulance Corps—September 20, 2013—The treasurer of a Queens volunteer ambulance organization allegedly embezzled more than $300,000 from the organization's bank accounts and used the money to fund vacations, expensive meals and luxury car service trips. MFCU arrested two others for receiving unauthorized wire transfers and making purchases with the organization's credit cards.

Bronx RN Indicted for Theft of Transdermal Fentanyl Patches from Ventilator-Dependent Nursing Home Residents—September 12, 2013—A Bronx RN faces 1 1/3 to 4 years in prison for stealing Fentanyl patches from ventilator-dependent nursing home residents for her own personal use.

Medicaid Beneficiaries Plea to Their Involvement in an Oxycontin Ring in Rochester—September 10, 2013—An office manager for a Rochester area physician wrote fraudulent Oxycontin prescriptions on her employer's prescription pad and then paid Medicaid beneficiaries to fill the prescriptions for her. The case against the office manager remains pending, but the Medicaid beneficiaries involved in the scheme pled guilty and were ordered to pay restitution and to serve three years probation.

Rochester Dentist Pays $480K Restitution and Pleads Guilty for Fraudulently Billing Medicaid—August 16, 2013—Between 2007 through 2010, a Rochester dentist charged Medicaid $480,000 for surgical extractions of teeth when only simple extractions were performed. The dentist also admitted that he "upcoded" claims for dental fillings and that he billed for immediate dentures, which are not permitted under Medicaid rules. The dentist was sentenced to full restitution and community service.

Rochester Man Who Used a Phony College Degree to Get a Job with a Rochester OPWDD Provider Pleads Guilty to Fraudulently Billing Medicaid—August 14, 2013—A Rochester area OPWDD provider hired a service coordinator under the false pretense that the individual had a college degree. The degree was phony. While on the job, the service coordinator performed services that, per the Medicaid regulations, must be performed by a person who has certain educational qualifications. Since the service coordinator did not meet the requirements, he caused his employer to bill and receive payment in violation of the Medicaid rules. The employee agreed to pay full restitution and serve three years probation.

Man Pleads Guilty to Practicing Medicine Without a License—August 2, 2013—A man from Michigan obtained a New York license to practice medicine under false pretenses since he failed to complete his residency training when he applied for licensure. Subsequently, he billed Medicaid for services he provided and ordered despite lacking the proper credentials to practice medicine. The man entered a guilty plea and paid a $300,000 settlement.

Queens Doctor Arrested for Selling Oxycodone Prescriptions—July 30, 2013—A Queens based pain management practice allegedly charged patients $250 for office visits during which the patients would receive a prescription for Oxycodone even though the doctor did not physically examine or question the patients about their need for the medications. The doctor running the practice faces up to 15 years in prison.

Wyeth Pharmaceutical to Pay $500 Million for Improperly Marketing Kidney Transplant Drug—July 30, 2013—Wyeth Pharmaceutical resolved a multi-state investigation into its marketing of the kidney transplant drug Rapamune. Rapamune is given after a kidney transplant to keep a patient's body from rejecting the new kidney. The Attorneys General charged that Wyeth marketed, sold and used the drug in connection with non-kidney transplants, even though the FDA only approved Rapamune in connection with kidney transplants. New York will receive about $8.5 million from the settlement.

Facebook Post of a Video Featuring a Nursing Home Patient Leads to Arrest of a Nurse's Aide—July 23, 2013—A former nurse's aide at a Long Island Nursing Home faces up to a year in prison after posting on Facebook a video showing the verbal

harassment of an elderly patient. The footage occurred in the common area of the nursing home. The State charged the nurse's aide with violating the Nursing Home Patient's Bill of Rights and provisions of New York's Public Health Laws.

Dental Clinic Pays Restitution for Claims of Excess Billings for Dental Services—July 22, 2013—MFCU found that an Erie County dental clinic billed Medicaid for excess services. Despite Medicaid regulations that permit reimbursement for one teeth cleaning in a six-month period unless there is a notation in the patient's chart showing medical necessity for more frequent cleanings, some Medicaid patients of this clinic received cleanings more often than once every six months. The clinic also billed for services that were not properly documented, and for services for which Medicaid does not allow for reimbursement. The clinic agreed to pay $268,000 in restitution to the State.

The Leader of a Hudson Valley Oxycodone Trafficking Operation Sentenced to 5 Years in Prison—July 16, 2013—MFCU previously announced the arrests of several people involved in a prescription drug trafficking scheme where the leader of the scheme supplied the others with forged prescriptions, a van ride to different pharmacies across New York and enough cash to pay to fill the prescriptions. The leader of the scheme pled guilty to his role and admitted that he obtained close to 16,000 Oxycodone pills. He was sentenced to 5 years in prison.

OMIG Investigation of a Durable Medical Goods Supplier Leads to Grand Larceny Charges from MFCU Relating to Illegally Billing Medicaid for Pediatric Nutritional Formula—July 12, 2013—A Brooklyn durable medical goods supplier billed Medicaid for expensive pediatric nutritional supplements but dispensed only Pediasure. Medicaid permits providers to bill specialized infant formulas at $4.58 per unit and Pediasure at $.60 per unit. In total, the supplier allegedly dispensed 946,874 units of the specialized formula. The MFCU investigation was triggered by an OMIG investigation that revealed the supplier had none of the formula on hand for which it was charging Medicaid. The defendants face up to 25 years in prison.

Ambulette Agrees to Pay Restitution for Improperly Subcontracting Services—July 10, 2013—A Brooklyn ambulette subcontracted with an unregistered medical transportation services operator. Medicaid rules prohibit an enrolled ambulette from subcontracting medical transportation services to an entity that failed to register with Medicaid. The ambulette billed Medicaid for the service, retained 20% of the fees and disbursed the remainder of the fee to the subcontractor.

Nurse's Aide from Albany Admits to Falsification of Business Records—July 8, 2013—In Albany, a nurse's aide placed through the State's Consumer Directed Personal Assistance Program submitted false time sheets that were then verified by the disabled patient's sister. The time sheets falsely attested that the nurse's aide provided overnight care to the patient. The nurse's aide did not provide such care. The nurse's aide will be sentenced to 1½ to 3 years in prison, and will be ordered to pay $3,232 in restitution.

Bronx Man Convicted for No-Fault Insurance Scheme That Involved Exploiting Relationships with Radiologists to Set Up Practices Without the Doctors' Knowledge— June 26, 2013—A Bronx man, after lying to radiologists to convince them to work with him, exploited his access to their personal information to set up various illegal radiology corporations. He then directed No-Fault insurance claimants to the clinic and collected, in bank accounts he established under the doctors' names, payments from No-Fault insurance carriers for radiologic services. In total, the scheme took in over $8 million from the insurance companies.

Assault of an Elderly Nursing Home Resident Leads to Arrest of Suffolk County Nurse and Nurse's Aide—June 25, 2013—An 88-year-old resident of a Hauppauge nursing home suffered personal injuries when a nurse and nurse's aide tied the resident's hands together, held them above his head and punched him multiple times in his torso, and restricted his oxygen by holding a pillow over his face in bed. The two women face charges of assault and Endangering the Welfare of a Vulnerable Elderly Person.

HIV Patients Paid Not to Fill Their Prescriptions—Leads to Arrests and Convictions in $16 Million Fraud Ring—June 19, 2013 —A physician's assistant from the Bronx operated an HIV clinic rent-free within the same building where a pharmacy operated. The physician's assistant would prescribe HIV medications to patients and then refer these patients to the pharmacy located within the same building. The pharmacy would pay the patients approximately $100 for the prescriptions, bill Medicaid for the prescriptions, but not fill the prescriptions. Approximately 70% of the pharmacy's patients never received the prescriptions. In 1991, the State convicted the pharmacy owner for Medicaid fraud and banned him from participating in the Medicaid program. MFCU alleges he used his son to avoid this ban. The owner since absconded to Pakistan, but faces up to 25 years in prison.

Home Health Aide Agency That Employed Unqualified Home Health Aides Settles Whistleblower Action for $1 Million—June 18, 2013—After charging a Brooklyn-based and state-licensed home care services agency with employing unqualified home health aides, MFCU and a whistleblower entered into a settlement where the agency agreed to pay a total of one million dollars in restitution. The agency admitted that it billed for hundreds of thousands of dollars of services performed by aides who were not qualified to provide that care.

Kickback Scheme Leads to $2.5 Million Settlement with State—June 12, 2013—A Bronx nursing home and a social worker from Columbia Presbyterian entered into an agreement whereby the social worker would steer patients discharged from Columbia Presbyterian Hospital to the nursing home in exchange for cash payments.

The social worker received $300 for every referral, plus a $1,000 bonus for each 10 patients. The nursing home received $1.25 million in payments from Medicaid in connection with these patients, and the social worker received almost twenty thousand dollars in referral fees.

Queens Nursing Home Director Arrested for Falsifying Business Records to Cover-Up Information About Elderly Patient That Went Missing—June 8, 2013—A Queens nursing home director covered up the fact that a 74-year-old resident was missing from the facility. The day after the patient went missing, the defendant removed notes from the patient's medical records and instructed a staff member to falsely state in the resident's records that the resident left the home and told staff not to call the police. The defendant faces up to four years in prison.

New York State Office of the Medicaid Inspector General Update

Compiled by the Editor

Three Nursing Homes Will Reimburse New York State a Combined Total of $1,069,348 Because of Overpayments Disclosed in a Series of OMIG Audits—September 10, 2013—The providers will repay for billing cars not used to transport patients and other issues—http://www.omig.ny.gov/images/stories/press_releases/ThreeSNFs9102013.pdf.

Audit Part of OMIG's Successful Efforts to Contain Costs, Fight Fraud in Medicaid Program, Over 100 Million in Identified Overpayments for the First Half of 2013—http://www.omig.ny.gov/component/content/category/18-latest-news.

Long Island Pharmacy Denied Enrollment in NYS Medicaid Program—August 27, 2013—A Manhasset pharmacy will not be allowed to serve the Medicaid population following an investigation by the Office of the Medicaid Inspector General (OMIG)—http://www.omig.ny.gov/images/stories/press_releases/manhasset_8273012.PDF.

Kings County District Attorney Charles J. Hynes, NYC Human Resources Administration Commissioner Robert Doar, and Medicaid Inspector General James C. Cox Announce Indictment for Illegally Collecting Over $25,000 In Medicaid Benefits Since 2003—August 6, 2013—http://www.brooklynda.org/press_releases/2013/Press%20Releases%2008-13.html#04.

OMIG Publishes an Updated List of Compliance Best Practices, Opportunities for Enhancement and Insufficiencies—August 1, 2013—These lists are based on what OMIG observed during compliance program reviews of Medicaid providers' compliance programs—http://www.omig.ny.gov/compliance/compliance-library.

OMIG Discovers Security Breach: Employee Suspected of Releasing Unauthorized Data— July 15, 2013—http://apps.cio.ny.gov/apps/mediaContact/public/preview.cfm?parm=E5EBBF49-5056-9D2A-10DAA90DCDDE22E1.

Audit Finds $316K in Medicaid Overpayments—July 9, 2013—A provider of OPWDD services received $316,018 in overpayments from the Medicaid program, according to an audit conducted by the Medicaid Inspector General (OMIG). The audit revealed issues with documentation for Medicaid service coordination—http://omig.ny.gov/images/stories/audit_reports/July2013/09-5246.pdf.

Developmental Disability Provider Overcharged Medicaid by $250K—June 27, 2013—An audit of the Medicaid program at a Westchester outpatient developmental disability service provider found that it overcharged taxpayers more than $254,000— http://www.omig.ny.gov/latest-news/682-abbott-house.

The Office of the Medicaid Inspector General and the New York City Taxi and Limousine Commission (TLC) Execute a Joint Field Operation to Identify Unqualified Drivers Operating Medical Transportation Vehicles—June 26, 2013— http://omig.ny.gov/latest-news/678-omigtlc2.

M.D. Arrested After Joint Investigation—May 20, 2013—A psychiatrist who was billing for more than two full-time jobs was arrested because of overbilling concerns—http://www.omig.ny.gov/latest-news/681-presman-20-people-a-day.

OMIG Audit Protocols Posted to the OMIG Website as of September 23, 2013—Certified Home Health Agency, Diagnostic and Treatment Center, Hospital Outpatient Department (OPD) Emergency Room/Clinic, Hospital Outpatient Department (OPD) Laboratory, Hospital Outpatient Department (OPD) Ordered Ambulatory Other Than Laboratory, OPWDD Day Habilitation, OPWDD Day Treatment, OPWDD IRA Residential Habilitation, OPWDD Medicaid Service Coordination, OMH Rehabilitation Adult Services, OASAS Inpatient Chemical Dependence Rehabilitation Services, OASAS Outpatient Chemical Dependence Services, OMH Comprehensive Psychiatric Emergency Programs, OMH Rehabilitation Services Family-Based Treatment, Pharmacy, Transportation Ambulette, Transportation Taxi/Livery.

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For Your Information

By Claudia O. Torrey

Items of Interest

- According to several *Health Affairs* authors[1] (employed at the Centers for Medicare and Medicaid Services), health spending growth through 2013 is expected to remain slow due to the sluggish economic recovery, increases in cost-sharing requirements for the privately insured, and slow growth in public programs (for example, the United States Supreme Court decision making Medicaid expansion under the Affordable Care Act ["ACA"] optional for States). Ironically, health insurance coverage was set to expand via exchanges under the ACA as of October 1, 2013.

In 2014, projected growth in health spending is 6.1 percent with a projection of 6.2 percent per year through at least 2022; the sustained growth is based on predictions of both improved economic conditions and an aging population. Time will tell whether or not coverage expansion under the ACA adds to the projected sustained growth in national health spending.

- According to the World Alzheimer Report of 2013 ("Journey of Caring: An Analysis of Long-term Care for Dementia"), cases of elderly dementia will nearly triple by 2050.[2] Alzheimer's is the best known form of dementia but there are several types; worldwide, dementia care currently costs more than $600 million or about one percent of global gross domestic product.

According to *Alzheimer's Disease International* governments around the world should make dementia care a high priority with long-term care planning; social and health care systems should be coordinated to meet people's needs; and caregivers (both paid and unpaid) need to be adequately trained. Thus, there is an urgent need for future debates regarding long-term care issues.

- "Word on the street,"—that is K Street in Washington, D.C.—the pharmaceutical industry is very concerned about what Congress might do regarding the regulation of compounding entities![3] Bills coming from both the House and the Senate propose various types of Food & Drug Administration ("FDA") oversight—as a result of deaths (about a year ago) from contaminated steroid injections produced at the New England Compounding Center in Massachusetts.[4]

One side of the policy debate wants strict oversight of large-scale compounders, and the other side is concerned that "over regulation" will get in the way of patients acquiring the unique medications they need. Traditionally, licensed pharmacists are allowed to compound a physician's prescription for a patient in order to fit that patient's need—all this is overseen by State Pharmacy Boards; however, in recent years, compounding has grown from a "tailored" service by one's local pharmacist into a mass-produced corporate industry that escapes FDA scrutiny.

A consortium of medical and pharmaceutical companies, known as the *Working Group on Pharmaceutical Safety*, is attempting to lead the way toward consensus legislation that will also prohibit mass production compounders from copying commercial products "under the guise of pharmacy compounding." Let us all hope for the best because at the end of the day we are *all* patients!

Endnotes

1. *National Health Expenditure Projections, 2012-2022: Slow Growth Until Coverage Expands And Economy Improves,* Cuckler, Gigi A. et al., http://content.healthaffairs.org/lookup/doi/10.1377/hlthaff.2013.0721 (Internet, September 2013).
2. http://www.alz.co.uk/research/world-report-2013.
3. www.politico.com (Internet, September 24, 2013).
4. See *For Your Information*, Claudia O. Torrey, Vol. 18, No. 1 NYSBA Health Law Journal 24 (Winter 2013).

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Analysis of the Coordination of Benefits Between Medicare and Qualified Health Plans Purchased Through American Health Benefit Exchanges and the Small Business Health Options Program

By Marcia M. Schiff

Medicare provides federal health insurance to individuals 65 years of age or older and to disabled individuals under 65 years of age. Some Medicare beneficiaries have additional health insurance coverage from a variety of sources such as an employer group health plan, a retiree plan or Medicaid. When there is more than one potential payer of a claim, coordination of benefit rules establish which coverage pays first on a claim. To understand how Medicare coordinates with Qualified Health Plans (QHPs) available through the Exchanges, a few initial questions must be examined: Can Medicare beneficiaries enroll in Qualified Health Plans purchased through the American Health Benefit Exchanges or the Small Health Option Program Exchange? What is "minimum essential coverage"? When is a Medicare beneficiary deemed to have "minimum essential coverage"? Is it based on Medicare eligibility, enrollment or both? Is enrollment in QHPs cost effective for Medicare beneficiaries? Is enrollment in such plans beneficial or detrimental to Medicare beneficiaries?

As of 2014, every individual (citizen, national, noncitizen lawfully in the country who is not incarcerated) who meet residency requirements must have "minimum essential coverage." If such an individual does not have "minimum essential coverage" and he or she is not exempt from the requirement, he or she will face a federal penalty. The Patient Protection and Affordable Care Act (PPACA) signed into law on March 23, 2010 by President Obama creates state-based exchanges. When a state opts not to create a state-based exchange or enter into a state-federal partnership exchange then a solely federally facilitated health insurance exchange will be established. The health insurance exchanges (state-based, partnership or federally facilitated) provide a marketplace for individuals through American Health Benefit Exchanges (AHBEs) and a marketplace for small businesses through the Small Business Health Options Program (SHOP) to obtain coverage and avoid the imposed federal penalties.[1]

Beginning on October 1, 2013, individuals and small businesses can enroll in Qualified Health Plans through the Exchanges. There are new laws and regulations streamlining the enrollment process and implementing these plans and the Exchanges. As such it is important to understand how these new laws and regulations impact Medicare and the coordination of its benefits with the Qualified Health Plans available through the Exchanges.

While having health coverage is mandatory, use of the Health Insurance Exchanges to purchase health insurance is voluntary. Individuals and businesses can opt to purchase health coverage outside of the AHBEs or the SHOP. To assist individuals and to encourage businesses to obtain and provide health insurance through the AHBEs or the SHOP, there will be incentives for them through advance payment of tax credits and cost sharing subsidies to purchase Qualified Health Plans (QHPs).[2] Advance payment of tax credits and cost sharing subsidies are only available to individuals enrolled in QHPs through an Exchange and to individuals not eligible for "minimum essential coverage."

"Minimum essential coverage" includes coverage under government-sponsored programs such as Medicare.[3] Originally, regulations deemed that a person aging into Medicare would be eligible for government-sponsored "minimum essential coverage" when requirements for coverage under the program are met. Actual enrollment in the program was not necessary. Individuals who age into Medicare have a seven-month initial enrollment period which begins three months before they turn 65, includes the month they turn 65 and terminates three months after they turn 65. The originally proposed regulations cut short the seven-month initial enrollment period provided to Medicare eligible individuals aging into Medicare by deeming such individuals as eligible for "minimum essential coverage" on the first day of the first full month after the individual turned 65 years of age.

To resolve this problem, it was subsequently decided that an individual is deemed eligible for "minimum eligible coverage" for the purposes of the premium tax credit only if the individual is enrolled in the coverage. Failing to enroll, he or she will be deemed eligible for "minimum eligible coverage" on the first day of the fourth full month after the event establishing eligibility. In this way the final regulations took into account the seven-month initial Medicare enrollment period. This change allows individuals to enroll anytime during the seven-month initial enrollment period, including the last three months after their 65th birthday and not risk losing their tax incentives until their seven-month initial enrollment period ended or until they enrolled in Medicare, whichever comes first.[4] However, under the revised rule, if a person fails to enroll in Medicare during the seven-month initial enrollment period by the first day of the fourth month following his or her 65th birthday, he or she will face a lapse in coverage or a high cost QHP. This person will lose premium tax credits for a QHP purchased through an Exchange since he or she will be deemed to be eligible for "minimum essential coverage" and he or she will be in-

eligible to enroll in Medicare until the General Enrollment Period because he or she missed the seven-month initial enrollment period.

The Treasury Department and the IRS have published additional guidance, explaining when or if an individual becomes "eligible for government-sponsored minimum essential coverage" when the eligibility for that coverage is a result of a particular illness or disease.[5] In the case where an individual become eligible for Medicare based on illness or disease, an individual will *not* be considered to have "minimum essential coverage" *until* a favorable determination of eligibility has been reached by the responsible agency. Until this determination is reached the individual will be able to continue receiving tax incentives. Additionally, the Department of Treasury and the Internal Revenue Service acknowledge that there is an issue regarding individuals who do not qualify for free Medicare Part A based on their work history and as such must pay a high Part A premium. If these individuals are deemed enrolled and meeting "minimum essential coverage" requirements under the above referenced rules applying to age eligibility, they will face a great hardship. This population will forgo subsidized qualified health coverage for high cost Medicare coverage. The Department of Treasury and Internal Revenue Service are considering this issue and request comments from the public.

Medicare and QHPs from American Health Benefit Exchanges

The issue surrounding the Coordination of Benefits between Medicare and Qualified Health Plans pertains not so much to eligibility but to the affordability and the benefits of purchasing a Qualified Health Plan through an American Health Benefit Exchange. Individuals over 65 are not excluded from purchasing a Qualified Health Plan through the American Health Benefit Exchanges. A Qualified Health Plan cannot "design benefits or reimbursement in a way that discriminates against individuals because of their age, disability, or expected length of life." However, a QHP may charge older people up to three times more than younger ones.[6]

While Medicare beneficiaries will not face penalties under ACA as of 2014, as previously cited, many will be ineligible for tax incentives and cost-sharing subsidies offered for purchases of QHPs made through the American Health Benefit Exchanges.[7] Without tax incentives and cost-sharing subsidies Medicare beneficiaries face the possibility that a Qualified Health Plan purchased through an American Health Benefit Exchange will cost more than the combined premiums of Medicare Part B, Medicare Part D and a Medigap policy or even the cost of a Medicare Advantage Plan. As such an individual QHP could be more expensive than Medicare coverage. This is especially true for Medicare beneficiaries who may qualify for assistance through the Medicare Savings and/or the Extra Help Programs. Note that an exception to this cost-based analysis may apply to the Medicare eligible individual who must pay for a Medicare Part A premium in addition to other Medicare premiums. For this person, the purchase of a QHP through an Exchange may be a less expensive alternative, especially if the Department of Treasury and the IRS decide such a person can retain tax incentives. A further cost-based analysis of this issue can be performed when new guidelines are established and the premiums for the QHPs are published.

Besides extra expense, Medicare beneficiaries may be hurt by purchasing a QHP through an American Health Benefit Exchange. Medicare beneficiaries will not be able to purchase Medigap, Medicare Advantage Plans or Medicare Part D coverage through the American Health Benefit Exchanges. Generally, Medicare beneficiaries must enroll in Part B during their seven-month initial enrollment period to avoid a late enrollment penalty. Delaying Part B enrollment in lieu of an individual Qualified Health Plan (QHP) could subject the Medicare beneficiary to a 10% Part B premium penalty for every twelve months he or she delays enrollment. If an individual decides to enroll in Part B later he or she must do so during the General Enrollment Period from January to March each year with coverage beginning six months after enrollment (unless he or she qualifies for a Special Enrollment Period). As such a Medicare beneficiary who delays Part B enrollment in lieu of a QHP may face a lapse in coverage.[8]

Delaying Part D enrollment in lieu of a QHP could also subject the Medicare beneficiary to a Part D premium penalty of 1% of the national base beneficiary premium for every month the Medicare eligible individual delays enrollment. To avoid the Part D premium penalty, a Medicare eligible individual must maintain creditable coverage for at least 63 days or more. However, there is no determination yet on whether or not prescription drug coverage provided by QHPs purchased through the American Health Benefit Exchange or the SHOP is considered creditable coverage. Therefore, it is imperative that a person who becomes Medicare eligible promptly enroll in a Part D plan as well.

Medicare beneficiaries can buy separate long term care or dental coverage from Exchanges to supplement Medicare; however, there are no subsidies or advance payment of tax credits available for these purchases.[9] No issues of Coordination of Benefits apply between Medicare and long term care or dental policies since these policies offer benefits that are not offered by Medicare.

Medicare and QHPs from the Small Business Health Operation Program (SHOP)

Prior to 2016 states can limit exchanges to businesses with 50 or fewer workers. Starting in 2017 states can allow businesses with over 100 employees to purchase QHPs from the SHOP.[10] This provides the Exchanges and QHPs time to establish themselves before additional applicants are added to the risk pool. This staggered timeline especially impacts the Coordination of Benefits for disabled workers as will be discussed below. It also prevents busi-

nesses from terminating their health coverage and sending their workers individually to the American Health Benefit Exchanges for coverage. As such, small businesses in New York can buy health insurance coverage for its employees through the Small Business Health Options Program (SHOP) Exchange. Such businesses can also take advantage of a Small Business Health Care Tax Credit if they qualify.

Current Employees

When an employee with coverage from a QHP purchased through the SHOP becomes Medicare eligible, the coordination of his or her benefits works as any employer provided health insurance works. It would be a violation of the federal Age Discrimination in Employment Act (ADEA) for a business to drop an employee who continues to work past age 65 from his or her employer's group health plan.[11] Businesses are also prohibited under the Medicare Secondary Payer Rules from reducing current employees' health benefits due to their reaching the Medicare-eligible age of 65. Exceptions to these rules apply for certain small businesses. As such coverage for current employees over age 65 may be coordinated with Medicare and if that group health plan is a QHP purchased from the SHOP, that also may be coordinated with Medicare following Medicare Secondary Payer Rules.

In general, the Coordination of Benefits depends on the number of employees in the company and whether the employee or spouse, if covered under the spouse's employee health plan, is working, retired or disabled.

If the individual is 65 years of age or older, and is working for a company with less than 20 employees, Medicare provides primary coverage and the QHP provides secondary coverage.

If the individual is 65 years of age or older, and is working for a company with 20 or more employees, the QHP provides primary coverage and Medicare provides secondary coverage.

If the individual is disabled and is working for a company with less than 100 employees, Medicare provides primary coverage and the QHP provides secondary coverage.

If an individual is disabled and is working for a company with 100 or more employees, than the employer's group plan provides primary coverage and Medicare is secondary.

Note: The ACA penalizes large companies that do not offer health insurance if any of their full-time employees enroll in exchange plans and receive premium credits.[12] Further, New York is one of the states that have decided to limit its Exchange to businesses with 50 or fewer workers. As such, employers with over 50 employees in New York cannot purchase QHPs through the Exchange until 2016 when companies with up to 100 employees can purchase QHPs through the SHOP. As such until 2016, a disabled worker's primary insurance coverage will not be from a QHP purchased from the SHOP. Employee coverage can be from either a self-insured group plan or one purchased from the private market assuming the company offers health insurance, and if so Medicare will provide secondary coverage. In 2017 when companies with 100 or more employees can purchase QHPs through the SHOP, then the QHP will provide primary coverage for disabled individuals and Medicare will provide secondary coverage.[13]

Retired Employees

In situations regarding retired employees, different rules apply to the Coordination of Benefits between Medicare and a Qualified Health Plan purchased through the SHOP. Normally, in this situation the Coordination of Benefits depends on the worker's age at retirement and not the size of the company. Medicare provides primary coverage for retirees 65 years of age or older and the individual's retiree plan provides secondary coverage.

As stated earlier, the ACA penalizes large companies who do not offer health insurance if any of their full time employees enroll in exchange plans and receive premium credits.[14] However, when dealing with retirees under the Medicare age of 65, exceptions have been made for large companies. This exception has been made to eliminate the "early retiree" dilemma. When an employer does not offer retiree coverage, many individuals who are under 65 years of age and either choose to retire or are forced into retirement due to prolonged unemployment face many years without health insurance coverage until they reach the Medicare eligible age of 65. The Consolidated Omnibus Budget Reconciliation Act (COBRA) provides coverage to employees upon a qualifying event which can include retirees.[15] However, this coverage is expensive and only provides health insurance coverage for up to 36 months, leaving many early retirees unable to afford or obtain adequate health insurance to cover their gap in coverage.

To alleviate the "early retirement" dilemma, the ACA allows such individuals to purchase QHPs through the American Health Benefit Exchanges with tax incentives and subsidies, if they qualify. This provides early retirees with affordable health care coverage until they become Medicare eligible. For these early retirees, the QHP will be their total coverage. Once retirees become Medicare eligible they can no longer purchase coverage through the Exchange. Nor would they want to continue purchasing health insurance from the exchange since any tax incentives and subsidies for which they qualify would terminate upon their eligibility for Medicare, making the cost of QHPs prohibitive. As such, once they become Medicare eligible, they will be treated as retirees 65 years of age or older with Medicare becoming their coverage.

Qualified Health Plans (QHP) do not automatically terminate upon Medicare eligibility. The QHP must be provided with "reasonable notice" as to the termination of coverage. "Reasonable notice" has been set as 14 days or more.

If the QHP is provided with reasonable notice, the Medicare beneficiary can choose a specific termination date for the policy.[16] If the QHP is not provided with "reasonable notice," termination of coverage under the QHP will not be effective until fourteen days after the request for termination is made by the enrollee.[17]

There are many benefits for a Medicare beneficiary in designating a specific termination date. First, by choosing a specific termination date the Medicare beneficiary is able to obtain a safe harbor for the tax benefits, allowing him or her to enroll in Medicare anytime during their initial 7 month enrollment period without losing the tax incentives and subsidies attached to the QHP. Second, by choosing a specific termination date the Medicare beneficiary can coordinate the start of Medicare coverage and the termination of his or her QHP, thereby avoiding a lapse in coverage.

There are many disadvantages for a Medicare beneficiary who does not provide "reasonable notice." First, without providing reasonable notice the Medicare beneficiary may need to wait two weeks before the termination of one's QHP is effective. As such, if not timed correctly, the Medicare beneficiary can find herself enrolled in both a QHP and in Medicare resulting in the termination of tax incentives and subsidies but continuation of coverage. It is imperative for the Medicare beneficiary to disenroll from a QHP prior to obtaining Medicare coverage since the triggered loss of tax incentives and subsidies will result in higher premium bills from the QHP. Second, without providing "reasonable notice" the Medicare beneficiary risks losing QHP coverage before his or her Medicare coverage becomes effective, leaving him or her with a lapse in coverage.

Applicants looking to obtain QHPs in AHBEs will be screened for Medicare, CHIP and Medicaid. Those newly eligible for Medicare will not be referred to a QHP but will be referred to apply to Medicare for health insurance coverage.

Understanding how Medicare will coordinate with the Qualified Health Plans purchased through the American Health Benefit Exchanges and the Small Business Health Options Programs is extremely important in order to make sure that those with Medicare retain coverage and avoid extra expense due to late enrollment penalties and reduced tax incentives and subsidies. The implementation of the Health Care and Education Reconciliation Act of 2010 and the Patient Protection and Affordable Care Act is an ongoing process. Additionally, changes in the law will affect how the Coordination of Benefits between Medicare and QHPs are applied. For example, the U.S. Supreme Court recently struck down the Defense of Marriage Act.[18] Since Medicare is a federally sponsored benefit, the coordination of those benefits (if covered under spouse's employee plan) must be applied to same-sex spouses as it is currently applied to heterosexual spouses. As such, regular updates on this subject are necessary in order to keep up with the changes that will occur.

Endnotes

1. 45 CFR 1.155.100 2013, 45 CFR 1.155.140 2013, 45 CFR 1.155.700 2013.
2. Eligible Individuals and families with incomes between 138 percent and 400 percent of Federal Poverty Level are eligible for premium tax credits. Additionally, those who have lived in the U.S. for less than five years with incomes between 100% and 138% of the Federal Poverty Level may also be eligible for subsidies. In addition to premium credits, the Affordable Care Act establishes cost-sharing subsidies for eligible individuals. Act of Mar. 23, 2010, Pub. L. No. 111-148, Stat.119 as modified by Act of Mar. 30, 2010, Pub. L. No. 111-152, 124 Stat. 1029.
3. 26 U.S.C. § 5000A(f)(1)(A)(i) (2011).
4. 26 CFR Parts 1 and 602 (2012). Note different rules apply for those who qualify for Medicare based on ESRD.
5. See 26 CFR Part 601.601(d)(2) (2012); Department of Treasury and IRS Notice 2013-41 (June 2, 2013).
6. Julie Appleby, "A Guide to Health Insurance Exchanges," Paper prepared for Kaiser Health News, January 2013. p. 1.
7. The Patient Protection and Affordable Care Act provides that premium tax credits and related subsidies are terminated automatically upon Medicare eligibility and or enrollment. 42 U.S.C § 18001 (Act of Mar. 23, 2010, Pub. L. No. 111-148, Stat. 119 as modified by Act of Mar. 30, 2010, Pub. L No. 111-152, 124 Stat.1029; Health Insurance Premium Tax Credit 76 FR 50933-4, August 17, 2011, 76 FR 50941, August 17, 2011. See 26 CFR Part 601.601(d)(2) (2012); Department of Treasury and IRS Notice 2013-41 (June 2, 2013). As such, Medicare beneficiaries with free Medicare Part A coverage will not be required and will have no incentive to purchase QHPs through American Health Benefit Exchanges.
8. Leaving a QHP will not automatically provide you with a Special Enrollment Period unless you were accidentally or fraudulently enrolled in the plan. Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule and Interim Final Rule 77 Fed. Reg. 18390 (to be codified at 42 CFR 4.1455.420 2013).
9. Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule and Interim Final Rule 77 FR 18411 (to be codified at 42 CFR 4.155.1065 2013).
10. http://www.whitehouse.gov/files/documents/health_reform_for_small_businesses.pdf.
11. Age Discrimination in Employment (29 U.S.C. § 623).
12. On July 2, 2013, it was announced that the requirement that businesses with 50 or more provide health insurance to their workers or pay a penalty will be delayed until 2015, http://m.usatoday.com/article/news/2484623. As such it is questionable if businesses with 50 employees will participate in the SHOP.
13. http://www.whitehouse.gov/files/documents/health_reform_for_small_businesses.pdf.
14. *Id.*
15. The original health continuation provisions were contained in Title X of COBRA (Act of April 7, 1986, Pub. L. No. 99-272, 100 Stat. 82).
16. Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule and Interim Final Rule, 77 FR 18371-18374, 18394, 18395, 18463 (to be codified at 45 CFR 4.155.330 2012 and 45 CFR 4.155.430 2012); Health Insurance Premium Tax Credit, 76 FR 50933, 50934, 50941.
17. *Id.*
18. *United States v. Winsor*, 570 U.S. __ (2013), 2013 U.S. LEXIS 4935.

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Liability of Health Care Providers for the Emotional Injuries of "Bystanders"

By Karen M. Richards and Geraldine Gauthier

Introduction

Theories of recovery for so-called "bystander claims" have evolved over more than one hundred years.[1] Today in New York, bystanders can recover damages from health care providers and other private parties for their emotional distress caused by witnessing the death or injury of a family member.

Part I of this article explores the evolution of American jurisprudence on bystander claims, with particular focus on New York. It explains the "zone of danger" rule and the elements required for recovery under the rule in New York. Part II reviews how New York courts have applied the zone of danger rule and explains how a direct duty of care running from the health care provider to the plaintiff circumvents the rule through the application of traditional tort principles. Part III looks specifically at the development and current status of theories of recovery for emotional distress in traditional negligence and medical malpractice cases, in cases involving loss or disappearance of a patient, and in obstetrical cases, including miscarriage, stillbirth, and *in utero* injuries.

Part I

A. Early New York Jurisprudence on Emotional Distress Claims for Acts Directed Toward Third Persons

At the end of the 19th century, New York courts established two rules on recovery for emotional distress: (1) damages for emotional distress were disallowed unless accompanied by a physical injury;[2] and (2) there was no recovery for emotional distress resulting from the witnessing of a death or injury of a third party, unless plaintiff also suffered personal injuries.[3]

The first rule remained good law in New York until 1961, when it was overruled in *Battalla v. State of New York.*[4] In overruling the 1896 doctrine, the New York Court of Appeals noted that the rule "has been thoroughly repudiated by the English courts which initiated it, rejected by a majority of American jurisdictions, abandoned by many which originally adopted it, and diluted, through numerous exceptions, in the minority which retained it."[5] The *Battalla* court allowed an infant plaintiff to recover for "severe emotional and neurological disturbances with residual physical manifestations" that resulted from the negligence of a state ski resort employee who failed to properly strap the child into a chair lift.[6] Put differently by a later court, "one may have a cause of action for injuries sustained although precipitated by a negligently induced mental trauma without physical impact."[7]

The second rule, which barred recovery for emotional distress resulting from the witnessing of a death or injury to a third party, without accompanying injury to plaintiff,[8] remained good law in New York until the mid-1980s, but California was first to reject it in 1968.

"Today in New York, bystanders can recover damages from health care providers and other private parties for their emotional distress caused by witnessing the death or injury of a family member."

In *Dillon v. Legg*, a closely divided California Supreme Court overruled its own recent precedent to permit a mother to recover damages for the emotional distress she suffered from seeing her child struck by a car and fatally injured in a crosswalk.[9] The decision turned on the foreseeability of the emotional harm, which the court described as the "chief element" in determining whether the defendant owed a duty to the plaintiff.[10] If a duty is owed, the plaintiff could recover for emotional injuries alone.

The *Dillon* court enunciated three factors to be considered in deciding whether emotional harm from a defendant's negligence is foreseeable, and thus gave rise to a duty owed to a plaintiff:

(1) Whether plaintiff was located immediately near the scene of the accident;

(2) Whether plaintiff's shock resulted from a direct emotional impact resulting from the sensory and contemporaneous observance of the accident, as contrasted with learning of the accident from others after its occurrence; and

(3) Whether plaintiff and victim were closely related, as contrasted with the absence of any relationship or the presence of only a distant relationship."[11]

Three dissenting California justices, including Chief Justice Traynor, warned that the majority was "embarking upon a first excursion into the fantastic realm of infinite liability,"[12] but the majority opined that a case-by-case analysis using the three guidelines "will not expose the courts to false claims or a flood of litigation."[13]

The year following *Dillon*, the New York Court of Appeals heard *Tobin v. Grossman*.[14] In *Tobin*, a mother sought damages for emotional injuries occasioned by shock and fear for her young child, who was struck by an automo-

bile and seriously injured. The accident occurred when the mother left the child unattended outside, and was herself inside a neighbor's home. She did not see the accident, but she heard brakes screeching, ran immediately to the accident scene and saw her injured child lying on the ground.[15] Faced with the *Dillon* issue—whether "duty in tort should be extended to third persons, who do not sustain any physical impact in the accident or fear for their own safety"[16]—the New York Court of Appeals described the dilemma as a "profound question," because to allow recovery would create a new duty and an "an entirely new cause of action."[17]

New York criticized California's "foreseeability" approach, because it lacked any rational way to limit the scope of bystander claims.[18] "Relatives, other than the mother, such as fathers or grandparents, or even other caretakers, equally sensitive and as easily harmed, may be just as foreseeably affected [,] [h]ence, foreseeability would, in short order, extend…ultimately to affected bystanders."[19] The *Dillon* court's three guidelines, it said, were of little help in "holding strict rein on liability"[20] and it was particularly critical of the first two *Dillon* factors. "Any rule based solely on eye witnessing the accident could stand only until the first case comes along in which the parent is in the immediate vicinity but did not see the accident.[21] It further described the *Dillon* guidelines as "inconsequential[,] for the shock more likely results from the relationship with the injured party than what is seen of the accident."[22]

Ultimately, the *Tobin* court denied recovery of damages for emotional distress without accompanying physical injury "regardless of the relationship and whether the [sic] one was an eyewitness to the incident which resulted in the direct injuries," and it refused to recognize this new, proposed cause of action.[23]

In 1975, the Court of Appeals distinguished *Tobin* in a case against a state hospital, in which the hospital erroneously notified plaintiff that her mother, a patient in the facility, had died.[24] The Court of Claims had denied punitive damages, but had awarded plaintiff damages for the funeral expenses she incurred and for emotional distress.[25] The Appellate Division modified the award, limiting it to plaintiff's monetary loss for funeral expenses.[26] The Court of Appeals held that the hospital had a direct duty to advise the proper next of kin of patient deaths, and thus owed a direct duty to plaintiff, upon whom its negligence was inflicted and for which she could recover.[27]

B. A New Era: The New York "Zone of Danger" Rule

After *Tobin*, New York courts "hesitated for a long time before recognizing a very circumscribed right of recovery for bystanders based on the negligent infliction of emotional distress."[28] But recognition did finally occur in 1984, when a sharply divided Court of Appeals adopted the "zone of danger" rule in *Bovsun v. Sanperi*, and for the first time allowed a bystander to recover for purely emotional injury.[29]

In *Bovsun*, mother, father and child were motoring in their station wagon on the Southern State Parkway in Long Island when they experienced mechanical problems and pulled off to the side of the road. Father got out of the car, went to the rear of the vehicle and opened the tailgate. A vehicle struck him from behind and he was pinned between the two cars. Mother and child did not see the accident, but they felt the impact and both saw that father was seriously injured.[30]

The Court of Appeals recognized the "zone of danger" rule as the majority rule in the United States, "which allows one who is himself or herself threatened with bodily harm in consequence of the defendant's negligence to recover for emotional distress resulting from viewing the death or serious physical injury of a member of his or her immediate family."[31] Explicitly rejecting the earlier *Battalla* arguments—that the rule invites fraudulent claims or that emotional injuries are incapable of sufficient proof[32]—the Court said that in this case, the plaintiffs were within the "zone of danger" because they too were subject to an unreasonable risk of physical injury.[33] It held:

> [W]here a defendant negligently exposes a plaintiff to an unreasonable risk of bodily injury or death, the plaintiff may recover, as a proper element of his or her damages, damages for injuries suffered in consequence of the observation of the serious injury or death of a member of his or her immediate family—assuming, of course, that it is established that the defendant's conduct was a substantial factor in bringing about such injury or death.[34]

The *Bovsun* majority said it was not creating a new cause of action, but merely recognizing a plaintiff's right to recover from a defendant from whom a duty of care is owed.[35] Adoption of the zone of danger rule relieved the apprehension of unlimited liability to bystanders who might feign emotional injury, and the Court laid out three separate elements that must be met for liability to attach:

1. Defendant's conduct is negligent;
2. Defendant's negligent conduct created an unreasonable risk of bodily harm to plaintiff and the conduct is a substantial factor in bringing about injuries in consequence of fright from his or her contemporaneous observation of physical injury or death inflicted by the defendant's conduct in plaintiff's presence; and
3. The Defendant's negligent conduct was inflicted upon a member of plaintiff's immediate family.[36]

Part II

A. The *Bovsun* Elements as Applied by Later Courts

1. Defendant's Negligence and a Direct Duty of Care

The first element, that a defendant's conduct must be negligent, is determined under traditional tort principles.[37] Accordingly, in cases where the duty of care is owed directly to the person seeking recovery for emotional injuries, the courts will permit such recovery under traditional tort law principles.

For example, in *Moreta v. NYC Health & Hosp. Corp.*, an infant plaintiff who contracted tuberculosis sued defendants for discontinuing his mother's tuberculosis medication while she was pregnant. Experts testified that failure to treat active tuberculosis exposes an infant to a 50% chance of contracting the disease in its first year of life. The court said it was foreseeable that the infant would contract tuberculosis soon after its birth, therefore defendants owed a duty of care to the plaintiff *in utero*.[38]

In *Perry-Rogers v. Obasaju*, the defendant mistakenly implanted the plaintiffs' embryo into another patient's uterus.[39] The court reasoned that the plaintiff parents were not seeking damages for the emotional injuries related to birthing, but rather from "their being deprived of the opportunity of experiencing pregnancy, prenatal bonding and the birth of their child, and by their separation from the child for more than four months after his birth," and held that the defendant owed a duty of care directly to the plaintiffs.[40]

The duty of care was also found to run from health care provider to the patient mother in *Garcia v. Lawrence Hospital*, where the mother fell asleep on top of her baby and smothered it to death. The plaintiff mother was medically sedated when hospital staff brought her newborn baby to breastfeed and they left her unattended with the infant. Although she was found to have no cause of action under the *Bovsun* zone of danger rubric, the court concluded that the hospital owed and breached its duty of care, and the direct result of that breach was emotional harm.[41]

The Fourth Department also explored the issue of duty of care and to whom it is owed in *Shaw v. QC Medi New York, Inc.*[42] In *Shaw*, the plaintiffs' daughter, born with severe and profound physical impairments, was ventilator dependent and required 24-hour nursing care. Her trachea tube became dislodged when one of the defendant's nurses was attending to her care, causing an oxygen deprivation. The plaintiff mother witnessed the incident and saw her child sweating profusely, turn very blue in color, and slip into near unconsciousness, although the child recovered and sustained no permanent injury.

The plaintiff parents brought an action for negligent infliction of emotional distress, arguing that the mother was in the zone of danger when the incident occurred, therefore no allegation or proof of breach of an independent duty by the defendant owed to the plaintiff was required.[43] The plaintiffs also asserted that their prior written notice to the defendants expressing concerns about the child's care gave rise to an independent duty of care. They also argued that the stress experienced by the plaintiff mother, a diabetic, "is literally killing her."[44]

The defendants, citing *Zea v. Kolb*, argued that speculative injuries satisfied no element of the zone of danger rubric, and exacerbation of the plaintiff's diabetic condition was not a bodily harm suffered within the zone of danger nor was it the same harm suffered by her daughter.

The court commenced its analysis by noting:

> The issue of what duty is owed to third parties in a medical malpractice setting is a troubling one. Courts have been reluctant to hold a medical provider liable to the patient's family for emotional distress as a result of malpractice in treating the patient [citations omitted].…
>
> * * *
>
> The Court of Appeals has taken a very restrictive view toward third-party liability in medical malpractice cases.[45]

Ultimately, the court dismissed the claim for emotional distress on grounds that the mother was not within the zone of danger, and it refused to extend the *Bovsun* liability on policy grounds.

> To permit liability under these circumstances would create untold numbers of claims by third parties. Familial concerns are present in most instances involving relationships between health care providers and patients.… Were we to permit such liability as is sought by plaintiffs herein, medical providers would necessarily be concerned with matters unrelated to their treatment of patients.[46]

Courts have also declined to extend a health care provider's duty of care to a husband or father because it could "expand traditional tort concepts beyond manageable bounds and create an almost infinite universe of potential plaintiffs."[47] Consequently, a husband's or father's claim for emotional distress is subject to the same "zone of danger" proofs as would be required of any other bystander. Frequently, fathers and husbands are able to satisfy more of the requirements than ordinary bystanders, including being immediate family, contemporaneously observing the death or serious injury, and suffering a serious and verifiable emotional injury from this observation. But unless he can also demonstrate that

he was exposed to an unreasonable risk of bodily injury or death, his claim will be dismissed, as the following three cases illustrate.

In *Reed v. Cioffi, Seftel & Soni, P.C.*, the plaintiff claimed emotional distress from observing his wife's death and the stillbirth of his daughter, both of which resulted from the defendants' alleged obstetrical malpractice. His claim was dismissed because there was no showing that the defendants' negligence exposed him to unreasonable risk of physical injury such that he was within the zone of danger.[48]

In *Schram v. Herkimer Memorial Hospital*, a mother was left alone in the delivery room with her husband.[49] When she began to deliver her baby, no medical personnel were present and her husband assisted. The baby was born with the umbilical cord wrapped around his neck, suffered oxygen deprivation and died the next day. The husband's claim for the emotional distress he suffered from witnessing his child struggle to breathe failed, because he was not within the zone of danger and exposed to any risk of physical injury, nor did he allege that he suffered physical injuries.[50]

Similarly, in *Saguid v. Kingston Hospital*, the key element, being within the zone of danger and at risk of personal injuries, was also missing. In *Saguid*, as a result of an obstetrician's alleged malpractice, a baby died two days after birth.[51] In dismissing the father's claims for emotional distress the court said "he was merely a bystander and was not personally at risk of any physical injury; plainly, he cannot be said to have been in the 'zone of danger.'"[52]

2. Plaintiff Must Be Within the "Zone of Danger"; Contemporaneously Observe the Physical Injury or Death Caused by Defendant's Negligence; and the Negligence Is a Substantial Factor in Causing Plaintiff's Emotional Distress

The second element is effectively comprised of three separate parts (i) presence in the zone of danger; (ii) contemporaneous observation; and (iii) causation of plaintiff's injuries. The New York courts have dealt with all three.

i. Presence in the Zone of Danger

Plaintiffs must themselves be threatened with bodily harm as a result of a defendant's negligence. Put differently, a plaintiff must have been within the zone of danger. The boundaries of that zone and the identity of the persons within it are not always clear.

a. The Boundaries of the Zone of Danger

In a traditional automobile accident case, *Zea v. Kolb*,[53] the plaintiff mother was ten to fifteen feet away from the defendant's vehicle when it struck her daughter, but she was never in any danger of bodily harm and was therefore clearly outside the zone of danger. Her claim for the emotional injuries she suffered from observing the accident was denied, because allowing such recovery "would unreasonably expand bystander liability."[54]

Expansion of liability is carefully guarded in New York, as illustrated in *Landon v. N.Y. Hosp.*, where the defendants failed to timely diagnose bacterial meningitis in an infant, resulting in its parents' prolonged exposure to the disease.[55] Although the Supreme Court concluded the parents were in the zone of danger and that they were the foreseeable victims of this communicable disease, the Appellate Division said the duty of diagnosis ran from the defendants to the infant, and refused to widen its scope to allow recovery for the parents' psychic injuries. The Court of Appeals affirmed.[56]

Yet in *Lancellotti v. Howard*, a plaintiff who had been misdiagnosed as pregnant and who was treated for pregnancy for seven months could not recover for emotional injuries resulting from the misdiagnosis on grounds that her psychic harm was "unaccompanied by any form of physical trauma."[57]

Similarly, the court took a narrow approach to defining the zone of danger in *Arroyo v. New York City Health & Hosp. Corp.*, a case where two siblings were admitted to the same hospital for treatment of lead poisoning, placed in adjacent beds, and administered the same intravenous solution.[58] Tragically, the younger child went into cardiac arrest and died, allegedly due to the defendant's failure to properly control the flow of the intravenous solution. The other child contemporaneously witnessed the death of his sibling, feared for his own safety, and sought to recover damages for emotional injuries. Yet the court found that the two siblings were treated with two different intravenous systems, and refused to "characterize the threat of bodily injury to the older sibling and the breach of defendant's duty of care as to him as identical to that posed to and suffered by the younger sibling."[59] Otherwise stated, the child that survived the negligence was not within the zone of danger.

b. Persons Identifiable Within the Zone of Danger

Claims for medical malpractice have been dismissed where, at the time the tort was committed, the parties were not identifiable beings within the zone of danger. For example, in *Weed v. Meyers*, the plaintiffs, individually and as parents of their two infant children, commenced medical malpractice actions against the father's ophthalmologist alleging failure to warn of the risk that plaintiffs' children could develop retinoblastoma, a hereditary form of eye cancer.[60] Three decades after the ophthalmologist began treating Mr. Weed, the plaintiffs had two children, both of whom were diagnosed with retinoblastoma. The court found that the causes of action on behalf of the children could not be maintained since the children were not identifiable beings within the zone of danger when the alleged medical malpractice occurred.[61]

The issue of whether a non-patient was an identifiable being when the tort was committed often arises when a psychiatric patient harms a third person. In *Pingtella v. Jones*, the question before the court was whether a psychiatrist treating a woman for major depression with psychotic features owed a duty of care to his patient's child. While under the psychiatrist's treatment, the patient stabbed her nine-year-old son, believing he was the devil.[62] Quoting a 1981 Court of Appeals decision, the Appellate Division noted that at the time a tort is committed, the defendant has an independent duty to all identifiable beings within the zone of danger.[63] Here, it reasoned, the patient sought treatment for severe depression, not to prevent injury to her son. Accordingly, when the alleged malpractice occurred, the child was not an identifiable being within the zone of danger and the psychiatrist owed no duty to him that was independent of the duty he owed to his patient, the child's mother.[64]

An opposite conclusion was reached in *Lizardi v. Westchester County Health Care Corp.*, where the father sought to recover damages for the wrongful death of his seven-month-old son who was strangled to death by his mother.[65] In the months before this tragedy, the mother allegedly had repeatedly informed her doctors that she had thoughts of hurting and killing her baby. The court issued an unpublished opinion denying one defendant's pre-answer motion to dismiss, on grounds that the child was an "identifiable being within the zone of danger" in view of the mother's expressed intentions to harm the child.[66] Thus, the defendants may have owed the child a duty of care independent of the duty they owed to the mother.

ii. Contemporaneous Observation

Contemporary awareness, as opposed to actual visual, contemporaneous observation, can satisfy this element as illustrated in *Khan v. Hip Hospital, Inc.*[67] In this medical malpractice action, although the mother was awake, conscious and subject to a reasonable fear of injury during a prolonged delivery, she was under general anesthesia when her stillborn child was delivered.[68] The lack of contemporaneous observation was not fatal to her claim, because when she regained consciousness, her first words were, "'Can I see my baby?' and thereafter she was taken 'in a wheelchair to see fetus in [the] morgue.'"[69] The court found that these circumstances constituted a contemporaneous observation and allowed recovery for emotional injuries.[70]

iii. Defendant's Negligence Was the Proximate Cause of Emotional Injuries

The *Bovsun* court clearly said that physical injury to plaintiff was not a precondition for recovery, so long as all required elements are satisfied.[71] However, the emotional injury cannot be "any trifling distress"; it must be serious, verifiable, and tied, as a matter of proximate cause, to the observation of the serious injury or death of an immediate family member.[72] Medical treatment or psychological counseling is not essential to establish a serious and verifiable emotional injury, although it may be relevant to damages.[73]

3. Defendant's Negligent Conduct Was Inflicted Upon a Member of Plaintiff's Immediate Family

The *Bovsun* plaintiffs were married or related in the first degree of consanguinity to the injured or deceased person; therefore, the Court of Appeals did not need to decide "where lie the outer limits of immediate family."[74] Courts in later cases have struggled to precisely define to whom the term "immediate family member" applies.

The first such case came out of a lower court in the year following *Bovsun*, with a decision that a stillborn fetus was immediate family.[75] "Immediate family" remained limited to relatives in the first degree of consanguinity, and the Court of Appeals did not have occasion to revisit this issue until 1994 in *Trombetta v. Conkling*, where plaintiff petitioned to have an aunt, who raised the plaintiff from age eleven when her mother died and with whom she had a close relationship, declared "immediate family."[76] The plaintiff urged the Appellate Division to adopt Nebraska and Hawaii law, which allow plaintiffs to prove the nature of their relationships with the deceased or injured person.[77] The court declined to do so, stating, "[i]n our view, conditioning defendants' liability upon plaintiff's being able to prove that he or she shared a 'strong bond' with the deceased or injured person would unreasonably extend the limits of defendants' duty… and would give rise to difficult proof problems and the danger of fictitious claims."[78]

The Court of Appeals said it did not wish *Bovsun's* "narrow avenue to bystander recovery" to "become a broad concourse, impeding reasonable or practicable limitations."[79] On policy grounds, it declined to "expand the cause of action for emotional injuries to all bystanders who may be able to demonstrate a blood relationship coupled with significant emotional attachment or the equivalent of an intimate, immediate familial bond,"[80] and held that recovery of damages by bystanders for emotional distress should be limited only to immediate family. The court denied the plaintiff's claim despite her presence in the zone of danger.[81]

In 2006 in *Shipley v. Williams*, a Staten Island Supreme Court combed New York statutes for definitions of "immediate family," and found that the penal law, public health law, social services law and regulations governing the landlord-tenant relationship swept numerous individuals into the category, including ex-spouses and in-laws.[82] Every definition, however, included the terms "siblings" or "brothers and sisters." The court held that "a brother and sister who lived together in the same household at the time of the accident" are "immediate family."[83] The case was not appealed and no other reported New York

decisions have dealt with the issue of whether siblings constitute immediate family under *Bovsun*.

Generally, "immediate family" has been strictly construed, and even where the injuries to another person were particularly gruesome and fatal, a bystander cannot recover for emotional distress even if he or she witnessed the decapitation of a stranger in an elevator accident[84] or, as a patient in the mental health unit of a hospital, overheard the murder of another patient.[85]

Bystanders have also been denied recovery when the injured person was a friend, a co-worker, a grandson, and a girlfriend, because these persons were not immediate family members.[86] "Immediate family" also excludes the family dog and means "an immediate family member who is a person."[87]

Part III

A. Emotional Distress Claims Against Health Care Providers After *Bovsun* in Traditional Medical Malpractice Actions

Under the zone of danger rule, claims for negligent infliction of emotional distress in medical malpractice actions are rarely successful, because one of the *Bovsun* elements is typically missing: defendant's negligent conduct does not generally expose a non-patient bystander to an unreasonable risk of bodily injury or death.[88] Moreover, since *Bovsun* did not depart from traditional tort principles, courts have been unable to extend liability for the emotional distress of third parties in medical malpractices, where the health care provider owes no duty to the third party.

This key *Bovsun* element was missing in *Colombini v. Westchester County Healthcare Corp.*, a case involving a fatal accident that occurred at a magnetic resonance imaging ("MRI") facility, when a heavy metal oxygen tank was drawn into the magnet of the MRI machine and struck a six-year-old boy in the head as he lay inside the machine. When this occurred, the boy's father was outside the room, but he rushed in to help extricate his son from the MRI machine. His subsequent claim for emotional distress was dismissed because there was no proof he feared for his own safety, only that he was, in his own words, "nervous" for his son's safety.[89]

B. Emotional Distress Claims Against Medical Providers for the Disappearance or Loss of a Patient

Plaintiffs have also unsuccessfully attempted to expand *Bovsun* to recover for emotional injuries caused by the disappearance of a family member from a hospital or nursing home. In *Johnson v. Jamaica Hospital*, the court denied the parents' claim for emotional injuries they suffered when their newborn daughter was abducted from the hospital and not recovered until nearly five months later.[90] Despite the grief and mental torment the parents suffered, the Court of Appeals denied recovery on the simple ground that they were not within the zone of danger, and again expressed its policy concerns on inappropriate extension of liability under *Bovsun*.

> [T]o permit recovery by the infant's parents for emotional distress would be to invite open-ended liability for indirect emotional injury suffered by families in every instance where the very young, or very elderly, or incapacitated persons experience negligent care or treatment.[91]

Even when a patient disappears and is never found, plaintiffs cannot recover for emotional distress, which occurred in *Oresky v. Scharf*.[92] The plaintiffs' mother, who suffered from Alzheimer 's disease, disappeared from her nursing home and was never located. Simply put, plaintiffs did not meet the *Bovsun* standards for recovery because they were not within the zone of danger and their emotional injuries did not result from contemporaneous observation of serious physical injury or death to their mother caused by the defendants' negligence.[93]

C. Theories of Recovery for Emotional Distress in Obstetrical Cases

There existed two avenues of recovery for emotional distress suffered in childbirth cases. The first arose under *Tebbutt v. Virostek*, decided by the Third Department in 1984 and affirmed by the Court of Appeals in 1985. Under *Tebutt* and its progeny, recovery for emotional injuries was not allowed for injury or death to the fetus or child, unless mother suffered an independent physical injury.[94]

In *Tebbutt*, the plaintiff mother alleged that a negligently performed amniocentesis caused the stillbirth of her baby, and inasmuch as the fetus was *in utero* when the injury occurred, she was within the zone of danger. The Third Department rejected her *Bovsun* claim, because she did not contemporaneously observe the injury to the fetus and became aware of it only several weeks later.[95] Moreover, it said, "'even assuming the death of the fetus *in utero* was caused by defendants' wrongful acts, absent independent physical injuries, the plaintiff wife may not recover for emotional and psychic harm as a result of the stillborn birth.'"[96] The Court of Appeals affirmed on the same ground, noting too that plaintiff failed to establish the existence of a duty owed to her by the health care provider.[97]

After *Tebbutt*, recovery for emotional distress was denied in obstetrical medical malpractice cases absent a showing that mother sustained an independent physical injury: (i) that was distinct from injuries of the fetus;[98] (ii) that extended beyond injury normally attendant to childbirth;[99] and (iii) that was an injury unassociated with routine medical procedures used during labor, prolonged labor, and delivery.[100]

The second theory, the zone of danger rule controlled by *Bovsun*, has rarely been found to be applicable "in actions arising out of fetal injuries unaccompanied by independent physical injury to the mother."[101] Generally, the insurmountable hurdle is the same one that obstructs bystanders in typical medical malpractice cases—the plaintiff mothers cannot demonstrate their presence within the zone of danger, which is a prerequisite to recovery for emotional injuries.

However, in *Khan v. Hip Hosp.*, *supra*, the alleged medical malpractice was so egregious that the plaintiff was able to defeat a summary judgment motion disputing her presence in the zone of danger because she was "subject to an unreasonable risk of bodily injury by negligent conduct.…"[102] Indeed the court said plaintiff "was not merely a 'bystander' but was as much a victim of the defendants' alleged malpractice as the stillborn fetus."[103]

Contrast *Khan* with *Miller v. Chalom*, where the mother claimed she was in the zone of danger because her doctor accidentally severed a portion of the baby's finger while performing an episiotomy.[104] The episiotomy, a medical procedure used routinely during labor and delivery, was not found by the court to expose the mother to an unreasonable risk of physical injury, and therefore, she could not recover damages for emotional distress under the zone of danger rule. As the court stated, "[e]ven if the 'zone of danger' rule was applicable, there is simply no evidence that [the mother] was *exposed* to an unreasonable risk of bodily harm during labor and delivery, despite the obvious injury to the child."[105]

The court permitted recovery of damages for emotional injuries in *Prado v. Catholic Med. Ctr. of Brooklyn & Queens*, a case where a mother delivered a stillborn child. However, recovery was for the mother's legitimate fear for her own physical injury—the rupture of a previously successful recto-cystocele repair—not for her emotional injuries associated with delivery of a stillborn child, and not because pain associated with a difficult childbirth was an independent injury or placed her in the zone of danger.[106]

1. The Landmark Decision *of Broadnax v. Gonzalez*

For 20 years after *Tebbutt*, plaintiffs' attempts to extend *Bovsun* to emotional damages arising from fetal injury were explicitly rejected by New York courts,[107] but two decades after *Tebbutt*, the Court of Appeals was no longer able to defend *Tebbutt*'s logic or reasoning,[108] because it could not withstand the "cold light of logic and experience" and did not fit comfortably in New York jurisprudence.[109]

The problem, said the Court of Appeals, was that *Tebbutt* rendered a "peculiar result" by exposing medical caregivers to malpractice liability for i*n utero* injuries when the fetus survived, but it immunized them against any liability when their malpractice caused a miscarriage or stillbirth.[110] The fetus was consigned to a state of "juridical limbo" because the deceased fetus could not bring suit, and since that was true, "'it must follow in the eyes of the law that any injury here was done to the mother.'"[111]

Thus, in the seminal case of *Broadnax v. Gonzalez* decided in 1994, the Court of Appeals expressly overruled *Tebbutt*, and held that "even in the absence of an independent injury, medical malpractice resulting in miscarriage or stillbirth could be construed as a violation of a duty of care to the expectant mother, entitling her to damages for emotional distress."[112] This decision fundamentally changed the law in New York in situations where there was a miscarriage or stillbirth.

Two months after the *Broadnax* decision, the Second Department considered *Sheppard-Mobley v. King*.[113] An obstetrician and a fertility specialist recommended the plaintiff mother abort her pregnancy due to her condition of uterine fibroid tumors, which would make it unlikely that she could carry a child to full term.[114] Relying on that advice, she underwent a chemical abortion but was allegedly given too small a dose, resulting in a failed abortion. The plaintiff was faced with the choice of undergoing a late term abortion, or giving birth to a child with birth defects. She chose the latter. The issue before the court was whether she could recover for emotional distress when her child is born alive, absent an independent physical injury to herself.

The Appellate Division could "discern no reasonable basis to limit the *Broadnax* holding to cases of stillbirth and miscarriage."[115] It reasoned that regardless of whether the fetus was stillborn or born in an impaired state, the duty owed to the mother remained the same.

The Court of Appeals disagreed, stating that the Appellate Division's decision was an improper extension of *Broadnax*. The *Broadnax* decision, it said, was narrow and intended to remedy the injustice created by the lack of remedy when the fetus is not born alive.[116] It held that there can be no recovery for emotional distress where the alleged medical malpractice causes *in utero* injury to a fetus subsequently born alive because, in these circumstances, a remedy exists—a child born alive can bring a medical malpractice action for its injuries caused by malpractice during pregnancy.[117]

Thus the Court clarified that under its precedents, a plaintiff seeking to recover for emotional distress in a case where the fetus is born alive must continue to show independent physical injury. In the case of a stillbirth or miscarriage, the requirement of independent physical injury was removed by *Broadnax*, to remedy the injustice that occurs when an infant stillborn has no cause of action and the law provides for no other remedy.[118]

Yet *Broadnax* and *Sheppard-Mobley* left unresolved the issue of whether a woman could recover for emotional

distress where her baby was pronounced dead within minutes of delivery and was neither conscious nor viable and its estate had no claim for conscious pain and suffering. That question arose before a Bronx Supreme Court three years later in *Mendez v. Bhattacharya*.[119] The court reasoned that "[s]uch a situation clearly comports with the rationale of *Broadnax* and *Sheppard-Mobley* that the plaintiff mother's cause of action 'fills the gap,' and permits a cause of action where otherwise none would be available, to redress wrongdoing resulting from physical injury inflicted in the womb at labor and delivery," and held that plaintiff mother had a viable cause of action for emotional distress.[120]

Conclusion

New York courts recognize that in limited circumstances, bystanders have a right to recover for emotional injuries under the zone of danger rule. The rule requires that bystanders must be identifiable beings present in the zone of danger created by the defendant's negligence at the time the negligence occurred. While in the zone, they must have contemporaneously observed the physical injury or death of an immediate family member proximately caused by the defendant's negligence. In medical malpractice cases against health care providers, such bystanders are typically unable to recover because the professional malpractice generally does not expose a non-patient bystander to an unreasonable risk of bodily injury or death and, as a consequence, they are not within the zone of danger.

In obstetrical cases, where the fetus is stillborn or miscarried and thus has no viable cause of action of its own for medical malpractice, the courts will construe the malpractice as a violation of the duty of care to the mother, and she will be entitled to damages for emotional distress without a showing of independent physical injury to herself.

Attempts to further broaden bystander claims for emotional distress in medical malpractice cases have been unsuccessful, for courts are still concerned about opening the door to potentially unlimited liability—the same concern the courts expressed before they adopted the zone of danger rule almost three decades ago.

Endnotes

1. *Hutchinson v. Stern*, 101 N.Y.S. 145 (App. Div. 1906); *appeal dismissed* 189 N.Y. 577 (1908).
2. *Mitchell v. Rochester Ry. Co.*, 151 N.Y. 107 (1896) (a negligently driven team of horses came so close to plaintiff that her head was between theirs when they came to a stop, but her subsequent miscarriage was not proximately caused from the negligence.)
3. *Hutchinson v. Stern*, 115 A.D. 791 (4th Dep't 1906).
4. *Battalla v. State of New York*, 10 N.Y.2d 237, 239 (1961).
5. *Id.*
6. *Id*
7. *Tobin v. Grossman*, 24 N.Y.2d 609, 613 (1968).
8. *Hutchinson v. Stern*, 115 A.D. 791 (4th Dep't 1906).
9. *Dillon v. Legg*, 68 Cal.2d 728 (Cal. 1968).
10. *Id.* at 68 Cal.2d 740-41.
11. *Id.*
12. *Id.* at 68 Cal.2d 749.
13. *Id.* at 68 Cal.2d 741; 747.
14. *Tobin v. Grossman*, 24 N.Y.2d 609, 611 (1969).
15. *Id*. at 24 N.Y. 612. In contrast, the *Dillon* mother actually saw her child be struck and killed by an automobile.
16. *Id.* at 613.
17. *Id.* at 614.
18. *Id.* at 618.
19. *Id*. at 615.
20. *Tobin*, 24 N.Y.2d at 615.
21. *Id.* at 617.
22. *Id* at 618.
23. *Tobin*, 24 N.Y.2d at 611-12.
24. *Johnson v. State of New York*, 37 N.Y.2d 378 (1975).
25. *Id.* 37 N.Y.2d 379.
26. *Id.*
27. *Id.*, 37 N.Y.2d 382-83. *See also Rainnie v. Cmty. Mem'l Hosp.*, 87 A.D.2d 707 (3d Dep't 1982) ("to recover for emotional harm[,] the plaintiff must be owed a duty and be the person directly injured by the breach of that duty.")
28. *Trombetta v. Conkling*, 82 N.Y.2d 549, 551-552 (1993).
29. *Bovsun v. Sanperi*, 61 N.Y.2d 219 (1984).
30. *Id.*, 61 N.Y.2d at 224-25.
31. *Id.*, 61 N.Y.2d at 228-29.
32. *Battella*, *supra*.
33. *Bovsun*, 61 N.Y.2d at 229.
34. *Id.*, 61 N.Y. 2d at 230-31.
35. *Id.*, 61 N.Y.2d at 233. ("There may be an enlargement of the scope of recoverable damages; there is no recognition of a new cause of action or of a cause of action in favor of a party not previously recognized as entitled thereto.")
36. *Id*, 61 N.Y.2d at 223-24.
37. *Id.*, 61 N.Y.2d at 233.
38. *Moreta v. NYC Health & Hosp. Corp.*, 238 A.D.2d 149 (1st Dep't 1997).
39. *Perry-Rogers v. Obasaju*, 282 A.D.2d 231, 1st Dep't 2001).
40. *Id*.
41. *Garcia v. Lawrence Hosp.*, 5 A.D.3d (1st Dep't 2004).
42. *Shaw v. QC Medi New York, Inc.*, 10 A.D.3d 120 (4th Dep't 2004). Ms. Richards represented the defendants before the Fourth Department in this case.
43. *Id.* at 122.
44. *Id*. at 121.
45. *Id*. at 124.
46. *Id.* at 125.
47. *Shea v. Catholic Health Systems, Inc.*, 5 Misc.3d 1021(A) at *2 (Sup. Ct. Erie Co. 2004) (no duty of care owed to father who was not in the zone of danger when the alleged medical malpractice occurred during a Caesarian section).

48. *Reed v. Cioffi, Seftel & Soni, P.C.*, 155 A.D.2d 796, *appeal dismissed*, 76 N.Y.2d 845 (1990), *reargument denied*, 76 N.Y.2d 890 (1990). S*ee also, Kaniecki v. Yost*, 166 Misc.2d 408 (Sup. Ct. Erie Co. 1995) (denying father's claim for emotional distress arising from witnessing a stillbirth because he was not in the zone of danger and did not suffer any independent physical injury).

49. *Schram v. Herkimer Memorial Hospital*, 115 A.D.2d 882 (3d Dep't 1985).

50. *Id.*

51. *Saguid v. Kingston Hospital*, 213 A.D.2d 770 (3d Dep't 1995), *appeal dismissed*, 87 N.Y.2d 861 (1995), *leave to appeal dismissed*, 88 N.Y.2d 868 (1996).

52. *Saguid v. Kingston Hospital*, 213 A.D.2d 770, 772 (3d Dep't 1995).

53. *Zea v. Kolb*, 204 A.D.2d 1019 (4th Dep't 1994), *leave to appeal dismissed by*, 84 N.Y.2d 864 (1994).

54. *Id.,* 204 A.D.2d at 1020.

55. *Landon v. N.Y. Hosp.*, 65 N.Y.2d 639 (1985).

56. *Id.*

57. *Lancellotti v. Howard*, 155 A.D.2d 588 (2d Dep't 1989).

58. *Arroyo v. New York City Health and Hospitals Corp.*, 163 A.D.2d 9 (1st Dep't 1990).

59. *Arroyo*, 163 A.D.2d at 9. *See also, Osborn v. Andrus Pavilion of St. John's Riverside Hospital*, 100 A.D.2d 840 (2d Dep't 1984) (dismissing the complaint because the plaintiffs did not sustain any bodily injury, and significantly, they failed to assert that they were subjected to an unreasonable risk of bodily injury).

60. *Weed v. Meyers*, 251 A.D.2d 1062 (4th Dep't 1998); *see also, Hughson v. St. Francis Hospital of Port Jervis*, 92 A.D.2d 131 (2d Dep't 1983)

61. The court further found that the ophthalmologist did not owe a duty to the children independent of the duty owed to their father.

62. *Pingtella v. Jones*, 305 A.D.2d 38 (4th Dep't 2003), *leave to appeal dismissed*, 100 N.Y.2d 640 (2003), *reargument denied*, 1 N.Y.3d 594 (2004).

63. *Pingtella*, 305 A.D.2d at 42, *quoting*, *Abala v. City of New York*, 54 N.Y.2d 269, 272 (1981) (finding hypothetical generations were outside the immediate zone of danger).

64. Pingtella, 305 A.D.2d at 42.

65. *Lizardi v. Westchester County Health Care Corp.*, 21 Misc. 3d 1133(A) (Sup. Ct. Westchester Co. 2008). The mother was tried for murder but was found not guilty by reason of insanity.

66. *Id.*

67. *Khan v. Kip Hospital, Inc.*, 127 Misc.2d 1063 (Sup. Ct., Queens Co. 1985).

68. *Khan, supra*.

69. *Id.*, 127 Misc.2d at 1071.

70. *Id.*, 127 Misc.2d at 1072.

71. *Bovsun v. Sanperi*, 61 N.Y.2d 219, 228-229 (1984).

72. *Bovsun*, 61 N.Y.2d at 231.

73. *Garcia v. Lawrence Hospital*, 5 A.D.3d 227, 228 (1st Dep't 2004).

74. *Bovsun*, 61 N.Y.2d at 234 n.13.

75. *Khan v. Kip Hosp.* 127 Misc.2d 1063, 1070 (Sup. Ct., Queens Co. 1985).

76. *Trombetta v. Conkling*, 82 N.Y.2d 549 (1993).

77. *Trombetta v. Conklin*, 187 A.D.2d 213, 215 (4th Dep't 1993).

78. *Id.,* 187 A.D.2d at 215.

79. *Trombetta*, 82 N.Y.2d at 552-53.

80. *Id.* 82 N.Y.2d at 553.

81. *Id.*, 82 N.Y.2d at 554.

82. *Shipley v. Williams*, 14 Misc.3d 682 (Sup. Ct., Richmond Co. 2006).

83. *Id.*, 14 Misc.3d at 688-89.

84. *Pizarro v. 421 Port Assoc., et al.*, 292 A.D.2d 259 (1st Dep't 2002).

85. *Moliterno v. Cmty. Gen. Hosp. of Sullivan Cty*, 282 A.D.2d 441 (2d Dep't 2001).

86. *Jorgensen v. B.F. Yenney Construction Co.*, 255 A.D.2d 1008 (4th Dep't 1998) (co-workers); *Casale v. Unipunch, Inc.*, 177 A.D.2d 1029 (4th Dep't 1991) (friend and co-worker); *Jun Chi Guan v. Tuscan Dairy Farms*, 24 A.D.3d 725 (2d Dep't 2005) (grandson), *appeal dismissed*, 7 N.Y.3d 784 (1996); *Santana v. Salmeron*, 79 A.D.3d 1122 (2d Dep't 2010) (girlfriend).

87. *Johnson v. Douglas*, 187 Misc.2d 509, 510-11 (Sup. Ct., Nassau Co. 2001), *aff'd*, 289 A.D.2d 202 (2d Dep't 2001).

88. Ordinarily, in the absence of a special relationship between the plaintiff and the patient's health care provider, the zone of danger rule is not extended to the patient's family members.

89. *Colombini v. Westchester Cty. Healthcare Corp.*, 24 A.D.3d 712 (2d Dep't 2005).

90. *Johnson v. Jamaica Hospital*, 62 N.Y.2d 523 (1984).

91. *Johnson*, 62 N.Y.2d at 528. The dissent wrote that "*Bovsun's* adoption of the zone of danger concept need not, and should not, be read as barring recovery by parents who suffer serious and verifiable emotional injury as the result of the negligent infringement by a hospital of the parents' right to custody of their child, even though the parents are not within the zone of danger when the infringement occurs." *Id.* at 532-33.

92. *Oresky v. Scharf*, 126 A.D.2d 614 (2d Dep't 1987, *appeal dismissed*, 69 N.Y.2d 868 (1987), *appeal denied*, 69 N.Y.2d 610 (1987).

93. *Oresky*, 126 A.D.2d at 617.

94. *Tebbutt v. Virostek*, 102 A.D.2d 231 (3d Dep't 1984), *aff'd*, 65 N.Y.2d 931, 932 (1985), *overruled*, *Broadnax v. Gonzalez*, 2 N.Y.3d 148 (2004).

95. *Tebutt*, *supra.*

96. *Tebbutt,* 102 A.D.2d at 233 (quoting *Friedman v. Meyer*, 90 A.D.2D 511 (2d Dep't 1982, *appeal dismissed* 59 N.Y.2d 763 (1983)).

97. *Tebutt*, 65 N.Y.2d at 932.

98. *Scott v. Capital Area Cmty. Health Plan*, 191 A.D.2d 772 (3d Dep't 1993), *lv. denied* 594 N.Y.S.2d 370 (1993) (mother's pain and suffering, described as "sequelae of fetal heart distress" and her emotional distress from delivering a stillborn child following nurse practitioner's failure to diagnose fetal cardiac and pulmonary distress were the direct result of fetal impairment and did not constitute an independent injury distinct for which mother could recover damages for emotional distress).

99. *Saguid v. Kingston Hospital*, 213 A.D.2d 770, 771 (3d Dep't 1995), *appeal dismissed*, 87 N.Y.2d 861 (1995), *leave to appeal dismissed*, 88 N.Y.2d 868 (1996) (mother's pain and suffering during a difficult delivery and emergency Cesarean section was not greater than that "naturally attendant to childbirth" and did not constitute an independent physical injury enabling recovery for emotional distress caused by the death of the newborn infant); *Parsons v. Chenango Memorial Hospital*, 210 A.D.2d 847 (3d Dep't 1994), *leave to appeal dismissed*, 620 N.Y.S.2d 604 (1995); (mother's pain and suffering from prolonged labor to deliver a stillborn child were not permanent and are not independent physical injuries enabling recovery for emotional distress); *Kakoullis v. Janssen*, 188 A.D.2d 769 (3d Dep't 1992) (mother's pain and suffering associated with childbirth was not a permanent, independent physical injury enabling recovery for emotional distress associated with the impaired condition of the infant); *Hayes v. Record*, 158 A.D.2d 874 (3d Dep't 1990) (mother's anxiety attacks do not constitute independent physical injury enabling recovery for emotional distress associated with the death of her six-day-old infant); *Bauch v. Verrilli*, 146 A.D.2d 835 (3d Dep't 1989) (an episiotomy is not an independent physical injury unless it is also alleged to have caused infant's death); *Keselman v. Kingsboro Medical Group*, 156 A.D.2d 334

(2d Dep't 1989), *appeal dismissed*, 76 N.Y.2d 845 (1990) (defendant's failure to diagnose fetus' fatal genetic anomaly foreclosing mother's ability to opt for alternative treatment sparing her from the pain and suffering of childbirth did not constitute independent physical injury enabling recovery for emotional distress); *Wittrock v. Maimonides Med. Ctr.*, 119 A.D.2d 748 (2d Dep't 1986) (pain and suffering incident to childbirth are unrelated to the stillbirth and is not actionable).

100. *Farago v. Shulman*, 65 N.Y.2d 763 (1985) (mother's blood loss and pain from negligently performed episiotomy are injuries attendant to childbirth and do not constitute independent physical injury enabling recovery for emotional distress from stillbirth); *Miller v. Chalom*, 269 A.D.2d 37 (3d Dep't 2000) (negligently performed episiotomy that severed infant's finger did not constitute an independent physical injury enabling recovery for the emotional distress caused by injuries to the child); *Sceusa v. Mastor*, 135 A.D.2d 117 (4th Dep't 1988), *appeal dismissed* 525 N.Y.S.2d 101 (1988) (Cesarean section for delivery of twins, one stillborn, did not constitute an independent physical injury enabling recovery for emotional distress from the death of one twin).
101. *Miller v. Chalom*, 269 A.D.2d 37, 40 (3d Dep't 2000).
102. *Khan v. Hip Hosp.*, 127 Misc.2d 1063, 1070 (Sup. Ct., Queens Co. 1985).
103. *Id.*, 172 Misc.2d at 1068.
104. *Miller v. Chalom*, 269 A.D.2d 37 (3d Dep't 2000).
105. *Miller*, 269 A.D.2d at 40-41.
106. *Prado v. Catholic Med. Ctr. of Brooklyn & Queens*, 145 A.D.2d 614 (2d Dep't 1988).
107. *Miller v. Chalom*, 269 A.D.2d 37 (3d Dep't 2000) (negligently performed episiotomy that severed infant's finger did not place mother in zone of danger); *Parsons v. Chenango Memorial Hospital*, 210 A.D.2d 847 (3d Dep't 1994), *leave to appeal dismissed*, 620 N.Y.S.2d 604 (1995) (mother's prolonged labor is not sufficient to prove she was in the zone of danger); *Guialdo v. Allen*, 171 A.D.2d 535 (1st Dep't 1991) (premature contractions resulting in stillbirth did not place mother in zone of danger); *Sceusa v. Mastor*, 135 A.D.2d 117 (4th Dep't 1988), *appeal dismissed*, 72 N.Y.2d 909 (1988) (Cesarean section did not place mother within the zone of danger); *Burgess v. Miller*, 124 A.D.2d 692, 693 (2d Dep't 1986) (difficult labor and delivery of severely impaired infant who died shortly after delivery from alleged medical malpractice did not place mother in zone of danger).
108. *Broadnax v. Gonzalez*, 2 N.Y.3d 148 (2004).
109. *Id.* at 156.
110. *Id.* at 154.
111. *Id.* (citing dissenting Judges Kay and Jasen in *Tebbutt*).
112. *Broadnax*, 2 N.Y.3d at 155.
113. *Sheppard-Mobley v. King*, 10 A.D.3d 70 (2d Dep't 2004), *aff'd as modified*, 4 N.Y.3d 627 (2005).
114. *Sheppard-Mobely*, 10 A.D.3d 70, 76 (2d Dep't 2004), *aff'd as modified*, 4 N.Y.3d 627 (2005).
115. *Id.*
116. *Sheppard-Mobley*, 4 N.Y.3d at 637.
117. *Id.* at 638. Although she could not recover for emotional distress resulting from the birth of her impaired child, she could recover for the emotional distress she suffered independent from the birth because of the difficult choice she had to make—whether to have a late term abortion or give birth to a severely impaired child.
118. *Id.*, 4 N.Y.3d 637.
119. *Mendez v. Bhattacharya, M.D.*, 15 Misc.3d 974, 981 (Sup. Ct., Bronx Co. 2007).
120. *Mendez*, 15 Misc.3d at 983.

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EHRs: A Prescription for Privacy Breach

By Nahid Shaikh

Introduction

An electronic health record (EHR)[1] is a digital collection of patient health information designed to enable the sharing of this information between health care providers. President Obama aspires for the nationwide adoption of EHRs by 2014.[2] For a nationwide network to function effectively, personal health care data will have to be accessible to over 12 million individuals, given the number employed in the health care industry.[3] Among others, physicians, nurses, dieticians, physical therapists, and X-ray technicians will all have valid reasons for viewing protected health information (PHI). The problem is that this same system enables users without valid reasons to access these records, infringing on the privacy of innocent third party patients. Although EHRs facilitate the easy exchange of information between health care providers nationwide, their information is also much easier to steal, intercept, and misuse than that of their paper predecessors. While both federal and state laws prohibit such snooping, enforcing these rules on a national scale is much easier said than done. As the federal government pushes for totally electronic systems, the vulnerability of patients' privacy rights increases exponentially.

In the rush toward EHRs, we may be losing sight of the cardinal rule of the medical profession: *Primum non nocere;* first, do no harm. Threats to PHI can be categorized into three types: natural and environmental threats, technology failures, and human threats. This article will focus on analyzing and mitigating the effects of these so-called human threats, mainly unauthorized access. The Health Insurance Portability and Accountability Act (HIPAA), passed in the United States in 1996,[4] developed a way to palliate the harm of these threats. HIPAA established rules for access, authentication, storage, auditing, and transmittal of PHI, including that contained in EHRs. These standards made restrictions for electronic records more stringent than those existing for paper records. However, concerns remain as to the adequacy of these standards.

As companies have adopted new technologies that tend to circumvent user control, regulations and tools directed at protecting consumer privacy have failed to keep up. In general, existing legislation must be re-worked so that it is more relevant to and protective of the PHI contained in EHRs. Supplemental regulations can be enacted in order to fill the gaps left in HIPAA and its amendments that leave patients vulnerable to privacy breach.[5] Additionally, non-legislative safeguards are available to limit opportunities for EHR misuse. First and foremost, there must be a public information campaign to educate both doctors and patients alike about the flows of PHI after a patient leaves a health care facility. Once patients are fully informed, patient-centered technologies can be utilized to alleviate unwanted exposure of PHI. Furthermore, only if patients understand the advantages and the disadvantages of an electronic system can they provide meaningful consent (or dissent).

I. Background

A. EHRs

An EHR is a "longitudinal electronic record" of patient health information generated by a patient's encounters in any health care delivery setting.[6] Everything from patient demographics, past medical history, immunizations, and medications, to progress notes, vital signs, laboratory data, and radiology reports are compiled in a patient's PHI. Doctors and nurses use these complex computer systems for nearly every task within a hospital, including recording patient notes, ordering medical tests and drugs, and even communicating with one another. Essentially, EHRs automate and streamline the clinician's workflow.[7]

> *"In the rush toward EHRs, we may be losing sight of the cardinal rule of the medical profession:* Primum non nocere; *first, do no harm."*

Both doctors and patients alike are able to reap the benefits of EHRs. Doctors have quick access to patient records from inpatient, outpatient, and remote locations, thus enabling them to provide more coordinated, efficient care. Electronic referrals allow easier access to follow-up care with specialists. EHRs offer advantageous performance-improving tools, including the ability for doctors to report in real-time and interface with labs, registries, and other EHRs. Because these reports are electronic, the age-old illegible doctor handwriting[8] issue becomes less of a problem.[9] The legible, complete documentation provided by EHRs not only facilitates accurate coding and billing, but, more importantly, safer prescribing. These e-prescriptions are conveniently sent to the pharmacy. Additionally, with the implementation of EHRs, patients no longer have to inconveniently fill out the same form each time they go to the doctor.

Advancement of any electronic medical record system requires what bioinformaticians call "interoperability."[10] Interoperability refers to the capability of repositories of EHRs, such as hospitals or doctor's offices, to access and exchange patient data through a common system. For a nationwide network to operate fluidly, PHI will have to be accessible to not only physicians and nurses, but also dieticians and social workers, physical therapists and X-ray technicians, and consequently, ex-spouses, co-workers, mothers, and fathers.[11] Unfortunately, this means that any-

one with a medical license and a motive to snoop has the ability to access patients' medical records. Dr. Budhdev Manvar, M.D., a specialist in cardiology who has been in private practice at the Brooklyn Hospital Center for 30 years, fully supports the switch to EHRs, although he admits the existence of privacy concerns that must be addressed.[12] According to Dr. Manvar, "EHRs are very beneficial as far as improving quality, consistency, and uniformity of patient care. Although allowing for more stringent regulation to prevent unauthorized access adds a layer of inconvenience to medical care, privacy is of utmost importance."[13]

Nevertheless, it is apparent that when fully functional and interoperable, EHRs offer far more benefits than paper records. Electronic records improve not only the quality, but also the convenience of patient care, accuracy of diagnoses, and care coordination. The practice efficiencies and cost savings of EHRs can be attributed to the automation of several time-consuming paper-driven and labor-intensive tasks.[14] Dr. Farhan Contractor, D.O., second year family medicine resident in South Hampton Hospital, believes EHRs are the future for coordinated health care.[15] Communication is facilitated between primary care doctors and specialists, and in dire situations, emergency room physicians. This doctor believes that EHRs are so integral to the functioning of any medical organization and so cost efficient that if consent options for patients were to ever arise, any patient opting out of EHR use for their care should be fined.[16]

In consonance with Dr. Contractor's line of thinking, as part of the 2009 economic stimulus, the Obama administration is spending over 27 billion dollars to accelerate the switch to EHRs.[17] Government incentives to accelerate the paper to electronic transition are justified both by improved care, by giving medical providers instant access to vital patient information, and cut costs, by elimination of unnecessary tests and procedures. Moreover, starting in early 2015, the government will begin imposing financial penalties against hospitals and doctors that have not adopted a form of EHRs.[18]

The switch from paper to digital is inevitable, but in the United States, Great Britain, and Germany, the idea of a national centralized server model of health care data has been poorly perceived.[19] This is likely due to the issues of privacy and security that arise in such a model.[20] The many benefits of using health information technology (HIT) are undeniable, but we must first acknowledge, then remedy, current misuse and minimize future risk of the systematic practice of unethical access to PHI, data mining, and data theft. In order to embrace EHRs, patients must understand what they are, what they do, and how they work.

B. Patient Privacy

Privacy is a right so embedded in American society that it is sometimes referred to as a fundamental human right. While the influential paper, "The Right to Privacy," written in the 19th century by Samuel Warren and Louis Brandeis, defined privacy as "the right to be let alone,"[21] today, some people seem to hold privacy as "the right to select what personal information…is known to what people."[22] Federal courts have consistently found that the Fourth, Fifth, and Fourteenth Amendments to the United States Constitution protect the right to information privacy.[23] Additionally, all 50 states and the District of Columbia recognize in tort law a common law or statutory right to privacy of personal information.[24]

Moreover, the United States has a long history of medical ethics and laws that ensure patients' control over their medical records. The obligation to keep health information private is embodied in the Hippocratic Oath taken by graduates of American medical schools.[25] Additionally, a physician-patient privilege is recognized in the laws of 43 states and the District of Columbia.[26] According to the American Medical Association's Council on Ethical and Judicial Affairs, "the purpose of a physician's ethical duty to maintain patient confidentiality is to allow the patient to feel free to make a full and frank disclosure of information to the physician with the knowledge that the physician will protect the confidential nature of the information disclosed."[27] Survey results indicate that people have a "common belief" and "strong expectation" that their personal health information will not be disclosed without their consent.[28] In short, patients expect that what they say in their doctor's office will stay in their doctor's office. Conversely, in 2004 the Justice Department said, "in light of 'modern medical practice' and the growth of third-party insurers, individuals no longer possess a reasonable expectation that their histories will remain completely confidential."[29] A key problem in the current system in place is the false sense of security some patients have in the privacy of electronic health systems.

C. Regulation of EHRs and Protection of Patient Privacy

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 provided the first broadly applicable federal protections for health information. HIPAA requires the government to establish national standards for electronic transactions, to protect the privacy of electronic health information, and to protect the security of that information.[30] The intent of the HIPAA standard was to discourage the ongoing haphazard treatment of paper documents in many health care facilities.[31] Likewise, HIPAA was meant to discourage access to and sale of patient records that may contain large accumulations of patient information without patients' written consent.[32] As such, the Privacy Rule issued under HIPAA in 2001 was originally written to require patient consent before any information could be shared. In an attempt to reduce the total cost of HIPAA, the U.S. Department of Health & Human Services (HHS) proposed final amendments to the Privacy Rules.[33] This final Privacy Rule eliminated the

right of consent.[34] The HIPAA Privacy Rule went into effect in 2002 and established a federal floor of protections for health information.[35]

HIPAA does not succeed in protecting patients' privacy because, among others, insurers, researchers, and pharmaceutical companies can still access private information. HIPAA allows many common disclosures without any consent. In general terms, the Privacy Rule permits the disclosure of identifiable health information for treatment, payment, and various health care operations without the express written permission of the patient.[36] The Rule also permits the disclosure of this information for research without patient permission, as long as a number of other specific conditions are met.[37] Some particular transactional flows of data require patient approval, but patients have little real information about these flows or the uses to which they will be put. From the patient perspective, HIPAA protection is often minimal because few patients actually understand the full ramifications of what they are agreeing to when they sign to acknowledge that they "understand" their rights under HIPAA.

As of 2009, the Privacy Rule was amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act. The HITECH Act was intended to give patients more control over the flow of their health information by regulating the use and disclosure of identifiable health information held by "covered entities" and their "business associates."[38] The terms "covered entities" and "business associates" include providers, employers, government agencies, insurance companies, billing firms, pharmacy benefits managers, pharmaceutical companies, collection agencies, marketing firms and data miners.[39] Under HIPAA before the enactment of the HITECH Act, 701, 25 entities and 1.5 million business associates had unfettered permission to PHI without patient consent after the patient had given general consent to his or her medical practitioner's HIPAA release.[40] The HITECH Act created more rigid disclosure requirements such as: restricting the disclosure of PHI by a health care provider at the request of the patient if it is for purposes other than treatment and the service has been paid for out-of-pocket; limiting the disclosure of PHI to the minimum necessary to accomplish the intended purpose; and requiring health care providers to make available an accounting of certain disclosures of PHI that occurred over the past three years at the patient's request.[41]

Although HIPAA has raised awareness of the need to protect health information and the HITECH Act has increased privacy protections, given advances in technology, these regulations have become obsolete in many ways.[42] Since the original implementation of HIPAA, some organizations' interpretations of HIPAA have proven detrimental to medical research and, potentially, care. For example, a 2005 study by the University of Michigan found that the implementation of the HIPAA Privacy Rule was followed by a drop from 96 percent to 34 percent of follow-up surveys completed by patients being monitored after a heart attack.[43] Similarly, a 2006 study by the U.S. Government Accountability Office found that health care providers were "uncertain about their privacy responsibilities and often responded with an overly guarded approach to disclosing information to ensure compliance with the Privacy Rule."[44] A 2009 Institute of Medicine (IOM) report concluded that the law needs to be fundamentally reconsidered to reflect new information technologies and to enhance personalization and the quality of care.[45] Implementation of the HITECH Act should be considered merely the starting point of America's health care reform.

II. The Diagnosis

A. Lack of Privacy

American ambivalence about integrating HIT into our health care system is rooted, in significant part, in concerns about privacy. Health information privacy is defined as "an individual's right to control the acquisition, uses, or disclosures of his…identifiable health data."[46] In the words of renowned national health privacy expert, Deborah Peel, M.D., "without control, we have no privacy."[47] As long as health care-related corporations and government agencies have control over Americans' PHI, Americans essentially have no right to privacy in their health information and no way to keep this information private.

Even though a majority of Americans believe that electronic health records will improve the coordination and quality of care,[48] many Americans also believe that there is a reasonable likelihood that unauthorized users will view their records.[49] For example, a 2006 survey for the Markle Foundation found that 88 percent of Americans believe digital records will reduce the number of unnecessary or repeated tests and procedures they undergo.[50] However, this same survey found that 80 percent of respondents are "very concerned" about theft or fraud; 77 percent are concerned about use for marketing purposes, 56 percent are worried about viewing by employers, and 53 percent express concern about viewing by insurance companies.[51] In addition, a more recent survey in 2010, conducted by the California Health Care Foundation, found that 68 percent of Americans are concerned about the privacy of medical records.[52]

Concern about the privacy of medical data is based on a range of factors. First, the potential for discrimination might influence health insurance[53] or employment. Second, there is a general consensus that medical data is "different" from other personal data and perhaps even more sensitive than financial data. From this perspective, financial data involves something an individual has, whereas medical data involves who an individual is.[54] Third, the use of personal medical data by others has the potential to be exploitative. People may be comfortable with having their de-identified data used for beneficial

purposes like disease research, but not if they believe that commercial interests will use such information to try to sell them something or otherwise exploit their data.[55] Finally, Americans harbor deep-seated fears about possible government access to *any* personal data.[56]

The lack of privacy in electronic health systems has materialized in dangerous ways, compromising patient care. Due to privacy apprehensions, one in every eight Americans put their health at risk by not seeing their regular doctor, avoiding tests, asking their doctors to alter a diagnosis, and/or paying for tests out-of-pocket.[57] The HHS estimated that due to privacy concerns, 586,000[58] Americans and two million[59] Americans did not seek earlier treatment for cancer and mental illness, respectively. Further, 150,000 soldiers suffering from Post-traumatic Stress Disorder did not seek treatment because of privacy concerns.[60] It is clear, if patients cannot control their personal information stored in EHRs, they will not trust HIT systems and will avoid them. This chain reaction will not only amount to an appalling waste of taxpayer dollars but also to decreased health care.

B. Secondary Uses of Personal Health Information

Few consumers are aware of the vast number of corporations and government agencies that use personal health information without their permission. According to Professor Latanya Sweeney of Carnegie Mellon and Harvard, the secondary use of Americans' personal health information in electronic health systems today is "unbounded, widespread, hidden, and difficult to trace."[61] One small EHR company with yearly revenues of 100 million dollars from software sales could earn an estimated 250 million dollars more annually just by selling patient data.[62] Currently, all prescription records are sold daily from all 55,000 U.S. pharmacies.[63] In 2012, the top two publicly held prescription data mining sales corporations in the U.S. reported revenues of 116 billion dollars.[64]

Health data from EHRs is released or sold using the "research loophole" in HIPPA.[65] Information is not classified as PHI and, therefore, not subject to the HIPAA Privacy Rule if it is "de-identified" as provided in 45 C.F.R. 164.514(b).[66] An organization can use a "limited data set" for research if it strips out certain identifiers and enters into a "data use agreement" under 164.514(e).[67] Although identifiers are expunged from this data, the data can be re-identified.[68] This was publicly brought to light in February 2004 when Attorney General John Ashcroft subpoenaed medical records from at least six hospitals in a search for documentation of partial-birth abortions.[69] When asked about patients' privacy, Ashcroft insisted that the Justice Department was taking "every precaution possible to mask indentifying characteristics of patients."[70] Accordingly, the Justice Department stood firm that "the subpoenas did not intrude on any significant privacy interest of the hospital's patients because the names and other identifiable information would be deleted." Despite the pacifying statements of the Justice Department, Kelly Sullivan, a spokeswoman for Northwestern Hospital, released a statement telling the public that de-identified data still contains "enough identifiable information…to identify these people."[71] Furthermore, Planned Parenthood officials publicly said that patients' identities are ascertainable from medical records even if names and addresses are deleted.[72]

Intrusions like these have left patients extremely concerned about the privacy of their PHI. According to a 2008 national survey commissioned by the IOM, over 80 percent of Americans oppose having their information used without permission even if it is de-identified.[73] However, 87 percent are supportive of research, as long as they are asked and have control.[74] Only one percent of Americans would allow researchers free and open access to their health information without permission.[75] Despite the widespread opposition to open access to the nation's health information, most of the health care industry and the IOM propose eliminating informed consent for research.[76] As Mark Rothstein, the Founding Director of the Institute for Bioethics, Health Policy and Law at the University of Louisville School of Medicine put it "the recommendation of the IOM Report would automatically convert all patients into research subjects without their knowledge or consent."[77]

III. Operating on EHRs

We live in a world where medical data is increasingly in electronic form and where there is a growing need for real-time aggregated data to improve health care. HIT programs will not earn the trust and cooperation of patients, vital to the success of any program, if privacy and security concerns are not adequately addressed.[78] As long as data sharing is invisible, patients cannot make informed decisions regarding their PHI and may avoid HIT altogether. Furthermore, it seems like the HITECH Act—in particular those provisions that require covered entities to track all disclosures to associates[79]— stifles innovation in the HIT field while providing little additional privacy protection.[80] The limitations of HIPAA and the HITECH provisions should be reformulated so that they ensure both patient privacy and patient benefit from medical research. A recent report from the IOM confirms that these policies need a major overhaul to enter the electronic age.[81]

A. Inform the Public About the State of Things

Primarily, patients must be better informed of the effects of HIPAA and HITECH and what their privacy rights actually are and should be under such regulations. A patient cannot make purposeful, informed privacy choices unless he or she understands the flows and uses of PHI.[82] Additionally, as health records go digital, even many doctors are completely unaware about where their patients' data goes.[83] To build and maintain the public's trust in HIT, clear rules must be in place concerning how patient data can be accessed, used, and disclosed, and, of course, these rules must be enforced.

According to Dr. Peel, if "you don't know where your data is going, harms are almost impossible to report and detect."[84] New laws that increase the transparency of information disclosure could help return some control and privacy to patients. An example of a plausible rule is that every time a user accesses a patient record, the user should have to sign in and his or her identity should be recorded. If patients notice that an unusual or unauthorized user is snooping through their medical records, they can report the incident. Alternatively, each patient in the database could be sent a quarterly list of all the individuals who have accessed his or her records. Another possible precaution could be to allow different employees in the health care industry varying levels of access to health care data. Data should be safeguarded by passwords and employees would only be given access to what is reasonably necessary to assist them in their job. Although awareness of the privacy problems created by EHRs has grown amongst the public, the custody chain of medical information ultimately needs to be more transparent. Increased transparency can be accomplished through data mapping.

Data mapping matches from a source to a target so that the two may exchange data meaningfully.[85] Frequent sources and targets include databases, data sets, and terminologies.[86] In 1997 and 2001, the National Academy Press and the California Healthcare Foundation, respectively, published data maps.[87] Both of these maps depicted routine sharing of patient information prior to HIPAA.[88] In 2010, Dr. Sweeney released a new data map depicting flows of patient information eight years after the promulgation of HIPAA.[89] The entities receiving information more than doubled.[90] Also, entities that previously received aggregate, temporary, or de-identified information began receiving identifiable data.[91] This reaffirms the critique that the HIPAA standard offers insufficient privacy safeguards to support the dramatic increase in data sharing.

Dr. Sweeney's new project, thedatamap.org,[92] focuses on sketching a more complete picture of how medical data is shared.[93] Mapping projects must carefully consider the data course and the intended use of the data for both primary and secondary purposes in order to ensure accuracy.[94] Data must be accurately mapped between each system because opportunity for error exisits at each relay point throughout the system.[95] In Dr. Peel's opinion, Dr. Sweeney's project is promising because even if the project gets little public input, the research can nevertheless be used to pressure lawmakers into mandating that data-sharing arrangements become more transparent.

B. Patient-Centered Solutions

With an informed public, it is inefficient and unethical to design HIT in a paternalistic manner. The former Administrator of the Centers of Medicare and Medicaid Services, Don Berwick, M.D., agrees that we should build a system that ensures "medical records belong to patients," one where "[c]linicians, rather than patients would need to have permission to gain access to them."[96] The new one-size-fits-all national privacy policy that the government is attempting to create is contrary to the long-standing rights and expectations of American patients.

Privacy-enhancing technologies can also effectively lower costs by enabling individual control over PHI. Patient control will simplify data exchange by eliminating the need for expensive data-sharing agreements between covered entities, business associates, and other secondary and tertiary businesses and corporations.[97] Although some medical professionals argue that patient control is too time consuming, expensive, or complex to implement,[98] remedies need to be put in place in order to balance a patient's right to privacy and a doctor's need to access sensitive medical information. Specifically, the federal government must require industry to build in patient control as an integral part of the foundation of all HIT systems as they are developed.

"Privacy by Design (PbD)"[99] is an approach to protecting privacy by embedding it into the design specifications of technologies, and business practices.[100] In simple terms, that means building privacy right into the basic foundation of new systems.[101] As new technology enables the collection of vast amounts of data online, it is essential that privacy be considered at each stage of product development.[102] "If you don't design privacy in at the architectural level, it can be devilishly hard to deal with later," says Jules Polonetsky of the Future of Privacy Forum.[103] PbD is predicated on the idea that as much as technology can be used to infringe privacy, it can be used to protect privacy.[104] The principles of PbD can be applied to all types of personal information, but should be applied with special attention to sensitive data such as medical information.[105]

Assurance of privacy and personal control over one's information are the objectives of PbD and may be accomplished by practicing the following "7 Foundational Principles."[106] First, the PbD approach is distinguished by proactive rather than reactive measures.[107] PbD anticipates and prevents privacy invasive events before they happen. Second, PbD advances the view that the future of privacy cannot be assured solely by compliance with regulatory frameworks, such as HIPAA or the HITECH Act; rather, privacy assurance must be an organization's default mode of operation.[108] The third foundational principle is related to the second in that PbD is embedded into the design and architecture of IT systems and business practices. This principle results in privacy becoming an essential component of the core functionality being delivered.[109] Fourth, PbD avoids the pretense of "false dichotomies," such as "privacy versus security," demonstrating that it is possible to have both.[110] Fifth, PbD extends securely throughout the entire lifecycle of the data involved, ensuring that all data is securely retained, and then securely disposed of at the end of the process.[111] The sixth foundational principle speaks to the point made in Part III. A. *supra*. PbD seeks to

assure that whatever technology is being utilized, its component parts and operations remain visible and transparent to users and providers.[112] The seventh foundational principle is the most important. Above all, PbD seeks to maintain a user-centric design that requires operators to consider the interests of the individual by offering such measures as strong privacy defaults, appropriate notice, and user-friendly options.[113]

Successful companies such as IBM, Hewlett-Packard, and Microsoft have incorporated PbD into their product development processes and have subsequently released supportive statements about the important role that privacy protection plays in their business models.[114] EHR developers should follow in these innovative companies' footsteps and adopt a PbD framework. It is important to note that PbD, while important, is insufficient to protect consumer privacy alone. PbD should be seen as one tool in a larger toolkit of privacy approaches.[115]

C. Consent: Let patients opt in

Additionally, HIT must enable patient autonomy and choice if it is to be successful. HIPAA currently allows many common disclosures without any patient consent at all. Patients should be given the opportunity to provide meaningful consent. Providing individuals with choice in decisions about how their health information is shared is expected to increase consumer confidence in electronic health information exchange.[116]

Participants in an Agency for Healthcare Research and Quality (AHRQ) report expressed that, as health care consumers, they should be able to control their personal health information individually. A large portion of participants felt that they should be asked for consent before their information was stored in an electronic system.[117] The primary goal of policy makers, regulators, and HIT vendors should be to honor patient consent decisions and to build HIT systems that enable patients' control over data use and disclosure, unless otherwise required by law.[118]

Ultimately, the right of consent must be restored to the HIPAA Privacy Rule. Some argue that relying on patient consent will result in patients signing the same kind of blanket consents that have historically been used to grant broad access to paper medical records.[119] Instead, informed consents should be detailed and direct, with a specific purpose and time frame. Those who are granted access should be clearly named or described. Patients should be given the opportunity to understand what they are signing and what rights are implicated by their signature.[120]

One way to help people learn how to use electronic consent systems is to create "privacy profiles" or sets of consent rules that individuals can choose from. This approach mitigates the risk of patients being overwhelmed with too much information. In addition to PbD, Private Access is another user-centric concept that is dedicated to protecting patient privacy.[121] Private Access has developed a number of privacy profiles using real people's consent directives as examples.[122] Those who share their privacy profiles explain why they made their choices to help others think about how to set their own consent preferences.[123]

Additionally, consent tools can offer simple check boxes and systems that allow patients to select exactly what data they want to share with whom. Patients can customize their disclosures by choosing which information on which occasions they would like to release. An example of this type of segmenting data technology is e-MDs' EHRs, which enable physicians to segment patients' sensitive data so that it is not disclosed.[124] E-MDs' EHR has received the highest ratings from the American College of Physicians and the American Academy of Family Practice.[125] This system could be easily adapted to allow patients, rather than physicians to choose which data is segmented.

Conclusion

A final report by the Federal Agency for Healthcare Research and Quality showed that while Americans have a desire to control their personal health information, they are still generally proponents of HIT.[126] "Privacy has historically been viewed as an impediment to innovation and progress, but that's so yesterday and so ineffective as a business model. Without user trust, technologies can't move forward."[127] It is clear that tremendous benefits can be extrapolated from the implementation of EHRs. But, it is also clear that facilitated access designed to aid medical practitioners cannot come at the cost of patient privacy. In order to ethically and effectively expand the use of EHRs nationwide, steps must be taken to protect PHI and earn the trust of patients in this system.

Without consumer approval, this invaluable system that promotes better health care could fall out of favor due to privacy concerns. The best way to get a complete and accurate picture of Americans' health data is to require those who want to use health data to first ask for patient permission. Consumer control of PHI, by giving or withholding informed consent, has the advantage of complying with state and federal privacy laws, legal and ethical requirements, and, also, the public's expectations. Concepts such as Private Access and Privacy by Design can be implemented to standardize this idea of patient control. These types of approaches should be supplemented by self-regulation, the reformulation of HIPAA and HITECH, and possibly the enactment of a new patient privacy statute that establishes more stringent baseline protections.[128] These affirmative steps can collectively ensure personal health data is available at the right time, in the right place, for the right person.

Endnotes

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NEW YORK STATE TASK FORCE ON LIFE AND THE LAW
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June 3, 2013

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Dear Senators Klein and Skelos, and Assembly Members Silver and Kolb:

On behalf of the New York State Task Force on Life and the Law (the "Task Force"), we are pleased to submit for your consideration *Recommendations for Extending the Family Health Care Decisions Act to Medicare and/or Medicaid-Certified and State-Licensed Agencies, Programs, and Settings*.

Established by Executive Order in 1985, the Task Force is comprised of 23 Governor-appointed leaders in the fields of religion, philosophy, law, medicine, nursing, and bioethics. The Task Force develops public policy on issues arising at the interface of medicine, law, and ethics, and has issued influential reports on cutting-edge bioethics issues, such as withholding and withdrawing life-sustaining treatment and organ transplantation.

The Family Health Care Decisions Act ("FHCDA"), which was modeled on the Task Force report *When Others Must Choose: Deciding for Patients Without Capacity*, directs the Task Force to examine whether the Act should be amended to allow surrogate decision-making for health care provided in settings outside of hospitals and residential health care facilities. *See* 2010 N.Y. Laws Ch. 8, § 28(2). In December 2010, the Task Force made an initial proposal to the Legislature recommending extension of the FHCDA to include hospice care. *See* New York State Task Force on Life and the Law, *Recommendations Regarding the Extension of the Family Health Care Decisions Act to Include Hospice* (Dec. 22, 2010), *available at* http://www.health.ny.gov/regulations/task_force/reports_publications/. This proposal served as the basis for the amendment passed in July 2011, providing surrogates with authority to make hospice decisions on behalf of patients who lack the capacity to provide first-person consent. *See* 2011 N.Y. Laws Ch. 167.

Although the FHCDA now confers upon surrogates the power to make decisions in hospitals, residential health facilities, and hospice, New Yorkers frequently receive care outside of institutional settings, such as in clinics, physicians' offices, home care, surgery centers, and adult homes. Similar to patients in institutional settings, patients in community settings also may lack the capacity to make health care decisions for themselves due to a variety of health conditions. Under the FHCDA as currently worded, however, in order for surrogates to have authority to make health care decisions for patients in non-institutional settings, patients would have to be transferred to a hospital, residential health care facility, or hospice. Such transfers may be burdensome, unnecessary, and potentially detrimental to patients' health and well-being.

In light of these concerns, the Task Force has extensively explored the legal and ethical dimensions of extending the FHCDA beyond institutional settings, including the need for surrogate appointment, as well as the procedural safeguards necessary to ensure proper oversight of health care delivery and protection of patients' rights. As is set forth in the enclosed statement, the Task Force hereby proposes for the Legislature's consideration its recommendation that the FHCDA be extended to decisions regarding health care provided by agencies, programs, and settings that are Medicare and/or Medicaid-certified and State-licensed, and that opt to comply with the requirements of the FHCDA. These recommendations may not extend to treatment decisions made in physicians' offices where such offices do not meet these criteria.

In the coming months, the Task Force will undertake a second project at the direction of the Legislature, convening a Special Advisory Committee to make recommendations about whether the FHCDA should be amended to incorporate procedures, standards, and practices about the withdrawal or withholding of life-sustaining treatment for patients with developmental disabilities and patients in mental health facilities and units. *See* 2010 N.Y. Laws Ch. 8, § 28(1).

Thank you for entrusting the Task Force with these important projects. We look forward to working with you in the future.

Sincerely,

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On behalf of the New York State Task Force on Life and the Law

Enclosure

cc: Nirav R. Shah, M.D., M.P.H., Commissioner, New York State Department of Health
Honorable Kemp Hannon, Chair, New York State Senate Health Committee
Honorable Gustavo Rivera, Ranking Member, New York State Senate Health Committee
Honorable Richard N. Gottfried, Chair, New York State Assembly Committee on Health
Honorable Andrew Raia, Ranking Member, New York State Assembly Committee on Health

Recommendations for Extending the Family Health Care Decisions Act to Medicare and/or Medicaid-Certified and State-Licensed Agencies, Programs, and Settings

New York State Task Force on Life and the Law

June 3, 2013

The Family Health Care Decisions Act (FHCDA) authorizes persons with certain enumerated relationships to make health care decisions on behalf of patients who lack decisional capacity and who have neither left prior instructions to direct their care nor appointed a health care agent.[1] As originally passed, the FHCDA limited surrogate authority to decisions made about care in general hospitals and residential health care facilities.[2] The Legislature directed the New York State Task Force on Life and the Law (the Task Force) to "consider whether the FHCDA should be amended to apply to health care decisions in [other] settings."[3] In December 2010, the Task Force submitted to the Legislature a proposal that the FHCDA be extended to allow surrogate decision-making for hospice care,[4] which formed the basis for legislation passed in July 2011.[5]

Recognizing the widespread need to authorize surrogates to make important health care decisions on behalf of adults lacking capacity who receive care outside of general hospitals, nursing homes, and hospice settings, the Task Force has continued to explore the legal and ethical dimensions of extending the FHCDA to home care and other non-institutional settings. As set forth below, the Task Force recommends that a modified form of the surrogate decision-making authority of the FHCDA should be extended to those agencies, programs, and health care settings that are Medicare and/or Medicaid-certified and State-licensed (not including those licensed pursuant to the professional licensure requirements under the New York State Education Law), and that opt to comply with the requirements of the FHCDA.

A. Health Care in the Community

i. Home Care Agencies and Programs in New York State

"Home care" is an umbrella term for a variety of agencies, health and social services, and programs that provide medical, nursing, social, and therapeutic care, and/or assistance with daily living activities. The wide range of home care agencies and programs offer acute, short-term, chronic long-term, and public health preventive care to people of all ages, including the elderly, chronically ill infants and children, patients who are disabled or recuperating from acute illness, and terminally-ill patients.

New York State has a diverse and integrated home care system, with a majority of home care patients being served by Certified Home Health Agencies (CHHAs), Long Term Home Health Care Programs (LTHHCPs), and Licensed Home Care Services Agencies (LHCSAs). CHHAs offer part-time, intermittent health care and support services to post-acute, extended care, and maternal/child cases.[6] LTHHCPs provide care management and comprehensive services according to a care plan designed to keep nursing home-eligible patients in their homes and are administered jointly by the New York State Department of Social Services and the New York State Department of Health (NYSDOH).[7] LHCSAs subcontract with CHHAs, LTHHCPs, county departments of social services, and other home care settings to assist with the services they offer.

These home care programs are subject to both federal and State oversight and must be licensed by NYSDOH.[8] Specifically, every CHHA, LTHHCP, and LHCSA may be surveyed periodically by NYSDOH to gauge the quality and scope of the medical, nursing, and rehabilitative care they deliver.[9] Although only CHHAs and LTHHCPs are required by law to meet the federal requirements for participation in Medicare and sometimes Medicaid,[10] LHCSAs may contract with CHHAs to provide services to patients with Medicare or Medicaid coverage, and therefore LHCSAs must comply with the same regulatory requirements that apply directly to CHHAs.[11]

In addition to these more formal agencies and programs, home care may also be provided through a variety of other programs that serve specific populations, including the Care at Home Program for Physically Disabled Children, Traumatic Brain Injury Waiver, Managed Long Term Care, AIDS Home Care Program, and Consumer Directed Personal Assistance Program.[12] Some—but notably, not all—of these and other home care programs are subject to State oversight and Medicare and/or Medicaid certification requirements.

ii. Other Non-Institutional Health Care Settings

Many patients receive health care outside of hospitals, nursing homes, hospice, and home care programs. Routine, major medical, and end-of-life decisions are made in community-based settings, such as clinics and physicians' offices, ambulatory care and surgery centers, adult homes

(including assisted living residences), ambulances and other emergency medical service (EMS) settings, and in the home (*e.g.*, by relying on private duty nursing pursuant to physicians' orders).

For example, routine or major medical decisions may be made in Enriched Assisted Living Residences (EALRs), a type of assisted living residence that provides aging in place services, including some nursing and health care.[13] Under certain conditions, a patient already residing in an EALR whose health deteriorates to the point of requiring around-the-clock medical or nursing care may remain in the facility.[14] EALRs require NYSDOH licensure both as an adult home[15] and as an assisted living residence,[16] as well as special certification as an EALR.[17] Health care services delivered in an EALR may be provided by a Medicare-certified agency, such as a CHHA.[18]

Ambulatory care is medical care delivered on an outpatient basis in settings such as clinics and urgent care centers.[19] It includes, for example, blood tests, X-rays, endoscopy, and biopsy procedures. Many of these tests and treatments are performed on an ambulatory basis in ambulatory surgery centers,[20] which are subject to similar State oversight as other Public Health Law Article 28 facilities, such as hospitals and diagnostic and treatment centers.[21] New York State requires the accreditation of ambulatory surgical facilities by one of three agencies: the Joint Commission, the Accreditation Association for Ambulatory Health Care, or the American Association for Accreditation of Ambulatory Surgery Facilities.[22] After an initial licensing inspection, NYSDOH accepts accreditation surveys in lieu of its own re-licensing inspections. NYSDOH has the ability to survey or investigate an ambulatory surgery center at any time. Further, ambulatory surgery centers may participate in Medicare and Medicaid.

Health care decisions also are often made in physicians' offices. Generally, NYSDOH does not regulate the individual, office-based, private practice of medicine outside of Article 28 facilities.[23] However, where a physician's office provides office-based surgery,[24] NYSDOH requires that it: (1) be accredited[25] and (2) report adverse events.[26] Although the law does not set level of equipment requirements, maintenance schedules, or mandatory inspections for physicians' offices that perform office-based surgery,[27] NYSDOH has issued nonbinding guidelines, which are intended to define the appropriate standard of care for such procedures.[28]

As the contours of health care delivery continue to change, Accountable Care Organizations (ACOs) and other integrated health care delivery systems will become more commonplace. ACOs are groups of doctors, hospitals, and other health care providers who come together voluntarily to give coordinated high quality care to the patients they serve. In March 2011, New York enacted a law to foster the development of ACOs within the State.[29] ACOs that seek Medicare incentives must meet requirements prescribed by the Centers for Medicare and Medicaid Services.[30]

B. Analysis

The flexibility essential to the delivery of care in the community, in addition to the variation in oversight, populations, and delivery of care, distinguishes care provided in non-institutional settings from that in hospitals, nursing homes, and sometimes hospice. Importantly, while the provision of health care in the community, including capacity assessments and assessments of health conditions, is "overseen" by a physician,[31] care is commonly provided by nurses, home health aides, and other paraprofessionals.[32] Often, these non-physician clinicians are the individuals who examine and administer care to patients in the community setting.

Regardless of where individuals receive care, they may suffer from a variety of serious conditions or may be terminally ill. According to the New York State Office for the Aging, 75% of care recipients over 60 years old who receive care from informal caregivers in the State have Alzheimer's disease or other forms of dementia.[33] These care recipients may have to rely on surrogates to make health care decisions—including routine, major medical, and life-sustaining treatment decisions—on their behalf. Proxy decision-making is not limited to elderly patients, however; patients of all ages may lack or lose capacity outside of health care institutions due to, for example, complications from a serious illness or the unexpected deterioration of one's health. Thus, surrogate appointment and decision-making would benefit individuals being treated outside of a hospital, nursing home, or hospice.

The FHCDA as currently worded does not give authority to family members and loved ones to consent to treatments or object to procedures on behalf of patients in non-institutional settings. In fact, there is little clear legal authority permitting family members or loved ones to make proxy decisions outside of the three categories of settings currently specified by the FHCDA.[34] Instead, in order for a surrogate to have authority to make health care decisions pursuant to the FHCDA, the patient would have to be transferred to a hospital, nursing home, or hospice, even where there is no emergency or clinical need for such a transfer.

Requiring patients to be moved from their residence of choice is often jarring and medically unnecessary, and contravenes the value intrinsic to receiving care outside of institutions: to allow a patient to remain in an environment where he or she is most comfortable. Evidence suggests that transitioning patients to a hospital or nursing home can lead to further deterioration of patients' health, including their capacity to provide first-person consent

to treatment.[35] Enabling surrogate decision-making on behalf of people who cannot provide legally and ethically appropriate consent for themselves—both in the community and across many venues of care—is essential.[36] Moreover, family members, loved ones, health care providers, and clinicians have a clear interest in knowing who can make decisions in such instances and the rules and principles that will apply.[37]

C. Task Force Recommendations

The Task Force recommends that the surrogate decision-making authority of the FHCDA should be extended, as modified below, on an "opt-in" basis to those agencies, programs, and health care settings that are both Medicare and/or Medicaid-certified and State-licensed, not including those licensed pursuant to the professional licensure requirements under the New York State Education Law. Where an agency, program, or setting has opted in, the Act should authorize surrogate decision-making for all care provided in that setting, including for the creation of a plan of care and for decisions to withhold or withdraw life-sustaining treatment.

In all cases, care should be provided by appropriately-trained clinicians, while focus is maintained on providing the surrogate decision-maker with support and information regarding treatment options. In the community setting, particular emphasis should be placed on ensuring that physicians are responsible for the care of the patient and for working with a surrogate to design a patient's plan of care.

Where the FHCDA has distinct requirements depending on the setting in which decisions are made, the standards applied should mirror the more stringent requirements currently set forth for nursing homes. Specifically, for surrogate decisions to withhold or withdraw life-sustaining treatment, a surrogate may only have authority to refuse life-sustaining treatment if an Ethics Review Committee (ERC), including at least one physician who is not directly responsible for the patient's care, or a court of competent jurisdiction, reviews the decision and determines that it meets the standards established in the FHCDA.[38]

i. Programs, Agencies, and Settings

The Task Force proposes that the FHCDA be extended to Medicare and/or Medicaid-certified and State-licensed programs, agencies, and settings. The scope of the Task Force's recommendations is not limited to the entities described in this statement, however. Given the constantly changing health care landscape, these settings are merely representative examples of those that *may* have the potential ability to comply with the FHCDA's procedural requirements.[39]

Some of the settings discussed herein may not, in fact, be able to abide by the FHCDA's surrogate decision-making rules. For instance, although this statement refers to the possible capability of some physicians' offices to meet the requirements of the FHCDA,[40] others may not meet the criteria because they are subject to fewer oversight and other legal requirements.[41]

ii. "Opt-In" System

Because not all programs, agencies, and providers will be willing or able to abide by the procedural requirements and oversight mechanisms of the FHCDA, the Task Force recommends an initial expansion of the Act to health care settings that can (and choose to) opt-in to the FHCDA. This proposal will achieve a number of ends. First, and most obviously, it would extend much needed authority for surrogate decision-making for vulnerable populations beyond the hospital, nursing home, and hospice settings. Second, an opt-in system would allow surrogate decision-making authority to be effected without requiring extensive changes to the FHCDA, as many programs may already be equipped to comply with the safeguards enumerated in the Act. Finally, the opt-in process will provide the opportunity to those who are currently unable to comply with the FHCDA to adapt and adjust their procedures and services over time if they so choose, yet will also allow agencies, programs, and settings that do not have the resources or desire to abide by the FHCDA the ability to continue in their current form.

Some of the FHCDA's procedural requirements may be difficult to apply in community-based agencies and programs because of the Act's institutional focus. For example, under the FHCDA, certain decisions and actions must be reviewed by an ERC.[42] However, having an ERC is not a mandate of community-based agency licensure, and many programs may not have their own such committee. Additionally, the FHCDA has detailed requirements for decisions involving the isolated patient.[43] The requirement that treatment decisions for isolated patients be made by at least one physician may be difficult to follow in home care settings where physicians are often absent.[44]

iii. Proposed Modifications to the FHCDA

Programs, agencies, and health care settings outside of hospitals, nursing homes, and hospice have varied and distinct practices, oversight, and regulatory requirements as compared to their more institutional counterparts. Accordingly, special safeguards are necessary to protect the interests of the patient. In recognition of these differences and because of the unique nature of health care delivery in the community, the Task Force proposes that the FHCDA be amended for agencies, programs, and settings that are both Medicare and/or Medicaid-certified and State-licensed, as follows:

(a) **Attending physician:** The definition of "attending" physician in Section 2994-a(2) should be amended to include a qualified physician as set by the rules and procedures of a qualifying agency, program, or provider, rather than just those de-

fined by "hospital policy." These policies must ensure that an appropriately trained physician fulfills the roles and duties of the "attending" physician under the FHCDA, and should focus on the primacy of the role of the physician in patient care.

(b) **Capacity assessments:** Before turning to a surrogate for decisions involving major medical care or decisions to withhold or withdraw life-sustaining treatment, a physician must determine that the patient lacks decisional capacity about his or her care. The physician shall assess, monitor, and where appropriate, re-determine capacity in accordance with professional standards.[45] However, for *routine* medical decisions, in order to allow for more flexibility in surrogate decision-making in the community setting, capacity assessments may also be made by a nurse practitioner, in collaboration with a physician.[46]

(c) **Ethics Review Committees:** An agency, program, or setting may not have its own internal ERC that meets the FHCDA's requirements under Section 2994-m for membership and procedures, and may lack the resources to meet the Act's ERC mandate.[47] Accordingly, the FHCDA should be modified to allow that, where a conflict arises that cannot otherwise be resolved by an ethics consultation or other informal means[48] *or* where a surrogate refuses life-sustaining treatment,[49] the physician and/or surrogate should seek consultative services from its own ERC (if one exists) *or* a hospital, nursing home, or hospice-based ERC. A program, agency, or provider's internal policy must include identification of the ERC with whom it will consult if conflicts arise.

D. Advance Care Planning

The Task Force strongly encourages advance care planning prior to or upon entering community-based care by patients who have capacity.[50] Advance care planning may include guidance regarding the types of care a person may wish to have—or avoid—in the event that the patient can no longer indicate his or her preferences, and/or the selection of a surrogate decision-maker if the patient loses capacity to make first-person decisions. Advance care planning promotes respect for the patient as an autonomous decision-maker,[51] alleviates stresses on surrogates who may face enormous emotional burdens when making certain types of medical decisions, particularly regarding end-of-life care,[52] and increases the likelihood that the individual patient receives care consistent with his or her preferences.[53]

When a patient enters certain care settings, such as CHHAs, LTHHCPs, and EALRs,[54] opportunities exist to engage in advance care planning. However, when a plan of care is created, often the primary focus is on identifying appropriate services and medical equipment for the patient.[55] Such plans of care do not necessarily include patient preferences or directions for the initiation, continuation, withholding, or withdrawal of care, although some home care agencies are required to conduct discussions of advance directives upon entrance.[56] Further, in other more informal care settings and programs, there is little if any emphasis placed on advance care planning.

Regardless of the care setting, discussions of end-of-life care preferences and consideration of individuals who may serve as surrogate decision-makers in the event that a patient loses capacity should be promoted to the greatest extent possible.

D. Conclusion

In summary, the Task Force recommends that the surrogate decision-making authority of the FHCDA be extended, with the modifications discussed above, to apply to health care decisions in those Medicare and/or Medicaid-certified and State-licensed agencies, programs, and health care settings that opt-in to the FHCDA requirements.

Should the Legislature adopt these recommendations, the Task Force intends to evaluate the ability and success of the programs that have opted in, in order to assess the effectiveness of extending the FHCDA. In the future, the Task Force may issue additional statements or recommendations on related issues.

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Endnotes

1. N.Y. Pub. Health Law Art. 29-CC.
2. Under the FHCDA as currently worded, a "general hospital" is defined in Pub. Health Law § 2801(10) and excludes wards, wings, units or other parts of a general hospital operated for the purpose of providing services for persons with mental illness pursuant to an operating certificate issued by the Office of Mental Health. Thus, the surrogate decision-making provisions of the FHCDA do not, at present, apply in psychiatric units of general hospitals. The recommendations contained herein are not intended to modify this definition.
3. 2010 N.Y. Laws Ch. 8, § 28(2).
4. New York State Task Force on Life and the Law, *Recommendations Regarding the Extension of the Family Health Care Decisions Act to Include Hospice* (Dec. 22, 2010), *available at* http://www.health.state.ny.us/regulations/task_force/docs/2010-11-30_recommendations_regarding_the_extension_of_family_health_care_decisions_act.pdf.
5. 2011 N.Y. Laws Ch. 167.
6. The Legislature has recognized the significant role that CHHAs play in the State's health care system. N.Y. Pub. Health Law § 3600 ("The certified home health agencies render a coordinated array of services to patients in their homes, thereby avoiding prolonged institutionalization, concomitant high costs and associated adverse social and medical implications.").
7. N.Y. Pub. Health Law § 3605.
8. CHHAs, LTTHCPs, and LHCSAs must be licensed by the State. *Id*. Moreover, home care agencies may also be accredited by the Joint Commission, Accreditation Commission for Health Care, or Community Health Accreditation Program. Standards for accreditation vary among accrediting bodies. Although accreditation is voluntary and not required for any home care agencies, these accrediting organizations have Medicare-deeming authority, in which private, national accreditation organizations are authorized by the Centers for Medicare & Medicaid Services (CMS) to determine that an organization is compliant with certain Medicare requirements. Alternatively, a home care agency or program may request certification directly from Medicare.
9. N.Y. Pub. Health Law § 3616-A.
10. 42 C.F.R. pt. 484. Throughout these recommendations, agencies, or programs determined by CMS or an accrediting agency to meet the federal statutory conditions necessary to participate in Medicare will be referred to as "Medicare-certified."
11. N.Y. Pub. Health Law § 3605.
12. *See, e.g.,* New York State Department of Health, *Care at Home Program for Physically Disabled Children,* http://www.health.ny.gov/publications/0548/care_at_home_physically_disabled.htm (last visited Oct. 17, 2012); New York State Department of Health, *Traumatic Brain Injury Waiver*, http://www.health.state.ny.us/health_care/medicaid/program/longterm/tbi.htm (last visited Oct. 17, 2012); New York State Department of Health, *Managed Long Term Care Program (MLTC)*, http://www.health.state.ny.us/health_care/medicaid/program/longterm/mltc.htm (last visited Oct. 17, 2012); New York State Department of Health, *Consumer Directed Personal Assistance Program (CDPAP)*, http://www.health.state.ny.us/health_care/medicaid/program/longterm/cdpap.htm (last visited Oct. 17, 2012).
13. The range of services that could be provided by a nurse in an EALR is dictated by the resident's health care needs—as described in the resident's individualized service plan—and what the EALR and nurse are each authorized by law to provide.
14. N.Y. Comp. Code R. & Regs. tit. 10, § 1001.7(e)(2). The patient may remain in the EALR provided the patient's physician decides that his/her care can be safely delivered there and the operator agrees to provide services or arrange for services and is willing to coordinate care.
15. N.Y. Comp. Code R. & Regs. tit.18, pt. 487.
16. N.Y. Comp. Code R. & Regs. tit.18, pt. 490. An assisted living residence is defined as an entity that provides or arranges for housing, on-site monitoring, and personal care and/or home care services in a home-like setting to five or more adult residents.
17. N.Y. Comp. Code R. & Regs. tit. 10, §1001.5.
18. In assisted living residences, resident care aides perform similar services to those provided by home health aides in home care agencies and programs, and are trained to the same level as home care aides. N.Y. Comp. Code R. & Regs. tit. 10, § 1001.10(j)(3).
19. N.Y. Pub. Health Law Art. 28.
20. N.Y. Comp. Code R. & Regs. tit. 10, pt. 755.
21. Urgent care centers are facilities in which surgical or invasive procedures using moderate (or deeper) sedation occur. They qualify as either Public Health Law Article 28 facilities or are subject to the office-based surgery law, N.Y. Pub. Health Law § 230-d.
22. N.Y. Comp. Code R. & Regs. tit. 10, § 755.2(f).
23. The State Education Department's Office of the Professions licenses the medical profession, including physicians and nurses. N.Y. Educ. Law Art. 131, §§ 6520-6529; Art. 139, §§ 6900-6910. Until the 2007 promulgation of the office-based surgery regulations (N.Y. Pub. Health Law § 230-d), there was almost no NYSDOH oversight of private office-based care, except where a physician became subject to professional misconduct proceedings pursuant to N.Y. Pub. Health Law § 230 or was sued for providing unacceptable care (*e.g.,* medical malpractice or otherwise).
24. Office-based surgery is defined as "any surgical or other invasive procedure, requiring general anesthesia, moderate sedation, or deep sedation, and any liposuction procedure, where such surgical or other invasive procedure or liposuction is performed by a licensee in a location other than a hospital…excluding minor procedures and procedures requiring minimal sedation." N.Y. Pub. Health Law § 230-d(1)(h).
25. Although accreditation is not the same as state regulation, NYSDOH noted that it may ensure a level of standardization among office-based surgery practices while assuring quality of care and patient safety. New York State Department of Health, *Office-Based Surgery Practices in New York State,* http://www.health.state.ny.us/professionals/office-based_surgery/practices/ (last visited Oct. 17, 2012).
26. N.Y. Pub. Health Law § 230-d.
27. N.Y. Pub. Health Law § 230-d(5); New York State Department of Health, *Office-Based Surgery*, http://www.health.state.ny.us/professionals/office-based_surgery/ (last visited Apr. 23, 2012).
28. Committee on Quality Assurance in Office-Based Surgery, *Clinical Guidelines for Office-Based Surgery*, ix (2000), http://www.auanet.org/content/practice-resources/office-based-surgery/pdfs/NY_protocols.pdf. *See also* New York State Department of Health, *Report of the Committee on Quality Assurance in Office-Based Surgery* (2007), http://www.health.state.ny.us/professionals/office-based_surgery/reports/docs/committee_on_quality_assurance.pdf.
29. N.Y. Pub. Health Law Art. 29-E. The law establishes a demonstration program that will allow for the evaluation of the viability of ACOs, and authorizes NYSDOH to approve a maximum of seven ACOs between the law's effective date and December 2015. N.Y. Pub. Health Law § 2999-p ("[T]he demonstration project is intended 'to test the ability of ACOs to deliver an array of health care services for the purpose of improving the quality, coordination and accountability of services provided to patients in New York.'").
30. Centers for Medicare & Medicaid Services, *Accountable Care Organizations (ACOs),* http://www.cms.gov/ACO/ (last visited Oct. 17, 2012). The federal Shared Savings Program would require that ACOs that meet certain quality performance standards to be eligible to receive Medicare shared savings payments. Among other requirements, the ACO must demonstrate that it meets patient-centeredness criteria, such as the use of patient and caregiver assessments or the use of individualized care plans.
31. *See* N.Y. Comp. Codes R. & Regs. tit. 18, §§ 505.21, 505.23; N.Y. Comp. Codes R. & Regs. tit. 10, § 766.4. At the federal level, the Patient Protection and Affordable Care Act and its related regulations now require a face-to-face encounter when physicians

certify eligibility for home health care. However, a nurse practitioner, a certified nurse midwife, or a physician assistant may perform the face-to-face visit instead of a physician. *See* Pub. L. No. 111-148 § 6407(a); 42 C.F.R. § 424.22(a)(1)(v).

32. Home health aides must complete State-mandated training classes, and are required to undergo annual physical assessment and meet in-service requirements. *See* New York State Department of Health, *Home Health Aide Training Program Application*, http://www.health.ny.gov/forms/doh-4396.pdf (last visited Oct. 17, 2012).

33. New York State Office for the Aging, *New York State Family Caregiver Council Report* (2009), http://www.aging.ny.gov/Caregiving/Reports/InformalCaregivers/FamilyCaregiverCouncilReport.pdf. The 2009 Caregiver Support Programs Participants Survey found that caregivers receiving caregiver support program services during fiscal year 2007 were generally at least 18 years of age and were family members, friends, or neighbors who help care for an elderly individual (aged 60 or older) who lives at home.

34. For a discussion of reasonable practices in decisions for patients who lack capacity, see Robert N. Swidler & Nina M. Daratsos, *Informed Consent and Decisions for Patients Who Lack Capacity*, *in* Legal Manual for New York Physicians 373-77 (Medical Society State of NY/NYS Bar Association, 3rd ed. 2011).

35. *See, e.g.*, William J. Ehlenbach et al., *Association Between Acute Care and Critical Illness Hospitalization and Cognitive Function in Older Adults*, 303 JAMA 763 (2010).

36. Research also has shown that, in comparison to patients who pass away in hospitals or hospice, patients who die at home without nursing services are the least likely to have an advance directive. Specifically, 55.6% of those whose last place of care was at home, without nursing services, had advance directives, as compared to 70.8% of those who received care at home with hospice services, 80.8% of those whose last place of care was at a nursing home, and 62.5% whose last place of care was in a hospital. Joan M. Teno et al., *Family Perspectives on End-of-Life Care at the Last Place of Care,* 291 JAMA 88, (2004). This finding is perhaps due to the fact that advance care planning conversations are more likely to occur at the time of admission to a nursing home, hospital, or hospice, or because death is more "unexpected" in the home than in other settings (and therefore the patient has not had the opportunity to have such conversations). Dying was "'extremely' unexpected" for 65% of those patients whose last place of care was at home, without nursing services, as compared to 7.1% of those who received care at home with hospice services, 12% of those whose last place of care was at a nursing home, and 23.8% whose last place of care was in a hospital. *Id*.

37. Under the FHCDA as currently worded, even when a surrogate was previously identified and appointed in an institution covered by the FHCDA, when the patient is transitioned to the community for care (and is not in hospice care), that surrogate will lose the ability to make decisions about on-going care.

38. N.Y. Pub. Health Law § 2994-d(5).

39. For example, due to resource sharing agreements and the coordination of care between health care providers and other participants in integrated health care delivery arrangements, ACOs and similar systems may be able to comply with the procedural aspects of the FHCDA, and thus a surrogate appointment may be able to travel with the patient throughout the various ACO participant settings.

40. Particularly where the doctor is affiliated with a hospital, physicians' offices may be able to meet the FHCDA's technical requirements for routine care decisions on an opt-in basis with additional patient protections. Further, extension clinics are considered part of a general hospital, and therefore physicians providing care in these settings must already meet the FHCDA's technical requirements.

41. Office-based surgery would generally fall under the FHCDA's classification of "major medical" care. N.Y. Pub. Health Law § 230-d(1)(h); § 2994-g(4).

42. N.Y. Pub. Health Law § 2994-d(5)(b). The FHCDA requires that ERCs be interdisciplinary, and be composed of at least five members, three of which are health or social service practitioners, and include a physician and a registered nurse. Further, at least one member must be a person without any governance, employment, or contractual relationship with the hospital or nursing home. In nursing homes, the Residents' Council of the facility, or of another facility that participates in the ERC, must be offered the opportunity to appoint up to two individuals, neither of whom may be a resident or a family member of a resident of the facility. N.Y. Pub. Health Law § 2994-m(3).

43. N.Y. Pub. Health Law § 2994-g. An "isolated patient" is an adult patient who would qualify for surrogate decision-making under the FHCDA but for whom no surrogate is reasonably available.

44. Under the FHCDA, a single physician can make decisions regarding routine medical care for the isolated patient. When the plan of care, which is established at the time of enrollment, involves major medical care, two physicians would need to be present and independently concur in such decisions. Decisions to withhold or withdraw life-sustaining treatment may be made on behalf of the isolated patient if two physicians determine that the treatment offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided, and the provision of the treatment would violate accepted medical standards (or, alternatively, if a court finds that the decision is appropriate). *Id.*

45. *See* N.Y. Pub. Health Law § 2994-c(2), (3), and (7).

46. This modification does not apply to decisions regarding major medical care or decisions to withhold/withdrawal life-sustaining treatment.

47. *See* N.Y. Pub. Health Law §§ 2994-c, d, m.

48. For example, where the physician objects to a surrogate's decision or where there is a conflict between an initial and a concurring determination of incapacity.

49. N.Y. Pub. Health Law § 2994-d(5)(b).

50. Some, but not all, programs and agencies require a discussion of advance directives and applicable State law upon admission. 42 C.F.R. § 484.10(c)(2)(ii) ("Medicare Certified Home Health Agencies require that the HHA must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable State law."). *See also* Rebecca L. Sudore & Terri R. Fried, *Redefining the "Planning" in Advance Care Planning: Preparing for End-of-Life Decision Making*, 153 Ann. Intern. Med. 256 (2010) (concluding that the objective for advance care planning ought to be the preparation of patients and surrogates to participate with clinicians in making the best possible in-the-moment medical decisions, and recommending steps for clinicians to follow to prepare patients and surrogates in the outpatient setting).

51. *See, e.g.*, Peter H. Ditto et al., *Advance Directives as Acts of Communication: A Randomized Controlled Trial*, 161 Arch. Intern. Med. 421 (2001).

52. *See, e.g.*, Karen M. Detering et al., *The Impact of Advance Care Planning on End of Life Care in Elderly Patients: Randomised Controlled Trial*, 340 BMJ c1345 (2010).

53. *See generally* N.Y. Pub. Health Law Art. 29-C; New York State Department of Health, *Medical Orders for Life-Sustaining Treatment (MOLST)*, http://www.health.state.ny.us/forms/doh-5003.pdf (last visited Oct. 17, 2012) (NYSDOH-approved physician order form, intended to aid physicians and other health care providers to discuss and convey a patient's wishes regarding cardiopulmonary resuscitation (CPR) and other life-sustaining treatment).

54. Assisted living residences must develop an individualized service plan for each applicant that includes a medical, functional, and mental health assessment based on the results of a physical exam within 30 days prior to admission. The plan describes the services that need to be provided to the resident, and how and by whom those services will be provided, and must be reviewed and revised as medical, nutritional, social, and everyday life needs change, but at least every six months. N.Y. Comp. Code R. & Regs. tit. 10, § 1001.7(k).

55. *See* N.Y. Comp. Codes R. & Regs. tit. 10, § 763.6; 42 C.F.R. § 484.18.

56. 42 C.F.R. § 484.10(c)(2)(ii).

Frequently Asked Questions for the NYS Prescription Monitoring Program (PMP) Registry

Bureau of Narcotic Enforcement, NYS Department of Health

Editor's Note—*As a result of the Internet System for Tracing Over-Prescribing Act (I-STOP)(Ch. 227 L. 2012) on August 27, 2013, practitioners became required, with limited exceptions, to check the NYS Department of Health's Prescription Monitoring Program ("PMP") Registry prior to writing a prescription for a controlled substance in schedule II, III, and IV for a patient. Pharmacists will have access to the PMP Registry after this date as well.*

This is a significant new requirement that impacts a broad range of physicians and health care providers. The Bureau of Narcotics Enforcement issued the following brochure to assist practitioners in understanding their obligations and complying with the new law.

Frequently Asked Questions
for the

NYS PMP
PRESCRIPTION MONITORING PROGRAM REGISTRY

Revised: July 2013

NEW YORK
state department of
HEALTH

NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Narcotic Enforcement

1-866-811-7957
www.health.ny.gov/professionals/narcotic

Online PMP

Q *What is the purpose of the Prescription Monitoring Program (PMP) Registry (formerly CSI)?*

A The Prescription Monitoring Program Registry provides practitioners and pharmacists with direct, secure access to view their patients' recent controlled substance prescription history to help them better evaluate a patient's treatment as it pertains to controlled substance prescribing and dispensing.

Effective August 27, 2013, practitioners will be required, with limited exceptions, to check the PMP Registry prior to writing a prescription for a controlled substance in schedule II, III, and IV for a patient. Pharmacists will have access to the PMP Registry after this date as well.

Q *Will pharmacists see the same information seen by practitioners?*

A Yes, if the pharmacist has an individual HCS account, he or she can access the same information when that patient presents a prescription for a controlled substance to the pharmacy.

Q *What are the benefits of the PMP Registry?*

A
- The program allows for better understanding of a patient's controlled substance utilization based on recent controlled substance prescription history.
- Provides a quick, confidential online report to the practitioner and the pharmacist.
- Available 24 hours a day, 7 days a week.
- Information is based on controlled substance prescription data from nearly 5,000 pharmacies.
- No cost to the practitioner or pharmacist.

Q *My patient appears on the Prescription Monitoring Program (PMP). Does this mean my patient is a "Doctor Shopper"?*

A Not necessarily. A PMP registry report indicates that your patient has received controlled substance prescriptions in the past six months. This report is intended to provide you access to your patient's controlled substance prescription history for purposes of making treatment decisions. The information in this report is provided to help reasonably inform a practitioner when he or she is deciding whether or not to prescribe or dispense a controlled substance.

Q *Who can access the PMP Registry?*

A Any New York State licensed prescriber, excluding veterinarians, may access the PMP Registry. Each prescriber ***must have an individual*** Health Commerce System Account (HCS) to gain access. The application to establish an account for a licensed professional is available on the following website: https://hcsteamwork1.health.state.ny.us/pub/top.html.

Important Note: Effective August 27, 2013, pharmacists will have access to the program and will need their own HCS accounts.

Q *How do I establish an HCS Account?*

A If you are a ***licensed professional*** the application to establish an account is available on the following website: https://hcsteamwork1.health.state.ny.us/pub/top.html.

If you are a resident, unlicensed professional, limited permit holder, or administrative staff acting as a designee, the HCS director or coordinator (e.g., prescribing practitioner or facility administrator) will log into the HCS system: https://commerce.health.state.ny.us, click on Coord Account Tools under My Applications, Under Account Request, click "User," and follow the process.

Q *I currently have an HCS account, do I still need to register for the PMP Registry?*

A No. There is not a separate registration for the PMP. By maintaining an HCS account, practitioners, pharmacists, and designees will have access to the PMP Registry.

Note: Pharmacists and designees will not have access until August 27, 2013.

Q *I submitted for an HCS account, what happens next?*

A New accounts are usually established within two weeks. Once your application is processed you will be e-mailed documents. They must be printed, notarized and received by the Department of Health for your user ID to be issued. For account information or help with your HCS Account please contact Commerce Account Management Unit (CAMU) at 1-866-529-1890, option 1.

Q ***I have an HCS account but do not know my user ID or password. Who should I contact?***

A For account information or help with your HCS Account please contact CAMU at 1-866-529-1890, option 1.

Q ***My password expired, who should I contact?***

A For expired passwords please contact CAMU at 1-866-529-1890, option 1.

Q ***Once I established an HCS account how do I access the PMP Registry?***

A

- Go to the HCS at: https://commerce.health.state.ny.us
- Log onto the system with your user ID and password (***If you can't remember your password, call the Commerce Account Management Unit at 1-866-529-1890, Option 1, for assistance).***
- Click on the NYS PMP Registry campaign button on the home page or select "Applications" at the top of the page. Click on the letter "P."
- Scroll down to "Prescription Monitoring Program Registry."
- Click the green plus sign under the Add/Remove column to add this application to your favorites so you don't have to scroll down each time in the HCS [optional].
- Click to open the program.
- Enter patient information and all other required information.
- Review the Frequently Asked Questions within the application for further information.

Q ***Am I required to review the PMP for any controlled substance prescribed, or is this review limited to certain drugs?***

A Effective August 27, 2013, the duty to consult the PMP is required of the practitioner prior to prescribing or dispensing any controlled substance listed on schedule II, III or IV.

Q ***Are any practitioners excluded from the requirement to consult the PMP prior to dispensing or prescribing?***

A Veterinarians are excluded. In addition, practitioners who are not veterinarians may be excluded if they meet the criteria defined within Section 3343-a Article 33 of the Public Health Law. Please review this section of the law, which may be accessed from the Bureau of Narcotic Enforcement's web page; www.nyhealth.gov/professionals/narcotic. Click on the link on the left hand side of the page for "Laws and Regulations" and follow the instructions on this page to get to Article 33.

Q ***Can I designate someone to check the PMP Registry for me?***

A Yes. Effective August 27, 2013 practitioners and pharmacists can designate staff to look up patients on the PMP registry on their behalf.

Designees for Practitioners: The designees, if unlicensed, will need to work with the HCS coordinator from their facility, or prescribing practitioner, to establish their own HCS accounts. After the designee obtains an HCS account user ID, the practitioner will need to log into the HCS, open the PMP application, and click on the Designation tab. On the designation screen, the practitioners will enter the HCS user ID of the individual that will be performing the look up on their behalf as a designee. The functionality to designate a staff member is currently not available. However, we encourage staff that will be designees to apply for their HCS account now.

Designees for Pharmacists: Designees for pharmacists, which are limited to other pharmacists and pharmacy interns, will need to work with the HCS coordinator for the pharmacy to establish their own HCS Account. After the designee obtains an HCS account user ID, the pharmacist will need to log into the HCS, open the PMP application, and click on the Designation tab. On the designation screen, the pharmacist will enter the HCS user ID of the individual that will be performing the look up on their behalf as a designee. The functionality to designate a staff member is currently not available. However, we encourage staff who will be designees to apply for their HCS account now.

Q ***Can I share the report reflecting my patient's controlled substance history with my patient?***

A Yes. Release of the information is allowed to your patients but should be based on your professional medical judgment. All state and federal confidentiality rules must be adhered to.

Q ***What type of information will the report provide?***

A Effective August 27, 2013 or sooner, patient search reports will include all controlled substances that were dispensed and reported by the pharmacy/dispenser for the past 6 months. Pharmacy and practitioner information will be provided as well.

Q ***How is the controlled substance data in the PMP Registry obtained?***

A All New York State pharmacies and dispensing practitioners are required to submit their controlled substance dispensing data to the Bureau of Narcotic Enforcement.

Q ***Are refills and partial-filled prescriptions listed in the report?***

A Yes. Dispensers are required to report refills and partial-filled prescriptions to the Department of Health.

Q ***How current will the data be that is reflected on the PMP when the practitioner is required to consult the PMP?***

A Effective August 27, 2013, the data will be submitted to the Bureau on a "real time" basis as defined by the commissioner within the regulations.

Q ***Do I have to report to the Department that I reviewed my patient's controlled substance history?***

A No.

Q ***What is the "Drug Listing"?***

A The "Drug Listing" tab in the horizontal menu at the top of the screen provides a reference of the brand names that are associated with the drug names shown on the Patient Search Results and lists the controlled substance schedule in New York State. Schedules of controlled substances are defined within section 3306 Article 33 of the Public Health Law. This information may be accessed from the Bureau of Narcotic Enforcement's web page; www.nyhealth.gov/professionals/narcotic. Click on the link on the left hand side of the page for "Laws and Regulations" and follow the instructions on this page to get to Article 33.

Q ***After reviewing the PMP for a patient, what do I do if I suspect diversion?***

A Please note a link on the bottom of the Confidential Drug Utilization Report to report a prescription discrepancy, or to send questions or comments about the report to the Bureau of Narcotic Enforcement. You may also contact the Bureau of Narcotic Enforcement office in your area to speak to a narcotic investigator.

- ***Albany/Central Office:*** (866) 811-7957 Opt. #2
- ***Western Area Regional Office (Buffalo Area):*** (716) 847-4532
- ***Rochester Office:*** (585) 423-8043
- ***Syracuse Office:*** (315) 477-8459
- ***New York City Metropolitan Area Regional Office:*** (212) 417-4103

Q ***My patient is claiming identity theft. How should I direct him or her?***

A Identity theft should be reported to the local police department.

Q ***How do I assist patients who want help for an addiction problem?***

A Treatment program information is available from the NYS Office of Alcoholism and Substance Abuse Services at www.oasas.ny.gov or by calling 1-877-846-7369. You may also access the Substance Abuse and Mental Health Services Administration (SAMHSA) website at www.buprenorphine.samhsa.gov to locate a participating opioid addiction physician in your area.

Q ***As a physician, how do I become eligible to prescribe buprenorphine for opioid addiction?***

A You must qualify for a Drug Enforcement Administration (DEA) waiver. You can obtain more information at the Center for Substance Abuse Treatment (CSAT) at 1-866-287-2728 or www.buprenorphine.samhsa.gov.

Q ***I have patients who receive Schedule II prescriptions which require a new prescription with each fill. Do I have to consult the PMP for the same patient each month when writing the same prescription?***

A Effective August 27, 2013, the duty to consult the PMP is required of the practitioner prior to prescribing or dispensing any controlled substance listed on schedule II, III or IV, regardless if it is the same patient being prescribed a controlled substance each month.

Q ***Is there a distinction between immediate release and extended release products when viewing drugs on the PMP?***

A The PMP will display the drug and strength, but does not specify the dosage form.

Q ***How can I integrate the PMP into our electronic health record or electronic prescribing software?***

A At this time, the PMP must be accessed through the Health Commerce System. The Department of Health is actively working on solutions to integrate the PMP Registry into electronic medical records.

Q ***What is the difference between the "Printer Friendly" and "Extended" options for the Data Detail Level?***

A The "Printer-Friendly" level is intended to be printable in landscape mode on 8.5" x 11" paper. When the "Extended" option is selected, additional fields are included in the search results; including the Payment Method and the Dispenser. The results area can be scrolled horizontally and there is no guarantee regarding printability.

Q ***What is the purpose of the "My DEA Numbers" tab?***

A The "My DEA Numbers" tab provides the option of entering one or more DEA numbers associated with the practitioner. It allows for separation of prescriptions associated with any of the entered DEA numbers from all other results on the Patient Search Results page. (My Prescriptions versus Other's Prescriptions)

Q ***Which DEA number should I use if I hold multiple registration numbers?***

A The DEA number associated with your prescriptions is the number that the dispenser submitted to the Department. You may enter all of your DEA numbers under the DEA listing tab. Patient Search results will be sorted by DEA number.

Q ***What is the difference between "other's prescriptions" and "my prescriptions"?***

A "Other's prescriptions" reflect prescriptions written by another prescriber (other than you).

Q ***Who do I contact if I didn't write the prescription shown under "My Prescriptions"?***

A Use the link on the page to report a prescription error to the Bureau of Narcotic Enforcement. The link is located below your patient's prescription information.

Q ***How do I contact the other physician(s) for a consultation?***

A Practitioner information is public and can be researched from the following web site: http://www.nydoctorprofile.com/.

Q ***What will happen if I do not enter my DEA number in the "MY DEA Numbers" tab?***

A If you do not enter you DEA number in the "MY DEA Numbers" tab, there will be no separation of prescriptions you wrote from prescriptions other prescribers wrote.

Q ***Do I need to rerun the patient search after I enter my DEA number(s)?***

A Only if you want to see your prescriptions separate from other prescribers. The same data will be displayed; just the format of the data displayed will change.

Q ***I entered my DEA number on the My DEA Numbers page, but made an error. Can I modify the entry?***

A Click on the check box next to your DEA Number and then click on "Remove." Then enter the correct DEA number in the "Enter your DEA number" field.

Q ***I changed my DEA number, how do I update this data in my HCS account?***

A To remove a DEA Number, click the check box next to it and click the "Remove" button. Multiple DEA numbers may be removed at the same time.

Q ***Will the PMP display a patient's controlled substance records for doctors within the same practice together?***

A No. The PMP will display a patient's controlled substance records for the practitioner under "My Prescriptions," provided that the practitioner entered his or her DEA number(s) using the "My DEA Numbers" menu option. The "My DEA Numbers" link is located in the horizontal menu at the top of the screen. All other controlled substance records for a patient, including records of prescriptions written by practitioners within the same practice, are grouped into "Other's Prescriptions" on the PMP display.

Q ***What is the "Update Personal Info" menu option for?***

A It is used to update business contact information, emergency contact information, and professional information.

Q ***Can I update my Physician Profile from the HCS account?***

A Yes; select the Applications Tab at the top of the page, select the letter "P" and scroll down to Physician Profile System.

Q ***I received an "Access Denied" message with a link to Update Personal Info. Why am I being denied access to the PMP application?***

A The system was not able to validate your license number to allow access to the application because your license number is either missing from your HCS personal account information or your current license number needs to be added to your HCS personal account information. Please click on the link and update your license information. Once updated, you should be able to access the PMP application.

Q ***I received an "Access Denied" message with a System Error Code of BNE8937. Why am I being denied access to the PMP application?***

A You are currently not allowed to access the PMP application because either your NYS license has expired or your license has an administrative action code on it. The PMP relies upon licensing data provided by the New York State Education Department (NYSED). Questions regarding the status of your license should be directed to NYSED.

Q ***Why does my patient's prescription information appear in "blocks" or "groups"on the Drug Utilization Review Screen?***

A The PMP utilizes matching criteria to determine if records for people with slight differences in demographic data could be for the same individual. The dispensed prescriptions are shown based on variations in the name, date of birth and address. Practitioners should compare patient name, date of birth and address in determining whether or not the different groups represent the same individual. For example, an address for the same patient may be similar, but the information will be grouped separately.

For example, information dispensed under an address of 33-33 Main St. may appear in a separate grouping from information dispensed under the address of 3333 Main St.

Also note that if you entered your DEA numbers on the 'My DEA Numbers' tab, you will see the prescriptions ***you*** wrote for that patient grouped first, followed by those written by others, if any.

Q ***How is the prescription data sorted?***

A Within each grouping, the information is sorted by date dispensed.

Q ***Will I have to attest every time I access a patient's information?***

A By clicking "Yes" on the Patient Search screen to advance the search, you are attesting to abide by the guidelines for use of the PMP in accordance with the New York State Public Health Law. You may view the guidelines by clicking the link at the top of the Patient Search screen.

Q ***Where can I find the guidelines that I am attesting to?***

A The guidelines or attestation is accessible via a link on the Patient Search page.

Q ***I wrote a prescription for my patient for a controlled substance. Why does it not appear in the PMP Registry?***

A The PMP Registry displays all of the controlled substance prescriptions, if any, that your patient has filled in the last six months. The information is compiled from data submitted to the Department related to prescriptions dispensed to your patient.

Q ***What is the purpose of the Search Terms Review page?***

A The Search Terms Review page allows you to review the entered search criteria and ensure its accuracy. You can choose either to complete the search by pressing "Continue," or to fix any mistakes by pressing "Revise Search Terms."

Q ***What is the System Alert Message?***

A The System Alert Message will allow announcements to be made regarding downtime and important events, and once set will appear on all pages within the application.

Recent Event

- **2013 Section Fall Meeting**

The Section's 2013 Fall Meeting was held on Friday October 25, 2013 at the Bar Center, One Elk Street, Albany, NY. The program was titled, "Affordable Care Act & Readiness for 2014 and Beyond—Public Benefit Exchange: Impact on Insurers Providers and Medicaid Program." Raul Tabora. Jr. of Bond Schoeneck & King, PLLC is Program Chair.

Upcoming Event

- **2014 Annual Meeting**

The Health Law Section's Annual Meeting program will be Wednesday, January 29. It will be held at the New York Hilton Midtown, in conjunction with the NYSBA Annual Meeting which runs from January 27-February 1. The Program will cover the latest developments across the range of New York State health law subjects. Margaret (Margie) J. Davino of Kaufman, Borgeest & Ryan, LLP is Program Chair.

Focus on Membership Committee and Diversity Subcommittee

The Membership Committee is responsible for Section recruitment and member support. Participation is especially useful for young attorneys who are trying to break into the Health Law field, as its activities provide rich networking opportunities.

The Committee maintains an Industry Contact List to provide members contact information for colleagues willing to speak with them about specific areas of health law. It also arranges representation of the Health Law Section at law school outreach events and organizes membership appreciation activities.

In addition, the Membership Committee includes a subcommittee devoted to the Section's participation in the Bar Association's Diversity Initiatives. This subcommittee is responsible for implementation of our summer internship program, our efforts to reach out to minority bar associations, and other initiatives within our Diversity Action Plan.

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Section Committees and Chairs

The Health Law Section encourages members to participate in its programs and to volunteer to serve on the Committees listed below. Please contact the Section Officers or Committee Chairs for further information about these Committees.

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