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Health Law Journal

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

Special Edition:
Nurses and Allied Health Professionals

- Producing a Nurse Witness in a Medical Malpractice Action
- Representing the Nurse with a Substance Abuse Problem
- The New York Health Care Whistleblower Law
- The Nurse as a Patient Advocate in Disaster Planning
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Special Edition Editor: Karen A. Butler, R.N., B.S.N., J.D.

NEW YORK STATE BAR ASSOCIATION

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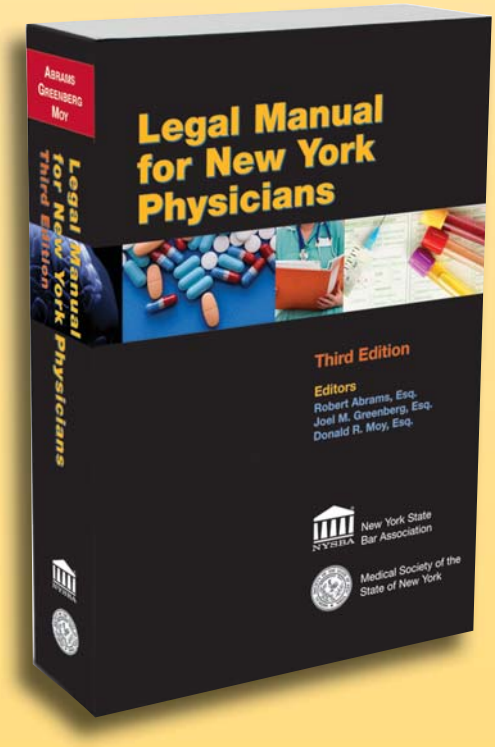

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HEALTH LAW JOURNAL

WINTER 2013

Vol. 18, No. 1

THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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About the Special Edition Editor—Karen A. Butler, R.N., B.S.N., J.D.

A 1971 graduate of Vermont College, Ms. Butler combines more than twenty years' experience as a critical care nurse with her skills as a practicing attorney. Ms. Butler is a partner in the law firm of Thuillez, Ford, Gold, Butler & Monroe, LLP. Her areas of practice include medical malpractice defense, professional misconduct, health law and civil rights litigation. Ms. Butler is admitted to practice law in all the courts of the State of New York, in both the Northern and Southern Districts of New York and in The United States Supreme Court. Graduating Magna Cum Laude from Albany Law School in 1995, Ms. Butler was Associate Editor of *Albany Law Review* and recipient of The Selma Mintz Memorial Prize for graduating with honors while raising a family. She is a member of The New York State Bar Association, The American Bar Association, The Defense Research Institute and The Association of Trial Lawyers of America. She is on the Board of The Capital District Trial Lawyers Association and was President in 2009. A member of The American Association of Nurse Attorneys since 1995, Ms. Butler is on the editorial board of *The Journal of Nursing Law*. She is also on the Board of Directors of Teresian House where she chairs the Ethics Committee. She has published several articles on health law-related topics and lectures extensively on health law, litigation and professional misconduct. She was appointed by the Governor to The New York State Task Force on Life and the Law in 2003.

Cover artwork: Alexandre Veron-Bellecourt (b.1773)
Nurse, patient and doctor, detail from painting of Napoleon Bonaparte (1769-1821) Emperor of France, visiting Napoleon Room of hospital at the Hôtel des Invalides, Paris, on 11 February 1808
Gianni Dagli Orti / The Art Archive at Art Resource, NY

A Message from the Section Chair

Legislative/Regulatory Agenda

The coming year promises to be extremely important, as our federal and state governments continue to implement the Affordable Care Act and the New York Medicaid Redesign Team ("MRT") initiatives. As New York State moves ahead with implementing health reform initiatives, our Section will continue to monitor and comment on proposed legislation and regulations. The state initiatives that warrant special attention in 2013 include the following.

(1) CON and Governance Reform. On December 6, 2012, the Public Health and Health Planning Council ("PHHPC") adopted a report entitled: "Redesigning Certificate of Need and Health Planning," which contains twenty-three (23) recommendations. See http://www.health.ny.gov/facilities/public_health_and_health_planning_council/docs/con_redesign_report.pdf. This report, as its name implies, includes numerous recommendations designed to reform the Certificate of Need ("CON") process, including what services are subject to CON review and the process for reviewing character and competence. What is not obvious from the title of the report is that it also includes significant proposed changes relating to oversight of provider governance. For example, this report recommends (i) requiring prior notice to the state Department of Health ("DOH") before commencing a "passive parent" relationship, and giving DOH 90 days to recommend disapproval to PHHPC, (ii) "relaxing the prohibition on revenue sharing among providers that are not established as co-operators," and (iii) supporting legislation to authorize DOH to appoint temporary operators of hospitals and freestanding clinics and to replace board members under certain circumstances related to patient safety and financial instability. The proposed state budget, released on January 22, 2013, includes legislation designed to implement some of the recommendations contained in this report. DOH is drafting proposed regulations to implement the remaining provisions. Our Section intends to play a role in commenting on these important provisions before they are adopted.

(2) Executive Compensation: DOH, as well as other state agencies, has issued proposed regulations designed to implement the Governor's Executive Order No. 38, which seeks to limit executive compensation and reduce administrative expenses for entities contracting with the state. Our Section submitted comments on the proposed and on the revised proposed regulations. The Section's comments are listed on our website at www.nysba.org/HealthLawComments.

(3) NY Practitioner Self-Referral Law: The Governor vetoed legislation developed by our Section that was designed to improve the NY Practitioner Self-Referral Law (see A3551-A/S4660). It is our intention to work with the Governor's office, the Health Department and the Legislature to craft a solution to the issues raised by the Governor's office so that this important legislation will be enacted into law.

Fall and Annual Meetings

Fall Meeting: Our Section held its Fall Meeting on October 26, 2012 in Albany, which focused on "New York Health Reform." We were delighted that key officials from DOH and the state legislature could join us in panel discussions on various health reform initiatives, including proposals to reform New York laws and regulations that form barriers to achieving the "Triple Aim." The materials for our Fall Meeting are available on our website at: www.nysba.org/HLS2012FallMtg.

Annual Meeting: We held our Annual Meeting on January 23, 2013 in New York City. The topics included: "Health IT Update: Key Impediments to HITECH implementation and the View Ahead towards 2014," "Two Current Issues in Legal Ethics: Rules for Internal Investigations and a Template for Avoiding Conflict," "New York Health Planning, Certificate of Need and Governance Reforms," "New York State Limits on Executive Compensation and Proposed Regulations," "Accountable Care Organizations (ACOs): Regulatory and Strategic Issues and Implementation Challenges," "Medical Indemnity Fund Update and Impact on Settlements," and "New York's Health Insurance Exchange and Its Impact on Providers, Payers and Employers." Again, we were delighted that our panels included several state officials, as well as Susan Waltman, General Counsel for the Greater New York Hospital Association, Professor Stephen Gillers of NYU, several physicians involved in implementing ACOs, and distinguished members of our Section. Thanks are due to Kathleen Burke of NY Presbyterian Hospital,

Margaret Davino of Kaufman, Borgeest & Ryan, and Julia Goings-Perrot of Tarshis Catania for organizing the program. The materials for our Annual Meeting are posted on our website at www.nysba.org/HLSAM2013Materials.

At the Annual Meeting, the Section elected its officers for the term June 2013–May 2014. Please join me in congratulating our incoming Section officers, and wishing them well:

Chair:	Kathleen M. Burke NY Presbyterian Hospital
Chair-Elect:	Margaret J. Davino Kaufman Borgeest & Ryan, LLP
Vice-Chair:	Kenneth R. Larywon Martin Clearwater & Bell, LLP
Secretary:	Raul A. Tabora, Jr. Bond Schoeneck & King
Treasurer:	Lawrence R. Faulkner ARC of Westchester

Committees

We are in the process of reorganizing certain of the committees and their missions. If you have any suggestions for improving the structure or function of an existing committee, or wish to suggest formation of a new committee, I encourage you to contact me. The Section's committees, their chairs and member rosters are listed at www.nysba.org/HealthLawCommittees. I also encourage all Section members to join a standing committee and to contribute by speaking at CLE programs, commenting on proposed legislation or regulations, or writing an article for the *Health Law Journal*.

I look forward to working with all of you in the coming year. It is certainly an exciting time to be a health care lawyer!

Ellen V. Weissman, Chair
Health Law Section

In the New York State Courts

By Leonard M. Rosenberg

Appellate Division Holds That Nurse, by Asserting a Claim Under Labor Law § 741, Waived Her Remaining Causes of Action Relating to Her Alleged Retaliatory Discharge

Minogue v. Good Samaritan Hosp., 100 A.D.3d 64, 952 N.Y.S.2d 52 (2d Dep't 2012). Plaintiff, a licensed practical nurse, alleged that the hospital terminated her employment in retaliation for complaining about the hospital's quality of patient care in violation of Labor Law § 741. The hospital moved to dismiss the action, arguing that the complaint failed to state a cause of action under Labor Law § 741(2)(a), and that by asserting a claim under Labor Law § 741, Plaintiff waived her remaining causes of action based on the alleged retaliatory discharge. Affirming the trial court, the Appellate Division, Second Department, denied that part of the hospital's motion seeking to dismiss Plaintiff's Labor Law § 741 claim and granted that part of the hospital's motion seeking to dismiss Plaintiff's remaining causes of action.

Labor Law § 741(2)(a) protects health care employees from retaliatory action for disclosing conduct that the employee reasonably believes constitutes improper quality of patient care, which the statute defines as "any practice, procedure, action or failure to act of an employer which violates any law, rule, regulation… [which] may present a substantial and specific damage to public health or safety or a significant threat to the health of a specific patient." The Court held that Plaintiff sufficiently pled a cause of action under Labor Law § 741(2)(a), by alleging that the hospital's practice of placing acutely ill and mechanically ventilated patients on non-critical floors without increasing the number of experienced nurses on those floors violated 10 N.Y.C.R.R. §§ 405.5 and 407.9. Those sections of the New York Hospital

Code address the provision of adequate nursing services. The Court also ruled that Plaintiff sufficiently alleged that the hospital terminated her in retaliation for disclosing such practices.

However, the Court held that by asserting a claim under Labor Law § 741, Plaintiff waived her remaining causes of action which included, among others, violations of the State Constitution and the New York Human Rights Law, and tortious interference with business relations, all of which related to the alleged retaliatory discharge. The Court explained that because Labor Law § 741 does not create its own private right of action, but instead contemplates enforcement though a Labor Law § 740 civil suit, the waiver provision applicable to Labor Law § 740 is equally applicable to § 741. Accordingly, the Court reaffirmed its earlier decision in *Pipia v. Nassau County*, 34 A.D.3d 664 (2d Dep't 2006) in which it held that the institution of a cause of action alleging a violation of Labor Law § 741 implicates the election of remedies provision under Labor Law § 740, and constitutes a waiver of other causes of action relating to the alleged unlawful discharge. In reaching its conclusion, the Court also found that although the waiver provisions of § 740 are in a separate subdivision from the enforcement provisions, every § 741 claim expressly relies on and incorporates § 740 for purposes of enforcement, and inasmuch as the whole purpose of the statutory waiver provision is to prevent duplicative recovery, "it makes little sense to prohibit duplicative recovery with respect to § 740 claims but not for § 741 claims."

In a Matter of First Impression, Second Circuit Holds That Government in False Claims Act Suit Is Entitled to Damages Equal to the Full Amount of Grant Payments It Made to Medical College Based on Defendants' Material Misrepresentations

U.S. ex rel. Feldman v. Van Gorp., 697 F.3d 78 (2d Cir. 2012). Plaintiff, a former research fellow, brought a *qui tam action* under the False Claims Act ("FCA") alleging that defendant medical college and one of its professors defrauded the government by providing false information in an application for research grant funds. After a jury trial, the district court awarded the government damages equal to the entire amount of grant payments it made for each year that defendants were found liable for submitting renewal applications containing misrepresentations. The Second Circuit affirmed, finding that where the government received nothing of tangible value from the defendant, the court may calculate damages as the full amount it paid based on the material misrepresentations.

In what is known as a "T32 program," the National Institutes of Health ("NIH") provides funding for pre-and post-doctoral training programs in biomedical, behavioral and clinical research. Institutions applying for T32 grants must undergo an intensive, two-tier review process, whereby the application is evaluated for its scientific or technical merit and relevance to the awarding institute's programs and priorities.

Defendants' T32 grant application was to establish a fellowship that "would train as many as six post-doctoral fellows at a time in child and adult clinical and research neuropsychology with a strong emphasis upon research training with HIV/AIDS." The application explained that the defendant professor would serve as

the program director, fourteen named faculty members would serve as "Key Personnel," the fellows would be required to take several core courses designed specifically for HIV Neurology in both years of their fellowship, the fellows' progress would be monitored and evaluated by a training committee, clinical resources were available at additional institutions, the majority of the work would be with persons with HIV infection, and the fellows would devote most of their time to research rather than clinical work.

Based on those representations, NIH approved funding for two fellows for one year with the possibility of additional funding for up to four years. In accordance with NIH's renewal guidelines, Defendants submitted renewal applications for each of these four years, all of which were approved. In the accompanying annual progress reports, Defendants represented that there were no material alterations to the program, and that the core structure and supporting faculty listed in the initial application remained the same.

Plaintiff, a former research fellow in Defendants' program, alleged that the actual fellowship deviated in several ways from that described in the grant application and that Defendants failed to inform NIH of these deviations. After leaving the program, Plaintiff wrote to NIH to complain that the fellows had limited access to HIV-positive patients and that the program focused on clinical work rather than research. Approximately one year later, Plaintiff submitted another letter to the NIH again complaining that the program deviated from the description outlined in the initial grant application. In response to Plaintiff's second letter, NIH asked the medical college to conduct an investigation into Plaintiff's complaint. The medical college complied and advised Plaintiff that the investigation uncovered no wrongdoing.

Thereafter, Plaintiff filed a *qui tam* complaint, alleging that Defendants made false claims to the United States in their initial grant application and in the four renewal applications.

At trial, Plaintiff presented evidence that (i) Key Personnel in the initial application did not in fact contribute in any substantive way to the program; (ii) fellows were unaware of research opportunities at medical centers outside the medical college; (iii) several core courses identified in the application were not regularly conducted and fellows were not aware such courses were required; (iv) fellows were never evaluated or supervised by training committees, and (v) much of the research the fellows performed had no relation to HIV or AIDS.

The jury found Defendants not liable for the statements made in the initial grant application and first renewal application, but found liability based on the statements made in the renewal applications for the third, fourth and fifth years of the grant. Based on this finding of liability, the district court awarded actual damages in treble the amount NIH paid for the last three renewal years of the grant.

Defendants filed a motion for judgment as a matter of law, or alternatively a new trial, arguing, among other things, that district court erred in determining, as a matter of law, that damages were equal to the entire grant amounts for the years in which liability was found. The district court denied the motion and Defendants appealed.

The circuit court explained that in most FCA cases, damages are measured using the "benefit of the bargain" test. Under this test, damages are calculated as the difference between the value the government received and the amount it paid. The Court held that in those cases applying the benefit of the bargain test, the government got what it bargained for, but did not get *all* that it bargained for, and the courts therefore treated the difference between what the government bargained for and what it actually received as the measure of damages. Here, the court reasoned, the government bargained for something "qualitatively but not quantifiably, different from what it received"—the government did not just get less than it bargained for, it in fact did not receive the neuropsychology program "with a strong emphasis upon research training with HIV/AIDS," *at all*.

The circuit court also rejected Defendants' argument that Plaintiff's theory of damages should not apply because the cases Plaintiff cites to support his theory all found the defendant liable for fraudulent inducement, whereas here, the jury found that Defendants' initial application contained no false statements. The circuit court held that "if the government made payment based on a false statement, then that is enough for liability in an FCA case, regardless of whether that false statement comes at the beginning of a contractual relationship or later." The circuit court further held that the district court properly determined the amount of damages as a matter of law, holding that where the amount of each payment is not in dispute, no further finding of fact is necessary to determine the amount of damages. Accordingly, the circuit court held that the district court properly measured damages as the full amount the government paid based on Defendants' materially false statements.

Court of Appeals Affirms That Physician's Sexual Relationship with Patient Can Constitute Medical Malpractice; Plaintiff Was Comparatively at Fault for Having an Affair with Her Doctor and Punitive Damages Were Not Justified Due to Lack of Malice

In *Dupree v. Giugliano*, 2012 WL 5948963 (Court of Appeals, Nov. 29, 2012), Plaintiff was receiving treatment for depression and anxiety from Defendant, a family practice physician. During the course of that treatment, the parties began to engage in a sexual affair, which ultimately led to the Plaintiff's divorce. The Plaintiff then sued Defendant for medical malpractice related to the affair.

The jury found that the Defendant's actions constituted malpractice, but that the Plaintiff was comparatively 25 percent at fault. The jury awarded plaintiff $154,000 for past mental distress, $50,000 for future mental distress, $134,000 for past lost income, and $166,000 in punitive damages.

The Defendant appealed the malpractice finding, asserting that the affair was unrelated to the treatment and could not support a malpractice claim. Plaintiff cross-appealed arguing that the jury should not have been charged on comparative fault. The Appellate Division, over a strong dissent, held that the Defendant's sexual relationship with the Plaintiff could constitute medical malpractice.

The Court of Appeals noted that the standard for medical malpractice is that the challenged conduct must be medical treatment or bear a substantial relationship to the physician's treatment of the patient. Given that in this case, the physician was treating Plaintiff's mental health problems, including medication and counseling, a jury could reasonably conclude that the sexual relationship was substantially related to, and interfered with, the treatment. However, the Court ruled that a finding of medical malpractice does not negate comparative fault. The Court of Appeals also held that charging the jury on punitive damages was improper, because there was no manifest evil or malicious conduct beyond any breach of professional duty. Accordingly, the $166,000 punitive damage award was vacated.

Under New York's Learned Intermediary Doctrine, Manufacturer of Prescription Drug or Vaccine Has Duty to Warn Physician, Not Patient, of Product's Risks

In *Ohuche v. Merck & Company, Inc.*, 2012 WL 4853038 (S.D.N.Y., Oct. 12, 2012), Plaintiff alleged that she suffered side effects after being injected with Zostavax, a shingles vaccine, by her physician. Plaintiff claimed that her injuries included headaches, fever, mumps, boils, eruptions on her face, and partial loss of eyesight. There was a dispute about the nature and extent of Plaintiff's claimed injuries, which were inconsistent with her medical records.

The FDA-approved labeling for Zostavax consisted of a product circular and a patient information pamphlet, which both listed potential adverse side effects. The Plaintiff's physician testified that she was aware of the adverse reactions associated with Zostavax, even though she had not reviewed the available medical literature, including the FDA-approved labeling, prior to vaccinating the Plaintiff.

In a failure to warn case against a drug manufacturer, the Plaintiff has the burden of proving that "the warning was inadequate and that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injury." That said, where a treating physician decides not to inform a patient of a side effect, it is an intervening cause "which shields the drug manufacturer from any possible liability under a failure to warn theory."

Under the learned intermediary doctrine, a manufacturer does not have a duty to warn the patient of the dangers of a product, but rather the duty is owed to a patient's physician, who acts as the "informed intermediary" between the manufacturer and patient, "evaluating the patient's needs, assessing the risks and benefits of the drugs, and prescribing and supervising their use."

In the instant matter, Merck fulfilled its obligations to disclose the risks and side effects of Zostavax. Accordingly, the Court granted summary judgment, holding that the Plaintiff's case against the manufacturer failed for lack of proximate cause. Plaintiff's claims, if any, were against her physician for malpractice.

The Office of the Medicaid Inspector General Has the Power to Conduct Its Own Audits of a Medical Facility's Patient Review Instruments

New York State Health Facilities Ass'n, Inc. ex rel. its member Residential Health Care Facilities v. Sheehan, 100 A.D.3d 1086, 953 N.Y.S.2d 712 (3d Dep't 2012). Petitioner, a trade association representing residential health care facilities that participate in Medicaid, commenced an Article 78 proceeding against Respondent Office of the Medicaid Inspector General ("OMIG"), seeking a writ of prohibition to prevent OMIG from conducting audits of patient review instruments ("PRIs"). PRIs detail the level of care required by each patient within a facility, and are used to determine the direct component of a facility's operating costs and reimbursement rates. The trial court dismissed the petition, and the Appellate Division, Third Department affirmed.

To ensure the accuracy of PRI information, Department of Health regulations provide for a three-stage audit process that is to be conducted by a contractor. Petitioner commenced this Article 78 proceeding after OMIG conducted its own audit of PRIs submitted to the Department of Health by certain members of Petitioner that had undergone a satisfactory audit by the contractor. In its audit review, OMIG did not use the three-stage process set forth in the regulations, and determined to recoup several million dollars per facility. Petitioner asserted that only the Department had the authority to audit PRIs.

The Court noted that prohibition is an extraordinary remedy, to be issued only when a body or officer acts or threatens to act without jurisdiction in a matter over which it has no power, or where it exceeds its authorized powers in a proceeding over which it has jurisdiction; prohibition does not lie as a means of seeking collateral review of an error

of law in the administration process, no matter how egregious the error. The Court ruled that OMIG did not act without jurisdiction or exceed its authorized power since the statute creating OMIG created it as an office within the Department of Health, to comply with Medicaid's requirement that a state program be administered by a "single state agency." The statute also expressly authorizes OMIG "to review and audit contracts, cost reports, claims, bills and all other expenditures of medical assistance program funds to determine compliance with applicable federal and state laws and regulations." Although PRIs are not fiscal, statistical or cost reports, PRIs significantly influence a facility's Medicaid reimbursement rate and thus fall within OMIG's audit power.

Finally, the Court ruled that Petitioner's arguments amount to claims that OMIG acted arbitrarily and capriciously in disregarding regulatory requirements, or that its interpretation of permissible audit methodology is affected by an error of law. Accordingly, such claims can only be raised in an Article 78 proceeding to review a final agency determination.

A Medical Provider May Owe a Duty to the General Public to Not Supply Prescriptions to Maintain an Addict or Habitual User of Controlled Substances

Malone v. County of Suffolk, No. 04112, 2012 WL 6629763 (Sup. Ct. Suffolk County, November 26, 2012). Plaintiffs commenced this action for recovery of damages against Defendants Abbott Laboratories ("Abbott"), Suffolk County, the Suffolk County Police Department and Richard Dormer, the former commissioner of the Suffolk County Police Department (collectively the "County Defendants"), and Stan Xuhui Li, M.D. for alleged conscious pain and suffering and wrongful death of decedent Jamie Taccetta. All three Defendants moved to dismiss the complaint. The trial court granted Abbott's and the County Defendants' motion to dismiss, but denied Dr. Li's motion.

On June 19, 2011, David Laffer shot and killed four people while robbing the Haven Drugs pharmacy in Medford, New York. Laffer was convicted on his plea of guilty to robbery and murder in the first degree. He is currently serving four consecutive life sentences. In their complaint, Plaintiffs alleged that the reason for the murders was that David Laffer was attempting to steal thousands of prescription narcotics because he was a drug abuser who regularly used prescription drugs, including hydrocodone, also known as Vicodin, in an unauthorized manner.

Plaintiffs sued Abbott, the manufacturer of Vicodin, for negligence claiming that: (i) Abbott owed a duty to the general public not to manufacture, sell, distribute, and/or advertise a highly addictive prescription narcotic that has a high potential for dependence; (ii) Abbott owed a duty to the general public to ensure that pharmacies and physicians would not prescribe or over-prescribe its products to drug addicts; and (iii) Abbott failed to safeguard the general public from the harmful, addictive effects of its product. Additionally, Plaintiffs also alleged that Abbott created a public nuisance by manufacturing and marketing prescription narcotics by failing to prevent drug addicts and criminals, such as David Laffer, from re-filling his stash of prescription narcotics.

In granting Abbott's motion to dismiss, the Court held that Plaintiffs failed to establish that Abbott owed a specific duty to Ms. Taccetta, and merely alleging a general duty to society was insufficient to sustain Plaintiffs' claim for negligence. In addition, the Court noted that Abbott had no duty to control the conduct of third persons so as to prevent them from harming others, even where as a practical matter Abbott could exercise such control. Finally, in dismissing Plaintiffs' public nuisance cause of action against Abbott, the Court held that a public nuisance claim cannot proceed against manufacturers of non-defective lawful products that are placed in the stream of commerce lawfully where harm is caused by the criminal activity of intervening third parties.

Plaintiffs also sued the County Defendants for negligence. In their complaint Plaintiffs alleged that in January 2011 the Suffolk County Police Department investigated a complaint by Palma Laffer, David Laffer's mother, that there had been unauthorized withdrawals of money from her bank account. While police detectives were at the Laffer home, David Laffer allegedly admitted to making the unauthorized withdrawals and also told the police that there were licensed firearms in the home registered to him and his mother. One of those firearms was allegedly used to commit the murders approximately five months later.

The Court rejected Plaintiffs' argument that the County Defendants had a duty to remove the firearms from the Laffer home, and granted the County Defendants' motion to dismiss. The Court reasoned that Plaintiffs were unable to establish the existence of a special relationship between Ms. Taccetta and the County Defendants sufficient to supply the requisite special duty of care.

Finally, Plaintiffs claimed that Dr. Li, David Laffer's physician, was reckless and negligent by: (i) prescribing approximately 2,500 narcotics pills to David Laffer between 2009 and 2010 when Dr. Li knew or should have known that David Laffer was a drug addict; and (ii) failing to prevent David Laffer from re-filling his supply of prescription narcotics.

In denying Dr. Li's motion to dismiss, the Court noted that, although generally there is no duty to control the conduct of third parties to prevent them from causing injury to others, such a duty may exist if there is a special relationship between the Defendant and the third party. Here, the Court ruled that a medical provider may owe a duty to protect the public from the actions of a drug addict, and may be found to have breached that

duty if he creates or maintains the addiction through his own egregious conduct.

Court Applies *Cy Pres* Doctrine to Charitable Dispositions to Hospital When Hospital Ceases Operations, Even Though Original Corporation Still Exists

In re Trustco Bank, 37 Misc. 3d 1045, 954 N.Y.S.2d 411 (Surrogate's Court, Schenectady County, 2012). Fiduciaries for three deceased donors petitioned the surrogate court to apply the doctrine of *cy pres* to the charitable dispositions made by their respective decedents to the St. Clare's Hospital of Schenectady, N.Y. Foundation, Inc. ("St. Clare's") because St. Clare's no longer operated as a hospital.

St. Clare's operated as a hospital, providing a wide range of in-patient and out-patient services. In June 2008, pursuant to an Asset Transfer Agreement entered into between St. Clare's and Ellis Hospital and Ellis Hospital Foundation, Inc. ("Ellis"), Ellis assumed some of St. Clare's assets and St. Clare's ceased operating as a hospital. However, St. Clare's Foundation, a not-for-profit corporation that assisted the hospital in expanding and developing its services to the community, still exists, although it no longer supports or operates the hospital. Ellis assumed sole responsibility for providing hospital and other health care services previously provided by St. Clare's, and became the sole remaining hospital in Schenectady County. Since June 2008, St. Clare's Hospital Foundation has not engaged in any fundraising activities, has not provided any charitable grants, and is not currently engaged in any charitable activities.

Because St. Clare's no longer operated a hospital, the fiduciaries asked the court to apply the doctrine of *cy pres* and change the charitable disposition to Ellis. For a Court to exercise its *cy pres* powers under EPTL § 8-1.1(c)(1), a three prong test must be met: 1) the gift or trust must be charitable in nature; 2) the language of the will or trust instrument, when read in light of all attendant circumstances, must indicate that the donor demonstrated a general, rather than specific, charitable intent; and 3) it must be determined to the court's satisfaction that the particular purpose for which the gift or trust was created has failed, or has become impossible or impracticable to achieve. Here, the first two prongs were not disputed. First, any gift for the promotion or advancement of health or medicine is charitable. Second, each donor had a general charitable intent because each executed instrument named several different charitable organizations as beneficiaries.

In considering the third prong, *i.e.,* changed circumstances that render the purpose of the gift impossible, the Court noted precedent in similar cases that "the bare legal existence of a charitable corporation to which a testamentary disposition is made does not ensure entitlement to receipt of the gift…cessation of its benevolent functions…[defeats] its claim…." Accordingly, the Court acknowledged a general rule that "…gifts to a hospital are intended to fund hospital activities, and when the designated hospital's functions have ceased, the [*cy pres*] doctrine requires that such gifts be redirected to an active, charitable hospital."

The Court then addressed whether the donors intended to benefit St. Clare's as a hospital, which no longer existed, or that they intended to benefit the corporation. To determine this issue the court applied the presumption that the purpose of a gift to a hospital is deemed to be for the objectives of the corporation and not the corporation itself. Therefore, it was St. Clare's burden to rebut the presumption, which it failed to meet. The court relied on the fact that none of the donors had any particular affiliation to St. Clare's as a corporation. In addition, all of the donors in their wills donated to a hospital or had donated to one in the past. Therefore, the court concluded that there is no doubt that each of the donors intended to benefit the operation of St. Clare's as a hospital, not the corporation itself.

Accordingly, the court held that Ellis was an appropriate alternate recipient of the gifts. Ellis is the only hospital in Schenectady County, thus redirecting the gifts to Ellis most effectively accomplished the general charitable purpose of the donors' wills.

Second Circuit Vacates Conviction of Pharmaceutical Representative for Promotion of Drug for "Off-Label" Use, as a Violation of First Amendment Right to Free Speech

United States v. Caronia, 2012 WL 5992141 (2d Cir., Dec. 3, 2012). Plaintiff Alfred Caronia, a pharmaceutical sales representative for Orphan Medical, Inc. ("Orphan"), appealed from his 2009 conviction for conspiracy to introduce misbranded drugs into interstate commerce in violation of the U.S. Food, Drug and Cosmetic Act (the "FDCA"). A jury in the Eastern District of New York convicted Plaintiff based on his "off-label" promotional statements to a physician about the drug Xyrem. Xyrem, a central nervous system depressant, was approved by the FDA only for treatment of certain categories of narcolepsy patients. Plaintiff informed a physician about Xyrem's use in treating other conditions including insomnia, fibromyalgia, and Parkinson's disease, and treating persons under age 16, for whose use the drug had not been approved. With one member of the three-judge panel dissenting, the Second Circuit held that Plaintiff was prosecuted for his speech and that a conviction for truthfully promoting the off-label use of an FDA-approved drug violated the First Amendment.

In vacating the conviction, the Second Circuit first analyzed the operative provisions of the FDCA and FDA regulations in determining if Plaintiff had been convicted for his speech or some other prohibited con-

duct. As the court noted, the FDCA and regulations do not expressly prohibit "off-label" marketing—the promotion or marketing of approved drugs for unapproved uses. Rather, the FDCA prohibits "misbranding," which occurs if a drug is sold when its labeling fails to bear adequate directions for its intended use. FDA regulations recognize that promotional statements by a pharmaceutical company or its representatives can serve as evidence of an intended use of a drug that has not been approved by the FDA and is not addressed on the drug's label.

Based on this statutory scheme, the government argued that it had not prosecuted Plaintiff for his speech, but merely had used Plaintiff's statements promoting the drug's off label applications as evidence of "misbranding," *i.e.*, of the true intended use of the drug, which was contrary to the label's directions. The Second Circuit rejected the government's argument. The court held that there had been no "misbranding" alleged separate and apart from the Plaintiff's promotional statements and, based on the government's own jury charges and arguments at trial, it had prosecuted Plaintiff for his commercial speech.

The court next turned to whether the restriction imposed on Plaintiff's speech was constitutionally permissible. The court relied in part on the reasoning of the United States Supreme Court in *Sorrell v. IMS Health, Inc.*, 131 S.Ct. 2653 (2011), a case involving speech restrictions on pharmaceutical marketing under a Vermont statute. First, the court determined that, as in *Sorrell*, a heightened level of judicial scrutiny applied to this case because the restrictions on speech were both content-based and speaker-based and, in addition, in this case the government had brought a criminal action against the speaker. The speech restriction was held to be content-based because it favored speech about approved uses of Xyrem while disfavoring speech about unapproved uses of the drug. The restriction was held to be speaker-based because it curtailed speech of pharmaceutical manufacturers and their representatives concerning off-label uses of drugs, while permitting other speakers, such as academics and physicians (who are permitted to prescribe FDA-approved drugs for any therapeutic use that is appropriate in their medical judgment) to speak on that subject.

Without determining whether the strictest level of judicial scrutiny might properly apply, the Second Circuit applied the four-factor test used to determine whether commercial speech subject to "intermediate" scrutiny is protected by the First Amendment. The court held that First Amendment protection was warranted because the speech concerned lawful activity (off-label use of drugs) and was not false or misleading, and that, although the government had a substantial interest in public health and safety, the speech restriction did not directly advance that government interest and was not narrowly drawn to further that interest. The court reasoned that the speech restriction did not directly advance the government's public health and safety interests insofar as it was selectively limiting the free flow of truthful, potentially relevant treatment information to doctors about a drug, while still permitting doctors to prescribe the drug for such unapproved uses. The court reasoned that the complete ban of off-label promotional speech by pharmaceutical company representatives was not narrowly tailored because other regulatory alternatives exist which would be less restrictive on speech, such as better disclosure and warning requirements related to off-label uses or even direct regulation of off-label uses rather than speech.

The dissenting judge disagreed with both of the majority opinion's holdings. First, it endorsed the government's view that the government did not prosecute Plaintiff for speech but, instead, relied on his speech as evidence of the drug's off-label intended uses and, thus, misbranding. To illustrate its holding, the dissent suggested that Plaintiff could have freely spoken about off-label uses of Xyrem if he was not making such speech in furtherance of a conspiracy to sell a misbranded drug. Next, the dissent opined that even if the conviction was aimed at speech, it did not violate the First Amendment under the four-factor test applied by the majority. Specifically, the dissent found that, in light of the entirety of the FDA's pre-market drug approval process, a restriction on manufacturers' and their agents' communications to promote unapproved uses of a drug did directly advance public health and safety interests and was narrowly tailored.

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 Legislature

By James W. Lytle

In recent years, a good deal of the legislation that has a profound impact on the health care system in New York State is proposed, debated and passed as part of the State Budget. Governors have learned that, as Samuel Johnson reportedly observed about impending hangings, nothing so concentrates the legislative mind as the need to pass a State Budget.

The proposed Executive Budget for 2013-14 is no exception. A host of legislative initiatives were advanced by Governor Andrew Cuomo in the legislation that accompanied the State Budget, including a series of proposals that would reform the State's health planning statutes. Among other elements, the legislation would continue to expand the role that publicly traded entities can play in the New York State health care system.

The legislation was presaged by a December 6, 2012 report of the Public Health and Health Planning Council ("PHHPC"), which, after a year-long study, proposed 22 recommendations to develop a framework for regional health planning and a redesigned Certificate of Need ("CON") program for New York State. The recommendations of the PHHPC can be found at http://tinyurl.com/a7xrghg. A number of the recommendations of the report have been incorporated within the budget legislation advanced by the Governor in his Executive Budget presentation, including the following:

Streamline CON review for certain projects: The proposal would permit the approval of a hospital's or clinic's proposal to construct a primary care services facility without regard to public need and would allow hospitals and clinics to undertake construction projects of whatever cost without consideration of public need, as long as they do not change capacity, broaden services provided, involve major medical equipment, or involve the replacement or changing the geographic location of the facility. At the same time, the bill would extend CON review to the transfer of any "direct or indirect" ten percent interest in a licensed facility to CON review.

Modify character and competence review in CON review process: The Article VII bill would extend existing character and competence review in CON applications to "members" and "principal members," would limit "look-back" for prior issues relating to the operation of other licensed facilities to seven (rather than ten) years, and would allow the proposed incorporators, directors, sponsors, stockholders, members or operators to demonstrate that any violations that might have occurred should not be attributed to them due to the "timing, extent or manner of the affiliation."

Allow for the appointment of temporary operators: The proposal would amend the Public Health Law to allow for the appointment of temporary operators for hospitals, diagnostic and treatment centers, and adult care facilities under certain circumstances. Parallel provisions would amend the Mental Hygiene Law to allow for the appointment of temporary operators of chemical dependence treatment programs certified by the Office of Alcoholism and Substance Abuse Services (OASAS). A temporary operator may be appointed where the facility seeks "extraordinary financial assistance," which involves the expenditure of state funds to address serious financial instability, such as default on loans or failing to meet other obligations, or where the commissioner finds that conditions within the facility endanger the life, health or safety of its residents or patients.

The provisions detail the obligations of the temporary operator to prepare and execute a work plan to address the operational or financial issues at the facility, provide for a reasonable fee to the temporary operator and authorize an initial 180-day term for the appointment. Two additional ninety day terms may be authorized by the commissioner. The established operator is given notice, the opportunity to meet with the Department and an opportunity for an administrative hearing to contest the determination, all of which would occur prior to the appointment of the temporary operator unless the Commissioner has determined that public health and safety is in imminent danger.

Authorize publicly traded entities to operate limited service clinics: Proposal would permit "limited service clinics" to be established within retail businesses, such as pharmacies or in shopping malls, by entities that are not natural persons and whose principal stockholders/members satisfy certain requirements relating to their experience and expertise and abide by requirements relating to the transfer of ownership of the entity. The Commissioner of Health will promulgate regulations on operational and physical plant requirements, which will limit the diagnoses and services rendered, will prohibit services to children under two, will address advertising, signage, referral, continuity of care, record keeping and informed consent requirements, among other things.

Establish demonstration authority to permit capital investment in health care facilities: A pilot program to "assist in restructuring health care delivery

systems" will allow for the establishment of two business corporations, one of which will operate a hospital or hospitals in Brooklyn (Kings County) and one shall operate a facility elsewhere in New York—specified as in upstate New York in certain materials from the Administration. The business corporation shall affiliate (with the extent of the affiliation to be determined by the Commissioner) with at least one academic medical institution, approved by the Commissioner, and the entity will be eligible to participate in Dormitory Authority, Local Development Corporation or other economic development corporation debt financing.

The business corporations would be relieved of various requirements that otherwise apply under the Public Health Law, relating to stockholders, disposition of voting rights and other provisions, provided that PHHPC may impose requirements relating to the disclosure of shareholders. The corporations could operate only the specifically named hospital, as well as affiliated home care agencies or hospices. The legislation sets forth various factors that would have to be considered by the board of directors of the business corporations as it discharges its duties, including the impact of its actions on the corporation itself, its shareholders, the employees and workforce of the business, the interests of patients of the hospital, the community and societal considerations, local and global environmental issues and the short and longer-term interests of the corporation.

The pilot would be the subject of a written evaluation by the Commissioner within two years after its establishment on the impact of the pilot on enhancing access to capital investment and its impact on quality of care.

Jim Lytle is the managing partner of the Albany office of Manatt, Phelps & Phillips, LLP.

In the New York State Agencies

By Francis J. Serbaroli

Limitation of New Enrollment to the Healthy NY High Deductible Plan Pursuant to Section 4326(g) of the Insurance Law

Notice of Emergency Rulemaking. The Department of Financial Services added section 362-2.9 (Regulation 171) to Title 11 NYCRR to mitigate large premium increases for current enrollees in Healthy NY by limiting new enrollees to the high deductible plan. Filing date: August 31, 2012. Effective date: August 31, 2012. *See* N.Y. Register September 19, 2012.

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

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 16 of Title 10 NYCRR to update quality assurance requirements for medical use of radioactive materials and radiation therapy equipment. *See* N.Y. Register October 3, 2012.

Authority to Collect Pharmacy Acquisition Cost

Notice of Proposed Rulemaking. The Department of Health proposed amending section 505.3 of Title 18 NYCRR to establish a requirement that each enrolled pharmacy report actual acquisition cost of a prescription drug to the Department. *See* N.Y. Register October 3, 2012.

Municipal Public Health Services Plan—Radioactive Material and Radiation Equipment

Notice of Emergency Rulemaking. The Department of Health amended Part 40 of Title 10 NYCRR to establish funding for certified counties to inspect radiation equipment and the NYCDOHMH to conduct licensing and inspections. Filing date: September 21, 2012. Effective date: September 21, 2012. *See* N.Y. Register October 10, 2012.

Audits of Institutional Cost Reports (ICR)

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 86-1 of Title 10 NYCRR to impose a fee schedule on general hospitals related to the filing of ICRs sufficient to cover the costs of auditing the ICRs. *See* N.Y. Register October 10, 2012.

Rates of Reimbursement—Hospitals Licensed by the Office of Mental Health

Notice of Adoption. The Office of Mental Health amended Part 577 of Title 14 NYCRR to amend the audit protocol for hospitals licensed by OMH pursuant to article 31 of the Mental Hygiene Law. Filing date: October 2, 2012. Effective date: October 17, 2012. *See* N.Y. Register October 17, 2012.

General Facility Requirements

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Part 814, and added new Part 814 to Title 14 NYCRR to update to reflect standards that are current as well as new provisions required by changes in other regulations. Filing date: October 3, 2012. Effective date: October 24, 2012. *See* N.Y. Register October 24, 2012.

Medicaid Eligibility

Notice of Proposed Rulemaking. The Department of Health proposed amending section 360-2.4 of Title 18 NYCRR to include time frames for issuance of Medicaid eligibility determination. *See* N.Y. Register October 24, 2012.

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

Notice of Proposed Rulemaking. The Department of Health proposed amending Parts 763 and 766 of Title 10 NYCRR to expand access to palliative care and eliminate physician from the LHCSA quality improvement committee. *See* N.Y. Register October 24, 2012.

Financial Reporting for Providers of OPWDD Services

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending Subpart 635-4 and sections 679.6, 686.13 and 690.7 of Title 14 NYCRR to expand the applicability of reporting requirements and to revise the sanctions for failure to report. *See* N.Y. Register October 24, 2012.

Limits on Administrative Expenses and Executive Compensation

Notice of Revised Rulemaking. 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 costs. *See* N.Y. Register October 31, 2012.

Limits on Executive Compensation and Administrative Expenses in Agency Procurements

Notice of Revised Rulemaking. The Department of Health added 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. *See* N.Y. Register October 31, 2012.

Rights of Patient

Notice of Adoption. The Office of Mental Health amended Part 527 of Title 14 NYCRR to extend rights in Part 527 to inmates receiving services at DOCCS regional medical units/ residential crisis treatment programs. Filing date: October 15, 2012. Effective date: October 31, 2012. *See* N.Y. Register October 31, 2012.

Medical Assistance Payments for Comprehensive Psychiatric Emergency Programs (CPEP)

Notice of Adoption. The Office of Mental Health amended Part 591 of Title 14 NYCRR to increase Medicaid fees paid to CPEPs effective July 1, 2012. Filing date: October 15, 2012. Effective date: October 31, 2012. *See* N.Y. Register October 31, 2012.

Limits on Administrative Expenses and Executive Compensation

Notice of Revised Rulemaking. The Office of Mental Health amended Part 513 of Title 14 NYCRR to implement Executive Order No. 38 to limit administrative expenses and executive compensation of providers of services. *See* N.Y. Register October 31, 2012.

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: October 26, 2012. Effective date: October 26, 2012. *See* N.Y. Register November 14, 2012.

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: October 26, 2012. Effective date: October 26, 2012. *See* N.Y. Register November 14, 2012.

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: October 29, 2012. Effective date: October 29, 2012. *See* N.Y. Register November 14, 2012.

Medicaid Managed Care Programs

Notice of Expiration. A proposed regulation filed on October 26, 2011 related to Medicaid Managed Care Programs has expired and cannot be reconsidered unless a new notice of the proposed rule is published in the New York State Register. *See* N.Y. Register November 14, 2012.

Smoking Policy Inside and on Grounds of OPWDD-Operated and Certified Settings

Notice of Emergency/Proposed Rulemaking. The Office for People with Developmental Disabilities added sections 633.23, 635-7.3(c)(8) and 635-7.4(b)(4) to Title 14 NYCRR to prohibit smoking at OPWDD-operated and certified settings and to delineate the exceptions to the prohibition. Filing date: October 30, 2012. Effective date: November 1, 2012. *See* N.Y. Register November 14, 2012.

Provider Requirements for Insurance Reimbursement of Applied Behavior Analysis

Notice of Emergency Rulemaking. The Department of Financial Services added Part 440 to Title 11 NYCRR to establish standards of professionalism, supervision and relevant experience for providers of Applied Behavior Analysis. Filing date: October 31, 2012. Effective date: October 31, 2012. *See* N.Y. Register November 21, 2012.

Medical Treatment Guidelines

Notice of Proposed Rulemaking. The Workers' Compensation Board proposed amending Part 324 of Title 12 NYCRR to require use of the Medical Treatment Guidelines for covered injuries and create processes for their use. *See* N.Y. Register November 21, 2012.

The Healthy New York Program

Notice of Adoption. The Department of Financial Services amended Part 362 (Regulation 171) of Title 11 NYCRR to mitigate large premium increases for current enrollees in Healthy NY by limiting new enrollees to the high deductible plan. Filing date: November 13, 2012. Effective date: November 28, 2012. *See* N.Y. Register November 28, 2012.

Early Intervention Program

Notice of Adoption. The Department of Health amended Subpart 69-4 of Title 10 NYCRR to eliminate conflicts of interest by evaluators, service coordinators, and service providers in the Early Intervention Program. Filing date: November 13, 2012. Effective date: January 1, 2013. *See* N.Y. Register November 28, 2012.

Prior Approval Review for Quality and Appropriateness

Notice of Adoption. The Office of Mental Health amended Part 551 of Title 14 NYCRR to repeal an outdated reference and establish consistency with Federal requirements regarding accessibility standard. Filing date: November 8, 2012. Effective date: November 28, 2012. *See* N.Y. Register November 28, 2012.

Filing Written Reports of Independent Medical Examinations (IMEs)

Notice of Emergency Rulemaking. The Workers' Compensation Board amended section 300.2(d)(11) of Title 12 NYCRR to amend the time for filing written reports of IMEs with

the Board and furnished to all others. Filing date: November 9, 2012. Effective date: November 9, 2012. *See* N.Y. Register November 28, 2012.

Pharmacy and Durable Medical Equipment Fee Schedules and Requirements for Designated Pharmacies

Notice of Adoption. The Workers' Compensation Board added Parts 440 and 442 to Title 12 NYCRR to adopt pharmacy and durable medical equipment fee schedules, payment process and requirements for use of designated pharmacies. Filing date: November 9, 2012. Effective date: November 28, 2012. *See* N.Y. Register November 28, 2012.

Operation of Hospitals for Persons with Mental Illness

Notice of Adoption. The Office of Mental Health amended section 582.8 of Title 14 NYCRR to add provisions regarding fire safety and smoking within buildings. Filing date: November 20, 2012. Effective date: December 5, 2012. *See* N.Y. Register December 5, 2012.

Personalized Recovery Oriented Services (PROS)

Notice of Adoption. The Office of Mental Health amended Part 512 of Title 14 NYCRR to adjust fees paid to providers as well as update and clarify existing PROS regulation. Filing date: November 19, 2012. Effective date: December 5, 2012. *See* N.Y. Register December 5, 2012.

Unauthorized Providers of Health Services

Notice of Emergency Rulemaking. The Department of Financial Services added Subpart 65-5 (Regulation 68-E) to Title 11 NYCRR to establish standards and procedures for the investigation and suspension or removal of a health service provider's authorization. Filing date: November 28, 2012. Effective date: November 28, 2012. *See* N.Y. Register December 19, 2012.

State Aid: Radioactive Materials and Radiation Producing Equipment; Individual Water and Sewage Systems; Calculation

Notice of Adoption. The Department of Health amended Part 40 of Title 10 NYCRR to establish funding for safety programs related to radioactive materials and radiation-producing equipment. Technical amendments. Filing date: December 3, 2012. Effective date: December 19, 2012. *See* N.Y. Register December 19, 2012.

Partial Hospitalization Medicaid Fee Increase

Notice of Adoption. The Office of Mental Health amended Parts 588 and 592 of Title 14 NYCRR to increase the Medicaid fees paid to all Partial Hospitalization Programs licensed by the Office of Mental Health. Filing date: November 28, 2012. Effective date: December 19, 2012. *See* N.Y. Register December 19, 2012.

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: December 6, 2012. Effective date: December 6, 2012. *See* N.Y. Register December 26, 2012.

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: December 7, 2012. Effective date: December 7, 2012. *See* N.Y. Register December 26, 2012.

Person-Centered Behavioral Intervention

Notice of Adoption. The Office for People With Developmental Disabilities amended Parts 81, 624, 633 and 681 of Title 14 NYCRR to establish requirements for interventions used in the OPWDD system to modify or control challenging behavior. Filing date: December 11, 2012. Effective date: April 1, 2013. *See* N.Y. Register December 26, 2012.

Authority to Collect Pharmacy Acquisition Cost

Notice of Emergency Rulemaking. The Department of Health amended section 505.3 of Title 18 NYCRR to establish a requirement that each enrolled pharmacy report actual acquisition cost of a prescription drug to the Department. Filing date: December 18, 2012. Effective date: December 18, 2012. *See* N.Y. Register January 2, 2013.

Pre-Payment Audits of Nursing Home Case Mix Data

Notice of Emergency Rulemaking. The Department of Health amended section 86-2.40(m) of Title 10 NYCRR to promote the accuracy and integrity of case mix data used for rate-setting purposes. Filing date: December 17, 2012. Effective date: December 17, 2012. *See* N.Y. Register January 2, 2013.

Medicaid Managed Care Programs

Notice of Emergency Rulemaking. The Department of Health repealed 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: December 18, 2012. Effective date: December 18, 2012. *See* N.Y. Register January 2, 2013.

Nursing Home Sprinklers

Notice of Adoption. The Department of Health added section 86-2.41 to Title 10 NYCRR to assist eligible nursing homes with accessing credit markets to finance the costs of installing automatic sprinkler systems. Filing date: December 18, 2012. Effective date: January 2, 2012. *See* N.Y. Register January 2, 2013.

Synthetic Phenethylamines and Synthetic Cannabinoids (SP & SC) Prohibited

Notice of Adoption. The Department of Health added Part 9 to Title 10 NYCRR to prohibit possession, manufacture, distribution, sale or offer of sale of some substances and products containing SP & SC. Filing date: December 18, 2012. Effective date: January 2, 2013. *See* N.Y. Register January 2, 2013.

Repeal of Outdated Forms and Conforming Amendments

Notice of Proposed Rulemaking. The Office of Mental Health proposed repealing Appendix 1, and amendment of section 15.1(c) of Title 14 NYCRR to eliminate antiquated forms. See N.Y. Register January 2, 2013.

Repeal of Outdated Forms and Conforming Amendments

Notice of Proposed Rulemaking. The Office for People with Developmental Disabilities proposed amending Parts 15 and 17, and repeal of Appendix 1 of Title 14 NYCRR to eliminate antiquated forms. *See* N.Y. Register January 2, 2013.

Orthodontic Screening

Notice of Emergency Rulemaking. The Department of Health repealed section 85.45 from Title 10 NYCRR, and amended section 506.4 of Title 18 NYCRR to provide Orthodontic Screening Provider Qualifications and Recipient Eligibility Criteria. Filing date: December 21, 2012. Effective date: December 21, 2012. *See* N.Y. Register January 9, 2013.

Audits of Institutional Cost Reports (ICR)

Notice of Emergency Rulemaking. The Department of Health amended Subpart 86-1 of Title 10 NYCRR to impose a fee schedule on general hospitals related to the filing of ICRs sufficient to cover the costs of auditing the ICRs. Filing date: December 21, 2012. Effective date: December 21, 2012. *See* N.Y. Register January 9, 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: December 21, 2012. Effective date: December 21, 2012. *See* N.Y. Register January 9, 2013.

Clinic Treatment Programs

Notice of Adoption. The Office of Mental Health amended Part 599 of Title 14 NYCRR to make a minor technical change and correct small inaccuracies in existing regulation. Filing date: December 21, 2012. Effective date: January 9, 2013. *See* N.Y. Register January 9, 2013.

Adult Homes

Notice of Adoption. The Department of Health amended Parts 486 and 487 of Title 18 NYCRR to limit the number of residents with serious mental illness in large adult homes. Filing date: December 31, 2012. Effective date: January 16, 2013. *See* N.Y. Register January 16, 2013.

Language Assistance and Official New York State Prescription Form Requirements

Notice of Proposed Rulemaking. The Department of Health proposed amending section 910.2 of Title 10 NYCRR to change the Official New York State Prescription Form to indicate whether an individual is limited in English proficiency. *See* N.Y. Register January 16, 2013.

Electronic Prescribing, Dispensing and Recordkeeping of Controlled Substances

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 80 of Title 10 NYCRR to allow practitioners to issue prescriptions electronically for controlled substances. *See* N.Y. Register January 16, 2013.

Operation of Psychiatric Inpatient Units of General Hospitals and Operation of Hospitals for Persons with Mental Illness

Notice of Adoption. The Office of Mental Health amended Parts 580 and 582 of Title 14 NYCRR to establish provisions prohibiting the discharge of persons with serious mental illness to transitional adult homes. Filing date: December 31, 2012. Effective date: January 16, 2013. *See* N.Y. Register January 16, 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 and FDA Business Group, in compiling this summary is gratefully acknowledged.

New York State Fraud, Abuse and Compliance Developments

Edited by Melissa M. Zambri

NYS Department of Health OMIG Audit Decisions

Compiled by Eugene M. Laks

No decisions since the last *Journal* edition.

New York State Attorney General Press Releases

Compiled by Charles Z. Feldman

COO of Drug Rehabilitation Center Arrested for Embezzlement—December 20, 2012—The COO of a non-profit that provided services to people with drug and alcohol addiction was arrested for orchestrating an embezzlement scheme that allegedly defrauded the State of $200,000. The COO signed timesheets and mileage logs that purportedly confirmed the activity of fictitious employees. He then wrote checks to the fictitious persons based on these records and cashed these checks personally. He faces 5 to 15 years imprisonment.

Amgen Settles Charges That it Marketed Drugs for Unapproved Uses, Including Treating Kidney Disease and Cancer—December 19, 2012—The results of multi-state investigations into big pharmaceutical marketing practices continue to bear fruit as the Attorney General announced a settlement with Amgen for marketing off-label drugs and offering kickbacks to health care professionals. Amgen agreed to pay $762 million, including $150 million in fines and forfeiture for criminal conduct, the bulk of these proceeds relating to the company's practice of marketing the drug Aranesp for the unapproved uses of treating cancer and kidney diseases. New York's share was $12.5 million.

Five Pharmacists Plead Guilty in Scheme to Defraud Medicaid—December 18, 2012—Five New York City based pharmacists pled guilty to several counts of Grand Larceny for submitting bills to the Medicaid program for drugs that were never dispensed. MFCU's investigation revealed that the pharmacies had not purchased enough inventory to fill all of the prescriptions for which they dispensed and charged Medicaid. In total, the defendants will pay almost $10 million in restitution to the State.

Staten Island Man Convicted After Admitting Involvement in Scheme to Obtain Oxycodone and Fentanyl Through the Filing of Fraudulent Serious Injury Claims and Then Selling the Drugs for a Profit—December 12, 2012, October 10, 2012—Michael Mancusi admitted that he used fraudulent claims of serious injury to obtain Oxycodone and Fentanyl through Medicaid, SSDI and Medicare. He admitted that he engaged in doctor shopping to find a provider who would prescribe him controlled substances.

CNA Arrested for Stealing Jewelry from Nursing Home Residents—December 5, 2012—A Long Island certified nurse's aide confessed to stealing jewelry from residents at a Long Island nursing home and then selling the jewelry at a nearby pawn shop. When she was arrested, she was in possession of Heroin, Xanax and Suboxone. She faces 1-1/3 to 4 years in prison.

Westchester Doctor Charged with Selling 15,000 Oxycodone Pills to a Drug Dealer—December 5, 2012—A Westchester Anesthesiologist conspired with a drug dealer to obtain 15,000 Oxycodone pills for resale on the street. The doctor issued many prescriptions to his co-conspirator, and also issued prescriptions for Oxycodone to at least three other patients recruited by his co-conspirator. The doctor faces up to 5½ years in prison.

Computer Error Causes Excellus to Deny Claims for a Failure to Satisfy Deductible When the Deductible Was Already Satisfied—November 28, 2012—Consumer complaints triggered a Health Care Bureau investigation into Excellus BlueCross BlueShield's high deductible plans. The investigation revealed that Excellus denied claims for failure to satisfy a deductible when that deductible had actually been satisfied. Excellus reported that these errors—nearly 12,000—were the result of technological errors and that Excellus made payments in excess of $3 million to remedy these mistakes.

Nursing Agency Facing Criminal Charges for Violation of Regulations That Limit Nurse Hours to No More Than 16 Hours in Any 24-Hour Period—November 14, 2012—The Manhattan-based Foster Nurse Agency routinely scheduled nurses to work more than 16 hours in a 24-hour period, in contravention of Medicaid regulations. To conceal this from Medicaid, Foster falsified claim forms by substituting the names and license numbers of other nurses in order to make it appear that no nurse worked more than 16 hours. The investigation revealed that some nurses worked 48 hours straight. The Foster Nurse Agency is alleged to have fraudulently billed Medicaid for more than 13,000 nurse hours.

Boehringer-Ingelheim Pharmaceuticals Agrees to Multistate Settlement for Marketing Drugs for Unapproved Uses and Offering Kickbacks to Medical Professionals—October 25, 2012—Boehringer-Ingelheim Pharmaceuticals settled claims that it marketed the drugs Aggrenox, Atrovent, Combivent and Micardis for unapproved purposes and that it violated the Federal Anti-Kickback statute by paying health care professionals to participate in advisory boards, speakers' training programs, speaker programs and consultant programs. The amount of the nationwide settlement was $95 million, with New York netting $3.1 million.

Cover-Up of Improper Care Administered by Nurse's Aides Leads to Criminal Charges for Two Westchester County CNAs—October 24, 2012—A patient at the Tarrytown Hall Care Center Nursing Home who was dependant on nursing home staff to move her from her bed to a wheelchair fell from a mechanical lift, causing various fractures that led to her death a few hours later. The nurses assigned to the patient had extensive training using the lift, which included instruction that two persons must operate the lift at all times. Only one nurse's assistant was operating the lift when the patient fell. Instead of seeking immediate help, the nurse's aide sought out another aide to say that she assisted with the operation of the lift. Only after the other aide agreed to this scheme did they seek additional help for the patient. The nurse who orchestrated the cover-up is charged with Endangering the Welfare of a Vulnerable Elderly Person, and the other CNA is charged with Falsifying Business Records.

Brooklyn Pharmacist Settles Charges That He Sold Black Market Medications for $1.2 Million—October 16, 2012—A Brooklyn pharmacist obtained prescription drugs from the black market and then dispensed the drugs at the two pharmacies that he owned. New York State requires pharmacies to purchase medication only from authorized wholesalers to protect the quality of the medications dispensed at New York's pharmacies. The pharmacist surrendered his pharmacist's license, withdrew from the Medicaid Program and agreed to pay more than $1.2 million to resolve the claims.

Walgreens Cannot Charge Patients for Flu Shots After Advertising "No Out of Pocket Costs" for Flu Shots—October 15, 2012—Walgreens advertised that NYS Empire Plan patients could receive flu shots at the pharmacy "for no out of pocket costs." Over three thousand Empire Plan patients took advantage of this deal. Thereafter, Walgreens charged the patients $30 for the cost of the vaccination when the NYS Empire Plan denied the claims because flu shots are covered only when they are administered in a physician's office. Walgreens paid restitution to the patients and paid costs to the State in the amount of $15,000.

Owner of Home Health Aid Provider Ordered to Pay $300,000 in Back Wages—October 4, 2012—Christopher Luis stopped paying about eighty employees in June, 2011 but his employees, including nurse aides, a nurse and office staff, continued to work for him, relying on his promises through emails, texts, conference calls and even You-Tube videos that he would pay all employee wages owed plus bonuses and benefits for employees who continued to work without pay. Luis paid $300,000 in restitution and was sentenced to 100 hours of community service.

Voluntary Disclosure by Kaleida Health Results in Payment of $1.6 Million Settlement with MFCU for Overbilling Medicaid Program for Dental Services—September 28, 2012—After voluntarily disclosing the results of an internal audit revealing that it had received excess Medicaid payments for dental services performed at the Buffalo Women's & Children's Hospital Dental Clinic, Kaleida Health entered into a settlement with MFCU for $1.6 million. Kaleida's audit showed that it violated Medicaid regulations by billing Medicaid for more than one teeth cleaning in a six month period and by failing to batch multiple services (cleanings, x-rays and exams) into one visit.

Queens Man Convicted of Practicing Plastic Surgery Without a License –September 7, 2012—After recruiting patients from a Queens spa, a Queens man performed liposuction and other invasive procedures on women without anesthesia, resulting in permanent disfiguration of the victims. The man was not licensed to practice medicine and pled guilty to one count of Unlicensed Practice of a Profession.

Hospital That Billed Medicaid for Treatment in Drug and Alcohol Treatment Programs Not Licensed by OASAS Settles Whistleblower Action for $13.4 Million—September 5, 2012—After charging NY Downtown Hospital with violations of state and federal anti-kickback laws for marketing and providing inpatient detoxification services without a license to run such programs, MFCU entered into a settlement where the Hospital agreed to pay $13.4 million in restitution. The allegations included that the hospital paid an out-of-state vendor $38,500 per month to refer Medicaid patients to its unlicensed inpatient detoxification clinic.

Johnson & Johnson, Janssen Agree to Pay $181 Million to Resolve Multistate Investigations Into Their Marketing Practices—August 30, 2012—Janssen Pharmaceuticals and its parent company Johnson & Johnson agreed to settle a multi-state investigation for $181 million. The investigation revealed that the companies marketed Risperdal and Invega for unapproved purposes and made false representations about the safety of these drugs.

New York State Office of the Medicaid Inspector General Update

Compiled by the Editor

OMIG Webinar #17, "The OMIG Exclusion and Reinstatement Process"—December 19, 2012—available on OMIG's website at http://www.omig.ny.gov/data/content/view/204/294/.

Brooklyn Doctor Sentenced to 30 Months in Prison—December 10, 2012—OMIG investigators assisted with investigation—a Brooklyn-based, board-certified colorectal surgeon who owned and operated a New York medical clinic was sentenced to 30 months in prison for his role in a fraud scheme that billed Medicare and more than ten private insurance companies for surgeries and complex medical procedures that never took place.

OMIG's New Compliance Online Certification Forms for 2012-2013 Became Available—November 30, 2012—http://www.omig.ny.gov/data/data/content/view/159/303/.

OMIG Webinar #16, "Certification for December 2012: What Every Provider Needs to Know About Changes to the OMIG Certification Process"—November 15, 2012—available on OMIG's website at http://www.omig.ny.gov/data/content/view/204/294/.

OMIG involved in indictment of Brooklyn woman—November 14, 2012—the woman lived in luxury waterfront apartments and fraudulently collected $29,000 in Medicaid payments since 2004.

OMIG Webinar #15, "OMIG's New Compliance Program Review Assessment Form and Compliance Program Review Process"—November 7, 2012—available on OMIG's website at http://www.omig.ny.gov/data/content/view/204/294/.

OMIG participates in major $30 million Medicare and Medicaid fraud case—August 30, 2012—http://www.omig.ny.gov/data/images/stories/press_releases/press_release_tai_complaint.pdf.

Ms. Zambri is a partner in the Albany Office of Hiscock & Barclay, LLP and the Chair of the Firm's Health Care and Human Services Practice Area, focusing her practice on enterprise development and regulatory guidance for the health care industry. She is also an Adjunct Professor of Management at the Graduate College of Union University, teaching Legal Aspects of Health Care.

Mr. Laks is Of Counsel to Hiscock & Barclay, LLP in its Albany Office, focusing his practice on health care reimbursement, health care networks and affiliations, managed care law, and federal and state statutory and regulatory compliance.

Mr. Feldman is an associate in the Albany Office of Hiscock & Barclay, LLP, practicing in the areas of healthcare compliance, health information technology and civil litigation, including professional malpractice and personal and premises liability.

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Nicholas A. Battaglia, Esq., is an associate at Conway & Kirby, LLP, in Latham, New York, where he does civil litigation and personal injury matters. Mr. Battaglia is admitted in the States of New York and New Jersey, and also the U.S. District Court of the District of New Jersey. Further, he is the founder and managing member of NAB Legal Marketing, LLC, a legal content writing business.

For Your Information

By Claudia O. Torrey

As this author sat down to put commentary thoughts to paper regarding the recent drug compounding public health tragedies, state health and pharmacy board officials from all fifty States were meeting on the same issue with Food & Drug Administration ("FDA") Commissioner Dr. Margaret Hamburg. For those readers who do not know, "yours truly" is a Non-Resident Member (Charter Member of the Health Law Section) of the New York State Bar Association who happens to hail from the State of Tennessee. As of December 18, 2012, Tennessee had the dubious honor of being the State with the highest death toll from the Fall 2012 fungal meningitis outbreak due to injections of preservative-free methylprednisolone acetate;[1] the drug was made by the now "defunct" New England Compounding Center of Massachusetts ("NECC")—a large compounding "pharmacy."

At this writing, the nationwide public health compounding crisis spans nineteen States, and has killed thirty-nine people. According to the United States Centers for Disease Control & Protection, 14,000 people have potentially been exposed to the tainted drugs. This data begs the question---What is drug compounding? Pharmacy compounding is an age-old practice wherein pharmacists combine, mix, or alter ingredients to create unique medications that meet specific needs of individual patients.[2] However, consumers need to be aware that compounded drugs are not FDA-approved; unlike commercial drug manufacturers, pharmacies are not required to report adverse events associated with compounded drugs.[3] Compounding falls into the gray area between state and federal oversight[4]—essentially a "black hole." Traditional compounding pharmacies are not registered as drug manufacturers with the FDA. Thus, the FDA does not approve their prescriptions before marketing, and related adverse events, as stated earlier, need not be reported to the FDA.[5] Compounders are under the purview of state law controls for licensing, recordkeeping, and certification(s).[6]

While the FDA has had authority since 1938 to regulate drug manufacturing via the Food, Drug, and Cosmetic Act ("FDCA"), policing the "dance" between drug manufacturing and traditional compounding was attempted in 1997 with a proposed Section 503A to the FDCA.[7] Section 503A(c) banned the advertising and promotion of compounded drugs; theory—since traditional compounding occurs in response to individual prescriptions, advertising was/is unnecessary. This issue was taken all the way to the United States Supreme Court, and in a 5-4 2002 decision, the Court held compounders have a constitutional right to advertise their drugs; ergo, 503A was struck down.[8]

Arguably, this decision laid the foundation for the slippery slope our country finds itself on today. One of the provisions of 503A would have required federal coordination of national scale compounding businesses. Perhaps if 503A had not been struck down, both the FDA and the State of Massachusetts would have been more directly involved in regulating NECC.[9]

It is believed the first known death from this current compounding tragedy is a legal professional—a Kentucky Judge.[10] According to a physician who is also a pharmacist,[11] advice for consumers regarding compounded drugs includes:

- Avoid sustained-release compounded products,
- Avoid antibiotic re-flavoring,
- Avoid compounded agents when sterility is important (esp. injectable or inhalation agents)
- Avoid a compounded product when a brand name or generic is available, and
- Investigate the price differences between the brand name or generic and the compounded product.

Ironically, the above pointers were revised on June 10, 2012—seventeen days before the first batch of contaminated product is believed to have arrived in Tennessee; the pointers were posted on October 6, 2012—before the NECC situation became a public health crisis.[12]

As the galley for this column was being proofed the media informed the public of a recently filed 55-page answer to a lawsuit against Saint Thomas Outpatient Neurosurgery Center ("STONC") in Nashville, which strongly asserts the liability responsibility of the FDA and state officials in both Massachusetts and Tennessee for the fatal outbreak of fungal meningitis; comparative fault is one of the legal damages "instruments" being utilized. STONC is the Tennessee clinic where a number of patients were injected with the tainted compounded drug (*See* Roche Jr., W.F., *Saint Thomas clinic blames FDA, state*, The Tennessean, Section A-1 (March 5, 2013).

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1. Wilemon T., *TN still tops meningitis toll,* The Tennessean, Section B-1 (December 18, 2012).
2. *The Special Risks of Pharmacy Compounding*, FDA Consumer Health Information (May 31, 2007), available at www.fda.gov/consumer/updates/compounding053107.html.
3. *Id.*
4. Outterson K., *Regulating Compounding Pharmacies after NECC, N. Engl. J. Med.* 2012; 367:1969-1972.
5. *Id.*
6. *Id.*
7. *Id.*

8. *Thompson v. Western States Medical Center, et al.*, 535 U.S. 357, 122 S. Ct. 1497, 152 L.Ed.2d 563 (2002).
9. *Supra* note 4.
10. *Meningitis Outbreak Timeline*, The Tennessean, Section A-14 (November 8, 2012).
11. Bouts, B. A., *The Misuse of Compounding By Pharmacists*, available at http://www.quackwatch.com (October 6, 2012).
12. *Supra* note 10.

Claudia O. Torrey, Esq. is a member of the Health Law Section's Public Health Committee, and served as the genesis for the Committee's "resurrection" under the Section Leadership of Salvatore Russo, Esq.

Producing a Nurse Witness in a Medical Malpractice Action: A Practical Guide

By Kelly Michael Monroe

Representing nurses raises unique challenges for the practitioner. Any practitioner who undertakes to represent hospitals, and by extension, the hospital's nursing staff, should be aware of the perils and pitfalls of representing nurses and especially of producing the nurse as a witness at a deposition. This article looks at the value of advanced preparation when representing a nurse at a deposition.

There are four elements a patient must establish for nursing negligence:

1. There was a nurse-patient relationship;
2. There was a duty that was owed by the nurse, as opposed to a duty owed by other health-care personnel;
3. There was a departure from "good and accepted practice." If there is more than one recognized method of care, a nurse will not be held negligent if an approved method was chosen even if that method later turns out to be the wrong choice; and
4. There is a relationship between the act that departed from accepted nursing care and the patient injury.

The scope of duty for a nurse and the scope of duty for a physician are not the same. The practice of the profession of nursing is defined as "diagnosing and treating human responses to actual or potential health problems through such services as case finding, health teaching, health counseling, and provision of care supportive to or restorative of life and well-being, and executing medical regimens prescribed by a licensed physician, dentist or other health care provider legally authorized under this title and in accordance with the commissioner's regulations. A nursing regimen shall be consistent with and shall not vary any existing medical regimen."[1] The practice of medicine, on the other hand, involves the "diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition."[2]

It is crucial to remember that there is a difference between a "nursing diagnosis" and a "physician's diagnosis." Where a medical diagnosis may be "myocardial infarction," a nursing diagnosis relates to the patient's response and may be, for example, "knowledge deficit related to risks of myocardial infarction," or "knowledge deficit related to risks of cardiovascular disease." A nurse does not practice medicine and does not make a medical diagnosis.

A clever plaintiff's attorney will know, and expect, that a nurse will have opinions about issues that fall outside the nursing scope of practice and will seek to elicit those opinions during the deposition of the nursing staff. The nursing staff may be legally restricted from practicing medicine, but when dealing with a nurse with any appreciable amount of experience, the nurse may have formed opinions about the physicians whose orders the nurse was legally required to follow and opinions about the medical care provided by those same physicians. Indeed, it is common to represent nurses who have decades of nursing experience and, as a result, have much information which would be valuable to a plaintiff's attorney. In some cases, the nurse may have greater experience than the physician involved. However, a nurse is not qualified to offer opinion evidence as to the standard of care of a physician.[3] The attorney must not allow the nurse witness to answer deposition questions regarding his/her opinions of the medical care rendered or as to the medical diagnosis. Any such testimony is beyond the scope of nursing care.

The Court of Appeals has addressed the scope of duty of nursing practice. In *Bleiler v. Bodnar*,[4] the plaintiff suffered an eye injury at work and went to the emergency room the next day. An emergency room nurse and the supervising physician both separately took medical histories which failed to elicit information that would have led to proper treatment of the eye. The plaintiff sought to hold the hospital vicariously liable for the misconduct of the doctor and the nurse. The Court of Appeals had to consider whether the applicable statute of limitations was for negligence or for medical malpractice. In finding that the latter limitations period applied with respect to the conduct of both the doctor and the nurse, the Court observed that

> [w]hile courts have in the past held that a nurse could be liable for negligence, but not for malpractice, the role of the registered nurse has changed, in the last few decades, from that of a passive, servile employee to that of an assertive, decisive health care provider. Today, the professional nurse monitors complex physiological data, operates sophisticated lifesaving equipment, and coordinates the

> delivery of a myriad of patient services. As a result, the reasonably prudent nurse no longer waits for and blindly follows physicians' orders.

(65 NY2d at 71 [internal quotation marks and citations omitted]).

The court concluded that by not taking a proper medical history of the plaintiff, the nurse failed to carry out her "role as an integral part of the process of rendering medical treatment to a patient." (*Id*. at 72).

A nurse does not have a duty to question a physician's orders unless such orders are so clearly contraindicated by normal practice that ordinary prudence requires inquiry into the correctness of the orders.[5] Moreover, a nurse does not have a duty to inquire into the propriety of a physician's order where both the nurse and the doctor have all of the same information regarding the patient's condition.[6] Even if a plaintiff is able to demonstrate that a nurse should have inquired into the correctness of a physician's order, a plaintiff may be required to show that the nurse's inquiry would have affected, or caused the physician to make, a different decision regarding treatment.[7]

In *Dumas v. Adirondack Medical Center*, plaintiff's decedent was admitted to the hospital after attempting to commit suicide. The decedent made two additional attempts to commit suicide during her admission at the hospital. The decedent's attending physician at the hospital determined that the decedent's condition required that she be immediately transferred to the mental health unit of another hospital. The attending physician signed the transfer order, but did not direct in those orders that the decedent be placed in restraints during the transfer. A nurse employed by the hospital met the ambulance attendants and advised them of the decedent's attempts at suicide and suicidal ideation. The ambulance attendants placed the decedent in the ambulance, secured her with standard safety belts across the waist and ankles and covered decedent with a blanket. An ambulance attendant was assigned to ride in the back of the ambulance and watch over the decedent during the transport. Several minutes into the transport, the decedent unlocked the safety belts, jumped up and threw herself out of the back of the moving ambulance, sustaining fatal injuries. In addressing the liability of the nurse, the Court stated as follows:

> plaintiff argues that [the nurse's] failure to question [the attending physician] why restraints were not being ordered when decedent was placed in the ambulance constitutes professional negligence. [The nurse] had no information regarding decedent that [the attending physician] did not have and, moreover, plaintiff's expert acknowledged that [the nurse]…had no authority to direct that restraints be used. In addition, there is no record evidence indicating that [the attending physician] would have ordered restraints had [the nurse] raised the issue. As a result, plaintiff failed to make a prima facie case of negligence against [the nurse], and the hospital vicariously, and Supreme Court's order directing a verdict in their favor should in all respects be affirmed.

A nurse involved in a lawsuit may be an individually named defendant or may be involved merely as the employee of the named defendant hospital. In the latter case, it is important to make it clear to the nurse that, even if it is the nurse's own act/omission or rendering of care that is at issue, the nurse is not a defendant in the lawsuit. A non-party nurse advised that he/she will have to give a deposition often assumes that this means he/she is being sued. The attorney must also address, in the case of an individually named nurse, whether or not the nurse has personal professional liability insurance. The attorney must also be alert to any possible conflicts when representing both the nurse defendant and the nurse's employer. One or both of the defendants may need separate counsel.

The most common claims for nursing malpractice are:

- Failing to monitor;
- Failing to notify a physician of changes in patient's condition;
- Failing to document;
- Falls;
- Injuries (i.e., burns, nerve damage);
- Retained instruments/objects;
- Wrong site for procedure;
- Wrong procedure;
- Elopement;
- Failure to intervene with impaired professional;
- Medication errors;
- Transfusions;
- Failure to question orders;
- Failure to follow "chain of command";

- Failure to communicate/continuity of care;
- Failure to follow the facility's procedures.

The Nurse as Witness

Producing nurses for deposition presents additional challenges to the practitioner. Establishing trust is extremely important in representing hospitals and their nursing staff. Nurses often believe that the mere fact that their care is being questioned puts their careers in jeopardy. It is imperative that defense counsel be able to calm those fears, along with fears that they may lose their professional license or their ability to work as a nurse. It is simple to do all of those things by following several simple rules.

Meet Early

Because nurses have so much information, defense counsel can learn a great deal from the nursing staff. The nurse usually knows the people involved in the case—physicians, therapists, other nursing staff—extremely well and will be able to provide invaluable insight into the workings of the unit where the alleged malpractice occurred. Many times they will eagerly volunteer information about their opinions during your initial meeting with them. Other individuals will be reticent at first, indicating that they are not sure whether they can trust the attorney whom they may see as working for the hospital and not protecting their best interests.

Therefore, it is critical that defense counsel meet with nursing staff well before they are scheduled for deposition. For the nurse who is anxious to divulge information, this is an opportunity to gather information which may prove valuable to your defense. Oftentimes the nurse will provide information which he or she has been holding onto waiting for the opportunity to provide it to someone. Defense counsel can and should be that person, assuring the nurse that any information provided will be kept confidential and using it as a tool in the investigation.

The other extreme is the nurse who trusts no one. He or she has been instructed at some point not to discuss the events in question with anyone and he or she assumes that includes defense counsel. Maybe a friend of theirs in the past had an unpleasant encounter with hospital administration and they have developed a distrust of the "system" since then. Or perhaps they just do not like attorneys, or administration, or anyone in a position of authority. Whatever the reason, these witnesses can be difficult to deal with simply because they are so untrusting of you and of the "system." Meeting early on in the legal process with such a witness offers clear benefits. Defense counsel will now be alert to the suspicious and untrusting nature of the witness, which provides an opportunity to turn the witness around and convince him or her that counsel can be trusted. These witnesses often have new information which has not been previously provided, so convincing this witness to share this information can open up new areas for defense counsel to explore. Getting this information early is critically important as defense counsel needs to be completely informed of the strengths and weaknesses of their case before producing a single witness at deposition. If a nurse is extremely uncooperative, it is important to tell the nurse that he/she has an obligation to cooperate in the defense of the action.

While some of the information these witnesses provides is useful, some of it will not be of any use to defense counsel. Not infrequently, it is the useless information which the witness is most concerned about providing to counsel. It is easy, therefore, to assuage the witness' fears that this information will not be disclosed, thereby solidifying in the nurse's mind that the attorney is trustworthy.

When meeting with the nurse it is also important to emphasize that the nurse needs to tell you the facts that he/she is aware of and that concealing information from the defense counsel is not only counterproductive, but can jeopardize an otherwise defensible case. Additionally, at the first meeting with the nurse, obtain the nurse's personal contact information so that the nurse can be contacted should he/she leave the employment of the hospital. Finally, make sure to give the nurse your contact information and advise the nurse that he/she may contact you directly.

Meet Often

One pitfall of meeting early is that the witness will forget what occurred at the initial meeting and come to the deposition unprepared. For defense counsel, this may be difficult to understand because to them, the case is important and some files, by their very nature, need attention daily or several times a week. To the nurse, however, this patient and his/her care is something which the nurse has difficulty recalling unless the circumstances were unusual or remarkable. Even when the witness firmly believes that he/she recalls the patient in question, or the circumstances in question, over time memories change and fade and it is easy for a witness to become confused. This can be dangerous for defense counsel as the witness who is adamant that they recall something, but who is actually mis-recalling the events in question, can unwittingly provide erroneous testimony. Because the witness is so convinced that he/she recalls the events, he/she may appear very credible both to defense counsel and plaintiff's counsel, even if this version of events does not mesh with other witnesses. Meeting often with these

types of witnesses can help clarify in their minds the actual events.

The medical record is the best, and sometimes the only, evidence of what happened in a medical malpractice case. It is imperative that the nurse witness is familiar and comfortable with all of his/her entries in the medical record. This may be complicated where the hospital is using an electronic medical record (EMR). When the pages of the EMR are printed for litigation purposes they bear little resemblance to how the record appeared on a computer screen when the nurse was inputting or reviewing information for patient care. It is important for the nurse to have ample time to become oriented to his/her own entries in printed form.

Discuss the Standard of Care

Discussing the standard of care with the nurse aids the nurse in recognizing a distinction between the nursing standard of care that he/she ought to be referring to in testimony and the nurse offering an opinion about those things which fall into the physician's standard of care and duty. Discussing the standard of care is also helpful in preparing the nurse with regard to any issues that may come up in the deposition such as a mistaken or omitted chart entry. While the nurse may feel that such a mistake or omission is a deviation from the standard of care, the mistake or omission may not be something that caused or contributed to the plaintiff's injury, and the nurse needs to understand that.

Hospital Policies and Procedures

If policies and procedures existed at the time applicable to the issues in the litigation, and especially if any policies and/or procedures have been produced in discovery, it is imperative that the nurse have an opportunity to review these documents and be prepared to respond to questions concerning whether the nurse's actions comported with the applicable policies and/or procedures. Conversely, if the nurse's actions clearly violated applicable policies or procedures, the nurse should be prepared to answer these questions as well.

The Basics

In addition to the customary instructions given to a witness in deposition preparation, some important things to point out for nurses are:

- It is not the nurse's job to volunteer information for the questioning attorney; nurses, by their nature, often feel an obligation to be helpful and may also view the questioning attorney as an authority figure (as they may often view a physician); it is also acceptable to answer with "I don't know," or "I don't recall"—the nurse may be accustomed to supplying information to the authority figure and will need to be specifically instructed that these are acceptable deposition answers;
- The questioning attorney may use medical language/terminology, but do not think that the questioning attorney has more medical knowledge; the nurse's medical knowledge and experience is almost always more extensive and accurate than the questioning attorney; if the question sounds funny, it is likely because the questioning attorney does not fully understand the medicine involved;
- Remind the nurse that the standard of care for the nurse is different from the standard of care for the doctor; the nurse should not offer opinions or comment upon the standard of care for a physician, just as we would instruct a physician to refrain from offering an opinion or commenting on the standard of care for the nurse.

Conclusion

The nurse as defendant or as witness can pose challenges to the attorney who is producing the nurse for deposition. However, with proper preparation, the nurse can be an effective witness for the defense of a nursing or hospital malpractice action.

Endnotes

1. NY Education Law § 6902 sub. 1.
2. NY Education Law § 6520.
3. *See Dombrowski v. Moore*, 299 AD2d 949 (4th Dept. 2002).
4. *See Bleiler v. Bodnar*, 65 NY2d 65 (1985).
5. *See Garson v. Beth Israel Medical Center*, 41 AD3d 159 (1st Dept. 2007).
6. *See Dumas v. Adirondack Med. Ctr.*, 89 AD3d 1184 (3d Dept. 2011).
7. *Id.*

Mr. Monroe is a partner in the Albany, NY law firm of Thuillez, Ford, Gold, Butler & Monroe, LLP where he regularly represents nurses and hospitals in medical malpractice actions.

Representing the Nurse with a Substance Abuse Problem in New York

By Karen A. Butler

How Does It Start?

A nurse withdraws the Dilaudid from Pyxis[1] for her post-op patient and signs that it was given in the EMR. She walks into the patient's room with every intention of administering the pain medication but her patient has fallen asleep. She's not going to wake him up—that would be ridiculous. She slides the pill into her pocket thinking she'll give it to him when he complains of pain again. Later at home she finds it in her pocket. She has been having trouble sleeping…she takes it. Within a year she is diverting narcotics from her patients on a regular basis. The medication records show she is giving twice as many doses of pain medication as any other nurse on the unit.

An ICU nurse is caring for two patients. They are both chemically paralyzed, on ventilators. He is administering doses of Versed for sedation. As ordered, he is giving less than the amounts in the prefilled syringes. The unit is extremely busy. He has trouble, as always, finding a nurse free to witness his waste. He enters the waste and asks his coworker to sign in the Pyxis "after the fact." In fact, the Versed was not wasted. He later injects himself. Within six months he is diverting Versed and other drugs regularly. When someone calls in sick or an extra nurse is needed he is the first to volunteer. He offers to pass meds for his overworked colleagues. Everyone loves him. He is considered for a management position. He isn't interested—he wants to stay at the bedside.

He is a Certified Registered Nurse Anesthetist (CRNA). No one pays much attention to how much medication is removed for patients undergoing anesthesia. He has been injecting himself now for over three years. He got caught, however, when he removed Fentanyl and signed it out for a patient who was already discharged.

She is a nurse and though she would never work under the influence of alcohol she does like her wine. "I work hard and I play hard" she tells herself. She calls in sick—a lot. Her excuses are more and more detailed and elaborate. The first time she was stopped she blew a .10 on the breathalyzer. It was 10:30 at night and she was driving home from the unit's Christmas party. She pled guilty to DWAI, a violation. It was not reported to the Education Department. Within three months she was arrested after a fender bender outside her daughter's preschool. Her three-year-old was in the car. It was 8:00 a.m. Her BAC was .18. This time she was charged with a felony.

We live in a society where addiction is prevalent. In 2011 it was estimated that 16.7 million Americans (6.5% of the American population) were dependent on alcohol or had problems relating to their use of alcohol. Approximately 1.8 million Americans are dependent on/abusing prescription pain relievers.[2] Nurses are not at an increased risk of addiction compared to that of the general population.[3] However, nurses face unique challenges in their recovery from addiction including an environment with access to drugs and threats to licensure.

Providing legal counsel to the addicted nurse requires familiarity with addiction, the New York State Office of the Professions, the Professional Assistance Program, SPAN and the elements of a successful recovery.

In working with the addicted nurse it is important to remember that everyone is working toward the same goal: to be sure the nurse does not return to practice until he/she is fit to provide safe care to his/her patients.

The Addicted Nurse—Uncovered

Many facilities that employ nurses are required by statute and/or regulation to report a nurse who is suspected of being an abuser of drugs or alcohol or who has been terminated, suspended, resigned or reassigned because of substance abuse problems.[4] These reports are made to the New York State Education Department's Office of Professional Discipline (OPD).[5]

Nurses may abuse drugs, alcohol or both. Often nurses obtain controlled substances by "diversion."

Diversion means stealing a narcotic or other controlled substance from a patient for the provider's own use. Nurses divert drugs in several ways including:

- using drugs meant for "waste;"[6]
- signing drugs out for a patient but not administering to that patient;
- taking unused medications;
- overriding the computer system;
- siphoning from IV, PCA bags;

- writing, e-prescribing or calling in prescriptions;
- taking used dermal patches;
- substitution (i.e., saline in a prefilled syringe).[7]

Diversion is a crime.[8]

Often evidence of a nurse's diversion of controlled substances is uncovered by the pharmacy that picks up on aberrant usage of narcotics by an individual practitioner. Other times an alert nurse manager or coworker recognizes behaviors that are often associated with addiction to drugs or alcohol. The following is a *partial* list of signs, symptoms and/or behaviors which may indicate substance abuse:

- Frequent, unexplained absences from the unit during work hours;
- Frequent reports of lack of pain relief from assigned patients;
- Narcotic or Pyxis obsession—offering to pass meds for other nurses;
- A large number of wasted narcotics from one nurse;
- Increased narcotic sign-outs;
- Altered orders;
- Shakiness, tremors, unsteady gait, frequent nausea, vomiting, diarrhea;
- Slurred speech;
- Odor of alcohol at work;
- Drinking heavily at parties, work events;
- Frequent use of mouthwash, mints or cough drops;
- Constricted/dilated pupils;
- Frequent call-ins with elaborate excuses, frequent absences or emergencies;
- Labile mood;
- Always wearing long sleeves (to hide track marks).[9]

Office of Professional Discipline

The Office of Professional Discipline (OPD) investigates and prosecutes licensed professionals in the state (excluding physicians and physician's assistants who are disciplined by OPMC). This includes the profession of nursing (both RN and LPN). Professional misconduct is the failure of a licensed professional to meet expected standards of practice.[10]

The Board of Regents is responsible for the final disposition of all disciplinary matters. Summaries of final disciplinary actions are posted on the OPD web site.

Professional misconduct is defined in Education Law and in the *Rules of the Board of Regents*. Professional misconduct includes the following (*this is not a complete list*):

- Practicing under the influence of alcohol or other drugs;
- Being habitually drunk or being dependent on, or a habitual user of, narcotics, barbiturates, amphetamines, hallucinogens or other drugs having similar effects;
- Engaging in acts of gross incompetence or gross negligence on a single occasion, or negligence or incompetence on more than one occasion;
- Practicing beyond the scope of the profession;
- Releasing confidential information without authorization;
- Being convicted of a crime;
- Being sexually or physically abusive;
- Abandoning or neglecting a patient in need of immediate care.

A range of penalties that includes censure and reprimand, fines (up to $10,000 for each violation), suspensions, probationary terms, and even revocation for severe cases may be imposed on licensees who have committed misconduct. The Board of Regents takes final action on the most serious cases of misconduct.[11]

Nurses charged with practicing while their ability is impaired by drugs or alcohol or who are charged with being habitually drunk or dependent on mind-altering drugs are subject to investigation and prosecution by OPD. OPD may take any action including suspension or revocation of the nurse's license. If the license is revoked the nurse must wait at least three years before applying for reinstatement.

Along with OPD, if the behavior involved controlled substances the Bureau of Narcotic Enforcement (BNE) may want to interview and charge the nurse. The BNE is a division within the New York State Department of Health. The BNE Narcotic Investigators investigate suspected drug diversion or illegal sales involving theft, forgery, and fraud. They work closely with local, state and federal law enforcement. In cases of diversion, forged prescriptions and/or theft, especially if large amounts are involved, the nurse may be investigated, interviewed and charged by BNE.[12]

Professional Assistance Program (PAP)

There are many paths to the realization that a nurse needs treatment for a substance abuse problem. Whether the nurse is discovered to have a drug and/or alcohol problem at work, the nurse comes to believe she needs help or even if the problem comes to light because of an arrest the goals are the same; (a) the nurse needs treatment for his or her addiction; (b) the patients need safe care.

New York Education Law § 6510-b provides a mechanism for a nurse (or other licensed professional other than a medical doctor or physician's assistant)[13] to surrender his/her license while undergoing treatment for a substance abuse problem. This is a confidential program which allows the nurse to receive treatment for addiction while avoiding the disciplinary process, thereby protecting his/her professional license.

The criteria for acceptance into the program is outlined at 8 NYCRR § 18.

8 NYCRR §18.3 Acceptance:

In consultation with the Committee for Professional Assistance, the department may accept an application for voluntary surrender of the license if the following conditions are met:

a. There has been no harm to the licensee's patients or clients that has resulted from a problem of drug or alcohol abuse. Any question of harm to a patient shall be investigated prior to the acceptance of the surrender of a license pursuant to Education Law, section 6510-b.

b. The applicant presents a proposed program of treatment that is acceptable.

c. The applicant accepts all monitoring requirements including a minimum of two years of monitoring by the committee or its designee. The minimum two years of monitoring shall include the period of active treatment.

d. The applicant provides an acceptable plan for informing patients or clients, who request professional services, of temporary withdrawal from practice.

The licensee must file an application along with releases for all medical and treatment records. The nurse may be required to appear before staff or committee members to answer questions about the application, nursing practice, and history of substance abuse.

Participation in the PAP program requires that the nurse temporarily surrender his/her nursing license, and participate in a substance abuse program certified by the Office of Alcohol and Substance Abuse Services or other PAP approved program.

If accepted into the PAP program the nurse must abstain from all mood-altering substances, including drugs and alcohol. The nurse must accept all monitoring requirements of PAP. The nurse must comply with toxicology screens which must be witnessed (i.e., the observer must actually observe the urine coming from the body and going into the cup) and the screens must be truly random (including weekends). The screens may also include a breathalyzer or saliva strip. The nurse is "strictly liable" for the screens and any excuse that eating poppy seeds or taking medication such as Nyquil or herbal supplements caused a "false positive" will not be accepted. Likewise the creatinine of the urine should be within normal limits so that there is no indication of a dilute sample. A positive toxicology screen is sufficient reason to be removed from the PAP program. PAP may require additional medical, addiction, psychological or mental health evaluations. The nurse should expect to sign releases for her medical and mental health treatment records.

The nurse also consents to at least two years of monitoring after his/her license is restored. After reinstatement PAP may require workplace monitors who must complete quarterly reports.

While the nurse is in good standing with the PAP program he/she is *immune* from the following charges of professional misconduct:

> § 6509-3: Practicing the profession while the ability to practice is impaired by alcohol or drugs and
>
> § 6509-4: Being habitually drunk or being dependent on, or a habitual user of, narcotics, barbiturates, amphetamines, hallucinogens or other drugs having similar effects.

The surrendering of the license and participation in PAP is confidential. It is not considered discipline and will not be reflected in the participant's license record or on OPD's web page. If the nurse fails to comply with PAP requirements the nurse may be removed from the PAP program and may also lose the immunity from disciplinary action. When the nurse and the treatment personnel determine that it is safe for the nurse to return to practice the nurse may apply for restoration of his/her license.

PAP is usually very timely in allowing the nurse to go back to work. The nurse must have a minimum of 90 days of recovery time, and must have a strong letter of support from his/her treatment provider and SPAN[14] as well as

eight clean, randomly observed drug screens the month prior to the reinstatement hearing. If the license is reinstated the nurse usually will have many restrictions on his/her nursing practice, such as narcotics access restriction, no nights, no overtime, no home care or hospice, no floating. They are also sometimes restricted from working in certain units, such as the emergency department.

As with all chronic diseases, persons suffering addiction may relapse. A nurse who has successfully had her license restored through PAP but who has suffered a relapse will be requested to appear before a PAP panel. The nurse may be asked to resurrender her license and restart the monitoring program. If the nurse demonstrates progress in his or her recovery, including letters of support from a sponsor and/or treatment providers (including SPAN described below), the nurse may, again, apply for reinstatement.

SPAN

The Statewide Peer Assistance for Nurses (SPAN) is part of the New York State Nurses Association. SPAN offers confidential services and support to nurses suffering from addiction throughout the state at no charge.[15] In addition SPAN offers education, resources and guidance to health care facilities and providers throughout the state on issues relating to the impaired nurse. SPAN is staffed by "nurses helping nurses" who are familiar with the psychological, professional and legal problems facing the addicted nurse as well as the pressures of the health care workplace especially as they relate to addiction.[16] All SPAN Regional Coordinators are Master's prepared and/or have a background in mental health or addiction nursing. In addition SPAN utilizes "advocates" who are trained as consultants to facilitate their support groups.

How does a nurse get to SPAN? Many nurses pick up the phone and call the SPAN hotline on their own asking for help. Other nurses are told about SPAN by employers, PAP, an attorney or a coworker. However, the nurse must make the call to SPAN. It is always self-referral.

SPAN offers nurses support and expertise in the area of addiction treatment. SPAN can offer referral to the appropriate treatment facility or even to inpatient addiction treatment.[17] SPAN offers support groups for nurses throughout the state where nurses can learn from their peers, share their experiences with addiction and everyday stresses, and receive the tools and "tough love" needed for sobriety. SPAN can guide the nurse into the world of 12-step programs, meetings, sponsors and "home groups." SPAN offers support and advocacy as the nurse goes through the process of PAP or even the disciplinary process. SPAN can assess whether the nurse is safe to return to work and offer guidance on workplace conditions and monitoring.

The SPAN process starts with the initial hotline call or other contact with SPAN. The nurse is assessed and a meeting is scheduled where the nurse undergoes a comprehensive assessment, completes forms and receives recommendations for treatment. The nurse is taken to her first SPAN meeting and then attends weekly support meetings. SPAN support meetings are typically about 90 minutes in length and may be attended by 4 to 20 nurses. Topics may include the disease of addiction, PAP, toxicology screens, relationships, back to work issues, relapses, and the benefits of a 12-step program.

SPAN and PAP collaborate to ensure the nurse is appropriately monitored both during the initial phases of recovery and treatment and later, when the nurse returns to work.[18] SPAN will advocate for the nurse who is compliant with the program and making satisfactory progress in his/her recovery. This may include writing letters of support, accompanying the nurse to PAP hearings and assisting with nurse monitoring. SPAN will assist the nurse to put together a portfolio to document her treatment progress, recovery and fitness for a safe return to the workplace.

SPAN has had success with some hospitals but not others in returning the nurse to employment. For example, in the Capital District, most hospitals will give the nurse one chance. However, in some regions of New York the hospitals tend to terminate the nurse. In the past, some hospitals had all the nurses who diverted arrested, but now most do not, although they often will not let them come back to work.

When PAP Is Not an Option

Every nurse with a substance abuse problem is not accepted into PAP. If the nurse has caused patient harm or there are other issues involving criminal conduct, professional misconduct or unsafe practice PAP may not be an option. The nurse who has not been accepted into PAP will face the OPD process without the confidentiality, immunity or support provided by PAP. The nurse must still pursue and make a commitment to substance abuse treatment if there is hope of reaching the best outcome in the disciplinary process. The nurse is still eligible for and needs the support of SPAN. Compliance with the SPAN program, toxicology screens, treatment (inpatient if necessary) attendance at 12-step meetings and support groups will assist the OPD in determining when/if your client is safe to return to practice. The OPD may determine that the nurse's practice must be monitored; he/she must continue to submit toxicology screens and may even require

a modification or restriction of your client's practice to avoid passing narcotics.

Direct Referral

Section 6509 of the Education Law states that professional misconduct includes "conviction of a crime...and violation of Article 33 of the Public Health Law (controlled substances)." When a licensed nurse is convicted of a misdemeanor or a felony the matter may be referred directly to the Regents Review Committee (Direct Referral). The RRC will hear testimony and arguments relating to the penalty to be imposed but will not permit any testimony or review evidence relating to the underlying crime.[19] Usually a direct referral will not allow for referral to the PAP program but it is certainly an option to suggest to the prosecuting attorney and/or panel. More often the Direct Referral will result in a disciplinary action depending on the severity of the underlying crime imposed by the panel or, more commonly, by a consent order. The order may require the nurse to participate in a substance abuse monitoring, workplace monitoring and a recovery program such as SPAN.[20]

The Goals[21]

As an attorney your goals for your client are to help him or her with specific legal problems relating to why he/she came into your office.[22] Often the nurse seeks an attorney because there are criminal charges pending from drug diversion, DWI, neglect/abuse or other issues which relate directly or indirectly to the nurse's addiction. Your client may need representation dealing with OPD or the Narcotics Bureau. The nurse may have come to see you because he/she is seeking your assistance to reinstate a license that has been suspended or revoked. It is important that when you help the nurse in the legal arena that you do not undermine the goal of successful sobriety. It is important that you possess some working familiarity with the addiction problem and recovery process.

SAMHSA (Substance Abuse and Mental Health Services Administration) has defined "recovery" as follows:[23]

> A process of change through which individuals improve their health and wellness, live a self-directed life and strive to reach their full potential.

SPAN has identified the following goals for the nurse in seeking recovery from drug and/or alcohol abuse: Abstinence; acceptance of the chronic disease concept of alcoholism and substance abuse; relapse prevention/trigger modification; development of a support network; development of coping skills; return to professional work site.

Abstinence: Your client may describe that he is addicted to Fentanyl. Why is he expected to forgo alcohol? Why can't he enjoy a glass of wine? Persons in recovery are required and will be tested to prove complete abstinence from all mood-altering substances. Generally speaking, in recovery, it is said that "a drug is a drug." Alcohol is a drug. It may be legal but it is still a drug. In recovery your client may describe that his "drug of choice" was Fentanyl but he is addicted to all forms of drugs, including alcohol. In the event your client must undergo surgery or some other procedure wherein he will need narcotic pain relief, he is required to inform his providers of his addiction and inform PAP, SPAN and any other monitors that he is expecting to receive a substance to which he is addicted for medical purposes. He should be switched to other pain relievers (i.e., Tylenol, Motrin) as soon as possible. He should stay close to his program during this vulnerable time and may need to increase meeting attendance, group support meetings and/or sponsor contact.

Acceptance of chronic disease concept of alcoholism: Addiction is a biological disease with a genetic and environmental component. It is chronic, progressive, and incurable, with relapses and remissions. If untreated it may, and often does, lead to premature death. By accepting this concept your client can also accept that she cannot "control" her drinking or drug use and that she needs professional help and support.

Relapse prevention/trigger modification: To achieve and maintain recovery the addict must identify those persons, places and things that the nurse associates with using drugs or alcohol. It could be anything. Maybe the nurse finds she drinks if her husband is away. Or a nurse might find resentments of her family cause her to pick up a drink or drug. Certainly going to a bar or a place one associates with drug use is easy to identify as a trigger. Persons in recovery are told to clear their homes of drugs and alcohol. But what if your "place" is the hospital or doctor's office where you work? Nurses face unique challenges when returning to the workplace, especially if the nurse was diverting drugs from patients. In some situations the nurse may need to modify her work environment to avoid the proximity of and ready access to drugs. Workplace monitoring is essential. Toxicology screens must be truly random, witnessed, and must test for the drugs the nurse was abusing.

Development of support network: Nurses are so accustomed to helping others it can be very difficult to ask for help. It is important, in the recovery process, that the nurse develop a network of support. If the nurse is in

SPAN he/she will attend weekly support meetings with his/her peers. The nurse may also need counseling with a substance abuse counselor, psychologist and/or psychiatrist. The nurse may need a time of detox treatment in a hospital or substance abuse facility if he/she is physically addicted and is withdrawing from drugs and/or alcohol. Many, if not most, substance abuse patients need inpatient treatment at a rehabilitation facility.

The nurse will be expected to attend and participate in a 12 -step program, usually Alcoholics Anonymous and/or Narcotics Anonymous. AA and NA meetings are held in virtually every geographic area of the United States and outside the United States. In recovery it is expected that new members will attend an AA or NA meeting every day for at least the first 90 days of recovery, starting the count the first day out of rehab.[24] The date and times of meetings in your client's area can be found online.[25] If your client is not working it can be beneficial to attend two meetings a day at least a few days a week, one in the morning or noontime and one in the evening. If your client has lost his driver's license, not to worry, someone will pick him up and drive him to a meeting. At the meetings your client should exchange phone numbers with other members but should stick with members of his/her own sex (men with men and women with women). AA and NA meetings are free but attendees are expected to put something in the basket when it is passed.

After attending several different meetings the nurse should pick a group to be his/her "home group." As a member of a home group the member will have a job, for example, making coffee or setting up chairs. When attending meetings the AA member chooses many different meetings but makes a commitment to attend his home group meeting every week.

The nurse should find a person (again of the same sex) to be his/her sponsor. The sponsor should be clean and sober at least one year and should have a strong commitment to the program. The new member is expected to stay close with the sponsor, often by daily telephone calls.

It is important that the nurse keep track of the meetings attended by keeping a log which will become part of her portfolio when she applies for reinstatement of her license. To keep the log the nurse should know the name of the group holding the meeting. Each group has a name (i.e., the "Live and Let Live" group) and/or the name of the venue (i.e., St. Michael's Church). It is not sufficient to put "that group that meets at the church on Swan Street." Someone from the group may need to sign the log. Your client should check with PAP and/or SPAN to see if this is required. The nurse should describe the type of meeting attended. There are "open" meetings where anyone can attend and closed meetings where anyone identifying himself or herself as an alcoholic or addict may attend. There are "beginner" meetings which are, of course, intended to introduce the newcomer to the program, and "step" meetings where a specific one of the 12 steps is explored. There are a few meetings exclusively for men or women.

Your client may protest about having to attend 12 step meetings for several reasons, including a perception of the other members that is not accurate, fear of lack of anonymity at meetings, lack of transportation, feelings that it is a religious-based program, or just an objection to joining groups in general. It is important for your client to put aside these prejudices and approach the meetings with an open mind.

There are two reasons.

When the nurse is applying for reinstatement of his/her license or to regain a license after suspension or revocation, the nurse wants to be able to show a commitment to sobriety by:

a. clean toxicology screens;

b. a record of compliance with PAP and SPAN;

c. attendance at peer support meetings such as SPAN;

d. a record of AA/NA meetings attended regularly and often;

e. a commitment to sobriety as evidenced by having a sponsor and a home group (making coffee is a plus).

More importantly, addiction is a very difficult disease to treat. A successful recovery depends on the support, knowledge and tools that, in many cases, can be found only from other addicts who have "been there." Hearing the stories of other members who have "hit bottom" but who have entered a period of stable sobriety through the tools of a 12-step program can be a powerful experience. From a practical perspective, if you have a commitment to call your sponsor every day you are likely to do it. If not, someone will be looking for you. Likewise, if you are expected to be somewhere to make coffee you're going to receive a lot of phone calls if you don't show up. Recovery must be the primary goal. Everything else is secondary.

Development of coping skills: The nurse addict has been using drugs and/or alcohol to cope with life. In recovery the nurse must identify new ways to cope with stressors. Everyone is different. Help to identify new coping mechanisms can come from SPAN support groups,

12-step meetings, individual counseling and/or one's sponsor. SPAN asks its clients to document, in periodic essay form, treatment, personal progress, steps taken to support sobriety, efforts to remain sober and what works best for personal recovery. This exercise will help the nurse to identify those strategies that work best for individual recovery.

Return to professional/work site: To return to work the nurse must first have a valid license.

Nurses in SPAN are encouraged to create a portfolio to bring to PAP meetings. The portfolio is developed throughout recovery. The following information should be documented in the nurse's portfolio:[26]

- A calendar documenting attendance at all meetings (AA, NA, SPAN, treatment groups, individual sessions);
- A copy of the nurse's registration;
- The SPAN participation Agreement and Consent Form;
- The PAP surrender statement;
- Contact information for sponsor, work site monitor, treatment monitor and toxicology monitor;
- A personal statement regarding events leading up to involvement with PAP, SPAN and plans for the future;
- A Fitness for Duty statement from the nurse's primary care provider;
- Copies of all toxicology reports;
- Periodic essays (1-2 paragraphs) about treatment, personal progress, steps taken that support sobriety, efforts to remain sober, and what works best for your personal recovery. These essays should be done quarterly for two years and twice a year thereafter;
- Return to work agreement;
- Any correspondence from the Office of Professional Discipline, Bureau of Narcotic Enforcement or any other agency that may be involved;
- Drug court agreements and contact information for drug court case manager;
- Copies of any legal charges and dispositions.

Other items that may be included in the portfolio are letters of support and/or advocacy, discharge summaries from detox and/or rehab, and records of continuing education courses completed.

If your nurse did not qualify for PAP but is seeking reinstatement of her license after a suspension or revocation the nurse should assemble a similar portfolio of information for submission when seeking a reinstatement hearing.

A nurse may not apply for restoration of a license that has been revoked until three years after the effective date of the revocation. The nurse has the burden to present compelling evidence that his/her license should be restored. The Board of Regents will consider a variety of issues which may include the factors leading to revocation, whether these factors are likely to recur, the remorse and insight shown by the petitioner, and whether the nurse is fit to practice.

Prior to license reinstatement through PAP or a restoration proceeding the nurse must have a workplace plan developed with her employer and in collaboration with her sobriety team. The nurse and her employer should enter into a back-to-work contract which provides for random drug and alcohol testing. The back-to-work plan should include a workplace practice monitor who will monitor the quality of the nursing care the nurse is providing to her patients and a sobriety monitor who will monitor the nurse's compliance with her recovery program. If the nurse is a diverter of medication the nurse may need to be placed in a different unit or in a role where she does not have access to narcotics. The nurse may need to avoid working in isolation (for example, home care) or in units where narcotics use is prevalent and fast paced (for example ICU or the ER). It is very important that the nurse is honest with her employer regarding her recovery and that she submit to all toxicology screens and workplace monitoring.

Successful reinstatement of the nursing license and return to professional employment is but the beginning of the nurse's recovery. The impaired nurse must submit to monitoring for an extended period. However, even when monitoring is over the nurse must remain active in her program of recovery to minimize the risk of relapse.

Conclusion

Addiction is a disease. When the addict is a nurse it is necessary that the appropriate steps are taken to assist the nurse through the recovery process while also protecting the patients that depend on her care. There are resources in New York to assist the nurse to receive the help and support she needs to enter into a successful recovery while protecting her license to practice. The nurse in recovery can return to employment in the appropriate setting with sobriety and practice monitoring in place.

Endnotes

1. Pyxis is a computerized system for dispensing medication.
2. *Drugfacts: Nationwide Trends*, www.drugabuse.gov/publications/drugfacts/nationwide-trends (visited December, 2012).
3. Cynthia Thomas & Debra Siela, *The Impaired Nurse; Would You Know What To Do if You Suspected Substance Abuse?* AMERICAN NURSE TODAY, Vol. 6, No. 8 (Aug. 2011).
4. In New York, Article 28 facilities are required to report to the Department of Health those health care professionals who have been suspended or have had their training or employment privileges restricted or curtailed or who have voluntarily or involuntarily resigned to avoid charges of impairment, malpractice, or misconduct. There is good faith immunity for reporting such individuals. New York regulations require that persons authorized to possess controlled substances under Public Health Law Article 33 are required to report to the Bureau of Narcotic Control the loss, theft or diversion of a controlled substance. New York regulations also require that hospital personnel policies have provisions for a physical and medical history of sufficient depth to ensure that an employee is not habituated or addicted to mood-altering substances, including alcohol.
5. Physicians and Physician Assistants are reported to the Department of Health's Office of Professional Medical Conduct (OPMC).
6. Hospital medication is often dispensed in prefilled syringes, vials or pills meant for single use but in an amount which exceeds the amount ordered for an individual patient. The nurse must, therefore, "waste" the excess medication. The process of discarding "waste" of a controlled substance must be witnessed by a second RN.
7. Barbara Nahmias, RN, NPP, PMHCNS, BC, *Addiction: Occupational Hazard for Nurses,* SPAN Power Point Presentation.
8. Diversion can be found under Article 178 of the Penal Law titled, "Criminal Diversion of Prescription Medications and Prescriptions." There are various degrees of Criminal Diversion. Criminal Diversion in the 4th degree (Section 178.10) is where a person commits a "criminal diversion act," a Class A misdemeanor (imprisonment up to one year). Criminal Diversion in the 3rd Degree (Section 178.15), 2nd Degree (Section 178.20) and 1st Degree (Section 178.25) are all various types of felonies and are primarily differentiated on the basis of the value of the benefit exchanged (in excess of $1,000 up to in excess of $50,000). If the nurse is convicted of a misdemeanor or felony she is subject to "Direct Referral" as described below. Additional charges may include: Falsification of Business Records, PL Section 175, if the nurse documented that she removed and/dispensed a narcotic; Criminal Possession of a Controlled Substance, PL Section 220, since she took the drug and thereby possessed it illegally; petit larceny for stealing; Endangering the Welfare of an Incompetent or Physically Disabled Person, PL Section 260, if by not dispensing the medications it endangered the patient/resident; Public Health Law violation 2803d, for failing to provide timely, consistent and appropriate services to a nursing home resident.
9. See *supra* note 4.
10. Though the terms are similar the standards for professional discipline should not be confused with the elements of malpractice.
11. New York Education Law § 6511.
12. www.health.ny.gov (visited December 2012).
13. The Committee for Physician's Health (CPH), a division of the Medical Society of the State of New York, provides non-disciplinary, confidential assistance to physicians, residents, medical students, and physician's assistants including counseling, monitoring, referral, support and advocacy for those providers who are impaired for any reason including substance abuse.
14. *See* SPAN *supra.*
15. SPAN is funded by a $5 surcharge on the nursing registration fee.
16. www.nysna.org/programs/SPAN (visited December, 2012). The SPAN Mission is to be the resource for New York State nurses affected by substance use disorders, while fostering public safety through outreach and education.
17. Typically SPAN will try to give the nurse two or three options for inpatient treatment. Unfortunately, many nurses get terminated from their jobs due to their addiction and do not have insurance. Therefore the majority do not go to inpatient treatment. SPAN will sometimes refer these nurses to the NYS Addiction Treatment Centers. Some outpatient facilities have sliding fee scales or charity care. Many nurses have to wait to qualify for Medicaid to get treatment.
18. SPAN does have the nurse sign a release of information so that they can communicate with PAP/OPD/BNE. SPAN will let PAP know that the nurse is not attending. SPAN would only report to OPD if there was a patient harm issue.
19. New York Education Law § 6510(2)(d).
20. NY Education Law § 6511.
21. Nahmias, *supra,* note 7.
22. Nurses often have insurance coverage for the attorney fees associated with the disciplinary process through an individual professional liability policy.
23. SAMHSA (Substance Abuse and Mental Health Services Administration) is a public health agency within the United States Department of Health and Human Services.
24. There are not as many NA meetings as AA meetings. Nurses who primarily used narcotics will need to supplement with AA meetings to meet the 90 in 90 goal.
25. www.aa.org; www.na.org.
26. *What Does a Recovery Portfolio Look Like?*, SPANING NEW YORK STATE—INFORMATION FOR AND ABOUT NURSES IN RECOVERY, Vol. 9, issue 1 (2011).

Karen A. Butler, Esq. is a partner in the law firm of Thuillez, Ford, Gold, Butler & Monroe, LLP in Albany, NY where she regularly represents physicians, nurses and other health care professionals in medical malpractice and licensure proceedings.

Ten Years After: An Analysis of the New York Health Care Whistleblower Law

By Noreen DeWire Grimmick

In the face of the numerous challenges which licensed health care professionals face with respect to the health care delivery system in this state, there are few laws that afford some level of protection to them when they confront institutional difficulties that may place their patients and their licenses in jeopardy. Inevitably, especially for licensed professional nurses rendering care in critical care units, obstetrical units, and trauma centers in health care facilities throughout New York, the standards of practice may, at times, feel as if they are being stretched thin, or at least bordering on some "new normal."[1] This is particularly true in units such as these, where the risks presented by sudden occurrences due to the acuity of patient care may, at times, require nurses to overextend themselves in order to address the needs of their patients and provide that level of care that complies with professional standards.[2]

The nursing shortage is a reality that we have long been living with in this state and in many other states across the nation since approximately 1998.[3] When a health care facility fails to adequately staff its emergency department or obstetrical unit or any other department, it runs the risk, of course, of violating rules and regulations imposed by the New York State Department of Health ("DOH") and other numerous state and federal regulatory bodies. In cases where short staffing becomes a pattern rather than an exception, the implications for patients, licensees, and health care facilities are wide-ranging. The patients, of course, are adversely impacted by an understaffed facility;[4] and the health care facility must then face the consequences of any such failure. But for the individual licensed professional nurse, his or her ability to immediately respond to the demands of patient care while complying with professional standards in the face of chronic staffing shortages is not simply the stuff of "burnout;"[5] it also becomes the substance for investigations and potential charges by the Office of Professional Discipline ("OPD") and, depending on the situation, the DOH.[6] In some circumstances, licensed health care professionals also face criminal charges, and further, the potential of being excluded from delivering professional services for any Medicaid and/or Medicare provider.[7]

A scenario where a registered professional nurse or any other professional health care licensee may be required to defend themselves in multiple venues at once is not unheard of; instead it is a well-known scenario to the attorneys who represent them. Professional health care licensees are often not only ill-prepared to respond to an initial notification from the N.Y.S. Department of Education or Office of Professional Medical Conduct ("OPMC") about an investigation, but many times they lack the financial means to pay for the legal representation they need and desire in order to protect their licenses. In many instances when investigations are initiated by OPD, particularly for nurses, the background of the investigation arises in a context where staffing shortages have played a direct role in the conduct for which the licensee is under investigation. Alternatively, a staffing shortage may be indirectly involved in the conduct of a licensee who is under investigation by OPD or DOH such as in cases where patient overload played a role in a charting error or an inability to properly supervise or mentor a newly minted nurse.

In the past several years, there has been new legislation proposed and enacted in this state to provide some protection for individual licensees who provide health care services. Against this backdrop, the legislature enacted §741 of the New York Labor Law, commonly known as the "Health Care Whistleblower Law" in 2002 (hereinafter "§741"). The objective of this legislation is to safeguard employees who perform health care services from retaliation by their employers when they report "improper quality of patient care"[8] to a supervisor or to a "public body."[9] Nursing shortages were given as an example of the kind of complaint made by health care providers, and employer retaliatory conduct in response to same, that the legislative sought to address by this law:

> This legislation does not specifically mention adherence to acceptable standards of professional practice or a code of ethics. The bill does allow a professional to go to court to be made whole after retaliatory action when the professional reasonably believes that a state law, rule or regulation has been violated. It is expected that a professional would reasonably believe that a practice identified in their professional standard or ethic as best practice or prohibited practice would be reflected in the determinations of the state agencies that regulate professional practice. A professional who knows that a colleague or a facility has been sanctioned or disciplined by the state for improper patient care could reasonably believe that the state's

> penalties were based upon a violation of state law, rule or regulation. Department of Health regulations (Section 405.5) require facilities to provide nurse staffing "to ensure, when needed in accordance with generally accepted standards of nursing practice, the immediate availability of a registered professional nurse for bedside care of any patient." Nurses would reasonably believe when, in their professional judgment, they were not immediately available to meet a patient's needs that there was a violation of state regulations. Therefore, they would be able to have their day in court following retaliation for speaking out about their perception of inadequate staffing levels.[10]

Section 741 broadened the scope of whistleblower coverage for health care workers in this state against employer retaliatory conduct. Section 741 applies to employees who perform health care services in facilities such as hospitals, nursing homes, schools, correctional institutions, and even in home care settings.[11] Prior to its enactment, health care workers seeking protection against retaliation for filing complaints about patient care had to rely upon New York Labor Law §740 which is available to employees of all description, not just health care workers. Section 740 was amended in 2006 to add protection under the statute for employees who face retaliation for reporting employer health care fraud.[12] This law, which is still in effect for all categories of employees, is commonly known as "The Whistleblower Law" (herein after referred to as "§740").[13] In order for an employee of any description to avail himself or herself of protection against retaliation for making a complaint of an employer violation under §740, the employee must prove that the employer practices complained of are *actual* violations of a "…law, rule or regulation which…*creates and presents a substantial and specific danger to the public health or safety*" (emphasis added).[14]

Cases previously brought by health care workers under §740 presented many challenges as courts required that employer "violations must be *actual* violations and not simply based upon an employee's reasonable belief that there was a violation."[15] Additionally, the requirement that the employer violation present a "substantial and specific danger to the public health and safety" served as grounds for dismissal in many cases where health care workers reported concerns that centered around a specific patient, rather than a threat to public health and safety.[16]

Section 741 is distinguished from §740 in that the kind of employer "violation" that is subject to the §741 is, as previously noted, one which relates to "improper quality of patient care." Section 740(4) requires that a claim be commenced within one year of the retaliatory conduct. By contrast, a health care worker has two years from the retaliatory conduct to commence an action under §741.[17] Additionally, §741 protects employees who merely have a "good faith" belief, or a "reasonable" belief that an employer practice constitutes "improper quality of patient care."[18] Both §740 and §741 require employees to bring violations to the attention of supervisors and give them a reasonable opportunity to cure prior to instituting action.[19] However, health care employees suing under §741 are not required to report a violation to a supervisor if the subject violation poses an imminent threat to a patient or to public health and safety, and the employee has a reasonable belief, in good faith, that such a report would not result in corrective action.[20]

Both §740 and §741 offer an employee the same type of relief, which includes injunctive relief; reinstatement to the same position the employee previously held or its equivalent; reinstatement of lost fringe benefits and lost wages; and payment by the employer of the employee's attorney's fees and reasonable costs and disbursements.[21] Successful claims brought by employees under §741 also allow a court to assess a civil penalty of up to ten thousand dollars against an employer, payable to the improving of patient care fund, if the court determines that the employer has acted in bad faith with respect to retaliation.[22] In response to any action brought pursuant to §740 or §741, an employer may successfully defend on grounds that their actions were not predicated on retaliation.[23] Employers may be awarded payment of their attorney fees and costs if a court finds that the claim brought by the Plaintiff in either a §740 or a §741 case brought a claim without a basis in law or fact.[24]

As the New York Court of Appeals noted, there is a unique interplay between these two whistleblower statutes, as enforcement of a claim under §741 requires reference to §740(4)(d). In the case of *Reddington v. Staten Island University Hospital*[25] the United States Court of Appeals certified two questions for review by the New York Court of Appeals which involved detailed analysis and review of the legislative history of both whistleblower statutes by the Court.

The first question presented to the New York Court of Appeals concerned the application of the waiver clause[26] of §740 to a claim brought under §741.[27] Ms. Reddington had filed claims under both §740 and §741 along with breach of contract and numerous federal and state claims alleging age discrimination in federal district court.[28] Therefore, Defendants interposed a motion to dismiss Plaintiff's §741 claim and all other claims based on the waiver provision of §740(7). The district court noted that

the waiver provision of §740(7) could not be a basis for dismissal of her age discrimination claims under state, city, or federal law because those discrimination claims were based upon other facts, distinguishable from a claim of retaliation under §741.[29] Additionally, according to the federal district court, federal discrimination claims are also protected under the U.S. Constitution, and they cannot be waived by electing a remedy under a state statute.[30] The district court dismissed her breach of contract claim for failure to state a cause of action.[31] Following the district court's determination, the Plaintiff eventually agreed to dismiss her discrimination claims, but she filed an appeal of the district court's dismissal of her §741 claim.[32] In response to Plaintiff's appeal the Second Circuit certified a question for the New York Court of Appeals concerning the dismissal of her §741 claim based upon the waiver clause of §740(7).

As noted above, the federal district court had earlier ruled that Ms. Reddington had waived her claim under §741, because she had also sued under §740 and had "elected her remedy" under §740(7).[33] The import of the answer to this question about whether §740(7) acted to preclude her §741 claim was critical because Ms. Reddington's §740 claim was brought beyond the one statute of limitations and would have been subject to dismissal on those grounds. Therefore, even though she had attempted to amend her complaint by withdrawing the non-viable claim under §740, the federal district court stated that an amendment of the complaint could not cure her waiver of her §741 claim which was effected when she commenced the action.[34]

The second question presented to the New York Court of Appeals by the Second Circuit in the *Reddington* case was whether a nurse working in a managerial capacity who did not render any patient care herself met the definition of "employee" under §741.[35] Section 741(1)(a) defines "employee" as "any person who performs health care services for and under the control and direction of any public or private employer which provides health care services for wages or other remuneration." The second question presented therefore was whether a nurse engaged solely in administrative matters who was not directly involved in providing "hands-on" care for any patient could pursue a claim within the ambit of §741.

With respect to the first question, in its analysis as to the applicability of the "waiver" clause under §740(7) with reference to a claim under §741, the Court of Appeals stated that

> …rather than creating its own private right of action, Labor Law § 741 contemplates enforcement through a Labor Law § 740(4) civil suit. This is critically important, as it completely changes the nature of the waiver inquiry in a case involving sections 740 and 741.… Put another way, section 740(7), as noted previously, is an election-of-remedies provision (*cites omitted*). *Yet no election of remedies is implicated when sections 741 and 740 are pleaded together, or section 741 is pleaded after a plaintiff has instituted a section 740 claim, because section 741 provides no independent remedy.* Section 741 sets out substantive legal requirements while explicitly relying on section 740 for their enforcement (see Labor Law § 741[4]). Importantly, as the entire point of section 740(7)'s waiver provision is to prevent duplicative recovery, a plaintiff health care employee can only recover damages for a section 741/740(4) violation (specific) or a section 740 violation (general), but not for both (emphasis added).[36]

While the Court's answer to this first question momentarily preserved Ms. Reddington's §741 claim with respect to the application of the 740 waiver provision, in the end, its answer to the second question—whether she was an "employee" as that term is defined under §741—resulted in the dismissal of her §741 claim. In the *Reddington* case, the Plaintiff 's job description proved that she was not directly involved in performing health care services. The Court of Appeals determined that the scope of §741 is limited to employees who actually perform health care services, though there is no requirement that the health care worker seeking its protection must have a professional license.[37] Nonetheless, in this respect, §741 is much more limited as to the universe of employees who may seek its protection as compared with §740.

As the *Reddington* case[38] makes clear, numerous threshold questions should be considered before any employee files a claim under either of New York's whistleblower laws. Prior to instituting a claim for relief under either §740 or §741, the other potential claims of an employee should be considered for the possibility of triggering the waiver clause of §740(7) resulting in those claims being dismissed. As can be seen from a review of the statutes, a claim under either §740 or §741provides limited relief. Therefore, Plaintiff attorneys will certainly consider the value of the ultimate relief of other potential claims before instituting an action that could trigger the election of remedies under either under §740 or §741 and possibly preclude more lucrative claims.

In considering the merits of a claim pursuant to §741, a job description and a detailed analysis of the employee's duties must be made to determine whether the employee

performs health care services, and whether the employer violation complained of concerns "improper quality of patient care." Under both §740 and §741, as we saw in the foregoing discussion, it is important at the outset that the Plaintiff's complaint specify the provision of the law, code or rule that was the subject of the employee's complaint; and whether the violation was actual—or merely a possibility. Adherence to strict pleading standards will reduce or eliminate the risk of a defense motion for failure to state a claim at the outset of the action.

The subject of staffing shortages as a violation of New York's Rules and Regulations under Title 10 has come up recently in a case brought under §741.[39] In the case of *Minogue v. Good Samaritan Hospital*,[40] the Plaintiff brought an action against the Defendant Hospital and its parent, Bon Secours Health System, Inc., alleging that her termination was retaliatory for ongoing complaints she had made about understaffing.[41] Plaintiff had been employed by the hospital as a Licensed Practical Nurse for 24 years.[42] Plaintiff allegedly complained to her supervisors and her union representatives about understaffing shortly after a cardiac care unit was opened at the hospital in 2007.[43]According to the evidence, the hospital's supervisory personnel responded to staffing complaints by stating that Plaintiff and other nurses would just have to "do the best they could."[44] Ms. Minogue's concerns also centered on her apprehensions that nurses with less than one year experience were being assigned to acutely ill patients, and none of these nurses were sufficiently experienced; nor were they qualified to take charge, even under the hospital's own policy.[45] This alleged failure to adequately staff the facility violated 10 NYCRR 405 and 407 as well as other various rules and regulations.

After first expressing her complaints to supervisors and her union, the Plaintiff was suspended for allegedly damaging a surveillance camera. When she was cleared of that charge and reinstated, she was then terminated for allegedly failing to cancel the insertion of a PICC line pursuant to a doctor's order. The Plaintiff asserted that this reason given by her employer for termination was "pretext." She submitted that a new secretary who had been "floated" to her unit had failed to properly enter the doctor's order after he wrote it on the order sheet. Plaintiff claimed that she had presented the order to the secretary for action, but the secretary failed to take appropriate steps to cancel the procedure.[46] No other employees were disciplined as a result of this failure to properly communicate this order to appropriate personnel.[47]

In her complaint, the Plaintiff alleged a violation of §741 as well as claims of violation of the N.Y.S. Constitution, N.Y. Human Rights Law, tortious interference with a business relationship, intentional infliction of emotional distress, negligent hiring, and negligent infliction of emotional distress.[48] The Defendants interposed a motion for dismissal of all claims for failure to state a cause of action.[49] The trial court granted Defendants motion with the exception of Plaintiff's claim pursuant to §741, reasoning that the waiver provision §740(7) applied to all the other claims, but that the Plaintiff had stated a cause of action pursuant to §741.[50]

The Defendants appealed the trial court's decision to the extent that the trial court denied their motion to dismiss the Plaintiff's §741 claim.[51] The Plaintiff cross-appealed the order of the trial court, to the extent that the trial court determined that she had elected her remedy pursuant to §740(7) and on that basis, the trial court dismissed all her other claims.[52] On appeal, the Appellate Division affirmed the order of the Supreme Court. The Appellate Division agreed that Plaintiff had stated a cause of action pursuant to §741.[53] It also agreed that since all the other claims brought by the Plaintiff had arisen out of the alleged retaliatory conduct, thus §740(7) was triggered and Plaintiff had elected her remedy by instituting an action under §741.[54]According to the Appellate Division, this determination was consistent with the legislative intent of preventing duplicate recovery under §740 and §741.[55]

In the case of *Novak v. St. Luke's-Roosevelt Hospital Center, Inc.*,[56] the Plaintiff was a registered nurse who was working in the emergency department of the hospital when a patient, who allegedly told her he wanted to die, came in for treatment for an overdose of morphine.[57] Though Ms. Novak determined the patient was a potential suicide, her charge nurse ordered the patient out of the emergency department.[58] The senior staff nurse alleged that the patient was a "homeless, manipulative drunk and a liar" and the hospital refused to treat him.[59] Later, this patient was found motionless and was rushed to the emergency department where he was pronounced dead.[60] The autopsy revealed that death resulted from massive amounts of morphine and other drugs.[61]

Though the medical examiner requested an interview with Ms. Novak, the medical director spoke with him instead.[62] Plaintiff then claimed that she became subject to continuing harassment.[63] She was finally terminated after allegedly returning late to her post.[64] This was occasioned by the fact that she was in conference with a director in the hospital.[65]

Plaintiff in this action sued not just the health care facility who employed her, but also the medical director of the emergency department and the nurse manager.[66] She brought claims under §741 and *prima facie tort* and intentional infliction of emotion distress.[67] Defendants moved to dismiss Plaintiff's causes of action for failure to specify a law, rule or regulation that was violated in her com-

plaint.[68] Additionally they asserted that individuals cannot be sued under §741 because they are not "employers" as defined under the statute; and they claimed that Plaintiff's own misconduct was a defense to her §741 claim.[69] Finally, with respect to the tort claims, the Defendants asserted that Plaintiff had elected her remedy pursuant to §740(7) and that the tort claims must be dismissed.

The court agreed that §740(7) required the dismissal of the tort claims.[70] The Judge determined, however, that the Affidavit of the Plaintiff in opposition to Defendants' Motion to Dismiss §741 was sufficient to support her claim under §741 in that Plaintiff provided factual detail and identified specific laws, rules, and regulations that were violated; thus he denied that branch of Defendants' motion.[71] Interestingly, as to the subject of individual liability, the court noted that there was some division in the federal courts as to whether §741 applied to individual defendants as well as companies.[72] While noting that other New York courts had not yet ruled on the subject of individual liability under §741, the trial court denied the individual Defendants' motion for dismissal of the §741 claim, relying on New York State cases which permit individual liability against individuals who have an ownership interest or authority to carry out the decisions of others under the Human Rights Law.[73] There is some doubt as to whether this assignment of individual liability under §741 will ultimately be deemed permissible under §741 by an appellate court in this state. The holding in the *Geldzahler v. New York Medical College*,[74] limiting the liability under §741 to "employers" only as that term is defined under the statute, would seem to be more consistent with the legislative intent of §741. Further, considering the limited relief available under §741, which includes reinstatement to one's previous position as well as lost wages and benefits, individual liability would not appear to have a place under the statutory construct.

For employers, the cases brought under §741 demonstrate that concerns expressed by employees about the delivery of health care services should be responded to in a manner which addresses those concerns directly without subjecting the reporting employee to conduct by supervisors or others that would amount to an adverse employment action. Training supervisory personnel to understand the implications of retaliatory conduct should be incorporated in their training programs, if it is not already addressed. While the relief offered to employees under §741 is limited as it is only intended to restore them to their position and level of compensation as was previously provided before the retaliatory conduct took place, there is still more at stake for employers who could be subject to a civil penalty for "bad faith," and who must compete in a marketplace where, more and more, consumers are knowledgeable about the quality of patient care and complaints made against facilities for failing to meet the professional standards. While judicial interpretation of this law is still evolving ten years after its enactment, it is clear that health care workers of every description are availing themselves of its protection.

Endnotes

1. Memorandum from Johanna Duncan-Poitier to the Honorable Members of the Board of Regents New York State Dept. of Education, dated April 16, 2001, discussing the nursing shortage.
2. Croke, *Nurses, Negligence, and Malpractice*, 103 American Journal of Nursing 54, 57, September 2003.
3. Mannino, *The Nursing Shortage Contributing Factors, Risk Implications, and Legislative Efforts to Combat the Shortage*, 15 Loy. Consumer L. Rev. 143, 144 2002-2003.
4. *Id*. at 151.
5. *Id*. at 147.
6. Memorandum from Johanna Duncan-Poitier to the Honorable Members of the Board of Regents New York State Dept. of Education, dated April 16, 2001, discussing the nursing shortage, pp. 14-15.
7. N.Y. Comp. Codes. R. & Regs. tit. 18, § 515.3 (2012).
8. N.Y. Lab. Law §741 (1)(d) (McKinney 2002) (Supp. 2012). "Improper quality of patient care" is defined as:

   > any practice, procedure, action or failure to act of an employer which violates any law, rule, regulation or declaratory ruling adopted pursuant to law, where such violation relates to matters which may present a substantial and specific danger to public health or safety or a significant threat to the health of a specific patient.

9. *Id*. at §741(e). "Public body" is defined as:

   > (1) the United States Congress, any state legislature, or any elected local governmental body, or any member or employee thereof; (2) any federal, state or local court, or any member or employee thereof, any grand or petit jury; (3) any federal, state or local regulatory, administrative or public agency or authority, or instrumentality thereof; (4) any federal, state or local law enforcement agency, prosecutorial office, or police or peace officer; (5) any federal, state or local department of an executive branch of government; or (6) any division, board, bureau, office, committee or commission of any of the public bodies described in subparagraph one, two, three, four or five of this paragraph.

10. Assembly Rules Comm. Mem. in Support, at 1, Bill Jacket, L 2002, ch 24.
11. N.Y. Lab. Law. §74 (b) defines "employer" as:

    > any partnership, association, corporation, the state, or any political subdivision of the state which: (i) provides health care services in a facility licensed pursuant to article twenty-eight or thirty-six of the public health law; (ii) provides health care services within a primary or secondary public or private school or public or private university setting;] (iii) operates and provides health care services under the mental hygiene law or the correction law; or (iv) is registered with the department of education pursuant to section sixty-eight hundred eight of the education law.

12. N.Y. Lab. Law §740(2)(a).
13. N.Y. Lab. Law §740(2) (b) and (c) (McKinney 2002) (Supp. 2012).
14. *Id*. at §740(2)(a).
15. *Bordell v. General Electric Co*., 208 AD2d 219 (3d Dept. 1995).
16. *Kern v. DePaul Mental Health Services*, 152 AD2d 957 (4th Dept. 1989); *Green v. Saratoga A.R.C*., 233 AD2d 821 (3d Dept. 1996).
17. N.Y. Lab. Law §740(4)(d).
18. *Kern v. DePaul, supra.*
19. N.Y. Lab. Law §740(3) and §741(3).
20. N.Y. Lab. Law §740(3).
21. *Id*. at §740(5).
22. *Id*. at §740(4)(d).
23. *Id*. at §740(4) c) and §741(5). *See also: Luiso v. Northern Westchester Hospital Center*, 65 AD3d 1296 (2d Dept. 2009).
24. *Id*. at §740 (6). *See also: Tomo v. Episcopal Health Services, Inc*., 85 AD3d 766 (2d Dept. 2011).
25. 511 F.3d 126 (2d Cir. 2007).
26. N.Y. Lab. Law §740(7) provides:

> Existing rights. Nothing in this section shall be deemed to diminish the rights, privileges, or remedies of any employee under any other law or regulation or under any collective bargaining agreement or employment contract; except that the institution of an action in accordance with this section shall be deemed a waiver of the rights and remedies available under any other contract, collective bargaining agreement, law, rule or regulation or under the common law.

27. *Reddington v. Staten Island University Hospital*, 11 NY3d 80, 87 (2008).
28. *Reddington v. Staten Island University Hospital*, 373 F. Supp. 177, 187-188 (E.D.N.Y. 2005).
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67. *Id*. at 7.
68. *Id*. at 3 and 4.
69. *Id*.
70. *Id*. at 7.
71. *Id*. at 6.
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> The clause prohibiting retaliatory action under Section 741, however, is directed only at the employer. N.Y. Lab. Law § 741(2)... Because the prohibition against retaliatory action in Section 741 is not directed at the employer's agents, Dr. Geldzahler's claim against Dr. Morales must be dismissed.

See also: *Sulieman v. Rosewell Park Cancer Insitute*, 2007 U.S. Dist. LEXIS 46599 (W.D.N.Y. 2007) and *Sulieman v. Roswell Park Cancer Inst*., 2007 U.S. Dist. LEXIS 81283 (W.D.N.Y., 2007) wherein the court adopted the Magistrate's denial of the individual Defendant's Motion pursuant to FRCP 8 (a) to dismiss Plaintiff whistleblower claim pursuant to §741.

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Noreen DeWire Grimmick is a Registered Professional Nurse and has been in legal practice in New York and Massachusetts since 1992. She is a Partner of Hodgson Russ LLP and is assigned to the firm's Albany Office. Ms. Grimmick focuses her practice in litigation including labor and employment law, professional licensing and discipline, and medical malpractice defense

Acknowledging the Unique Needs of the Frail Elderly in Disaster Planning: A Challenge for the Nurse as Patient Advocate

By Molly Casey

In just over the past year, New York was hit by two hurricanes, Irene in August of 2011 and Sandy in November of 2012. Both of these natural disasters wreaked devastation on thousands of individuals and families whose homes lay in their paths. Irene's hurricane force winds extended outward up to 90 miles from the center and tropical storm force winds extended an additional 200 miles beyond that.[1] Several towns in upstate New York were wiped out, and the damage caused is still felt in those communities.[2] While New York City was spared the devastation that Irene's hurricane-force winds brought upon these other areas of New York State, Hurricane Sandy was not as kind.[3] Coastal areas faced record-breaking storm surges that devastated communities in and around New York City.[4] Disasters strike without warning, catching everyone off guard and without adequate time to prepare. For this reason, planning efforts must take a preventative approach. As patient advocates, nurses play a vital role in planning to meet the needs of the elderly in disaster situations.

While natural disasters pose threats to everyone within their potential danger zone and require careful planning by and for the population as a whole, certain populations require a different type and/or level of planning. The frail elderly make up one such vulnerable population. The unique characteristics of this class of people dictate the provision of special preparedness measures. This article will outline the qualities and conditions that necessitate special measures for the elderly, and address how hospitals, health care workers, especially nurses, communities, families, and individuals can establish a framework of protocols and partnerships so that the frail elderly population does not suffer increased devastation when an emergency strikes.

Acknowledging and Accounting for Challenges with Elderly Patients

Following Hurricane Katrina, about 88,000 elderly people were displaced and about half of the deaths were among people over the age of 75, despite the fact that this population made up less than 12% of New Orleans's population.[5] The average age of mortality was 69 years old.[6] Most of the deaths occurred as a result of drowning on the day of the storm, but one-third of the deaths occurred in homes.[7] The elderly also had a higher percentage of owner-occupied housing damaged than any other age group.[8] During the heat wave that struck the Midwest in 1995, the elderly suffered similarly disproportionate negative effects.[9] The oppressively hot conditions resulted in over five times the amount of heat-related deaths typical for the entire country to see in any given summer.[10] Of the 465 deaths in the city of Chicago, the median age was 75.[11] The statistics from Hurricanes Irene and Sandy were similarly troubling with respect to the elderly population. Since Hurricane Katrina, much reflection, discussion, and work has been directed toward the area of planning for the management of elderly disaster victims. Public and private departments, organizations and associations have convened and partnered to research, combine areas of expertise, and promulgate guidelines, tools, and suggestions for best practices. These resources are intended for use by hospitals, communities, and nurses and other health care providers as well as individuals, to ensure that the highest level of preparation and planning is done to minimize the negative impact that a disaster can have on the elderly, and to alleviate the potential domino reaction on other patients if care for the elderly is not given efficiently. Reports and recommendations account for the unique characteristics of the frail elderly and offer suggestions for how to best provide accommodations that will allow care following an emergency to be administered to the elderly, and to everyone, as smoothly as possible.

Elderly individuals pose unique challenges for nurses and other caregivers when an emergency situation has disrupted their lives and routines. As the advocate for the patient, the nurse plays an integral role in both preparing and executing plans in hospitals and other care facilities. The role of the nurse is to deal directly with the patient and to liaise between patient and doctor to ensure that the treatment is understood and needs are accounted for. Particularly in an emergency, the nurse is a source of comfort and support for the patient, which is of heightened importance for a frail elderly patient who is likely confused and agitated.

When an elderly individual presents for treatment and/or care in the wake of an emergency, it can be difficult to obtain an accurate history due to cognitive conditions such as delirium and dementia.[12] The omission of important details relating to other health conditions and medications is common, and names and contact informa-

tion for family members who would have access to this information are often forgotten.[13] This can be exacerbated further by diagnostic difficulties if the individual is seen by a provider who does not have training and/or experience in treating elderly patients. A provider who is unaccustomed to the subtleties in conditions affecting the aged population may be unable to account for heterogeneity among the elderly, or an atypical presentation could result in misdiagnosis.[14]

Disruption caused by a disaster can worsen existing health conditions.[15] The most common conditions among the elderly affected by Katrina were hypertension, diarrhea, diabetes and upper respiratory infection.[16] Circumstances that accompany an emergency such as stress, lack of food and water, extreme temperatures, lack of medication, disruptions in treatment and care, and exposure to infection can worsen existing health conditions, frailness, and confusion, and result in physical limitation and higher susceptibility to infection.[17] To minimize these negative effects, plans should be in place which specifically account for the elderly in terms of locating them, identifying their problems and ensuring there are sufficient resources and staff equipped to handle frail, confused, elderly patients.

Special Needs Require Specially Trained Personnel: The Importance of Staffing and Training with the Needs of the Elderly in Mind

Nearly all of the recommendations promulgated post-Katrina addressed the national shortage of geriatric specialists, and attributed the lack of expertise in dealing with elderly disaster victims to this shortage. Providers of geriatric medicine, social work, and nursing care are the best-prepared professionals to care for vulnerable adults.[18] Geriatric syndromes can render the elderly unable to access help, obtain meals, and manage their medications.[19] Many times these syndromes go undiagnosed because their symptoms may evade those not specifically trained in geriatric medicine.[20] Those professionals should have active participation in policy decisions, planning, direct care and training of front-line disaster workers.[21]

Hospitals should train nurses and other staff in the basics of geriatric care including medications, dealing with dementia, ethical and legal issues, how to communicate with elderly patients and how to deal with potentially angry responses.[22] Gerontologists, professionals who specialize in the phenomenon of aging and the problems of the aged, would be able to train nurses and staff and enable those without specific expertise to better assist elderly patients.[23] Hospitals should also take steps to identify staff members who already have training and/or expertise in dealing with the elderly, and establish coalitions of professionals from diverse fields who would work and train together.[24] New York State law requires personnel who are responsible for hospitals' accommodations in emergency situations to be trained in "all aspects of preparedness" for any disaster.[25] However, the nuances that exist in the presentation of health conditions in the elderly could easily evade any rudimentary level of training.[26] This is why hospitals should prioritize the employment of geriatric specialists and facilitate that an emphasis is placed on the specific needs and care of the elderly during any training.

There is a nascent trend in hospitals where emergency rooms designed specifically for the elderly are being installed in hospitals across the country.[27] These units allow seniors to be treated appropriately even when they present with different symptoms than a younger person, or experience confusion that renders them unable to accurately describe their condition.[28] The special senior ER zones provide a quieter and more nurturing environment and have the mutual goals of treating the problem that led the senior to the ER and uncovering underlying problems and risks that may be harmful to the senior's health.[29]

Outside of the hospital setting, simple prophylactic measures can be taken by elderly individuals and their families to mitigate issues arising from confusion and irregular presentations. For example, a portable medical record with histories and current medications would give the nurse who evaluates them following an emergency a head start in addressing their needs.[30] It is also widely suggested that primary care physicians be encouraged to identify frail, disabled and vulnerable elderly patients accordingly *prior* to a disaster.[31] By making this identification ahead of time, more prompt and effective care can be provided.

Other Addressable Considerations and Strategies in Disaster Planning

Hospitals must also be prepared to deal with difficulties that arise attendant to an influx in elderly patients with heightened needs. For example, elderly patients who enter through a hospital's emergency department may be medically sound enough for discharge, but unable to leave the hospital due to a disruption in home care or services.[32] These displaced elderly patients are "inherited" by the emergency department, which means less space and resources remain available for others.[33] This problem is exacerbated by the fact that the elderly use a disproportionate share of resources which, during an emergency, are already limited.[34] One solution is the establishment of a "soft care" unit, where elderly patients can stay until they are able to return to their homes, or find temporary or permanent shelter elsewhere in the event that their

home was destroyed.[35] Establishment of a soft care unit makes needed space within the emergency department available while ensuring that the elderly are provided with medications and assistance with activities of daily life such as eating, bathing and toileting. Nurses, both those employed by the hospital as well as volunteers, would be the primary personnel responsible for taking care of these patients' needs. Treating the ongoing needs of the elderly in a soft care unit would also allow the hospital to utilize the nurses trained in geriatrics most appropriately.

Also as part of the hospital's "disaster shelter plan," hospitals should enter into agreements with alternative care sites such as nursing homes, clinics, or inpatient hospice centers for the placement of frail elderly following a disaster.[36] These agreements should be in contract form, subject to activation upon the occurrence of an emergency.[37] This would ensure that facilities equipped with specialized need capabilities are available for the transfer of elderly patients following their initial assessment.

Under New York State law, hospitals are required to have a written plan that includes procedures to be followed for the proper care of patients and personnel in the event of any internal or external emergency, or whenever normal services are interrupted.[38] The plan must be rehearsed and updated at least twice per year.[39] Nursing homes have similar requirements including drills twice per year, and also require written policies concerning missing residents.[40] The New York State Department of Health Office of Emergency Preparedness (OHEP) coordinates and manages preparedness activities for public health as well as health care facilities.[41] OHEP ensures there are enough volunteers, pharmaceuticals, medical supplies and medical equipment by streamlining those resources that are made available through state and federal programs and coordinating their receipt as well as coordinating evacuations and placement of affected individuals.[42] To supplement the statutorily-required emergency measures, hospitals are recommended to have a specific "elderly plan" within their general hospital preparedness plan.

The New York State Department of Health (NYSDOH) works with local governments to address disaster preparedness for all kinds of situations—natural disasters, contaminations, chemical emergencies, bioterrorism, and mass casualties.[43] NYSDOH has worked with local health departments to implement plans and strategies to ensure that the response is as quick and effective as possible.[44] In 2009, each of the 57 counties outside of New York City was given a score reflecting its disaster readiness mechanisms. Scores ranged from lows of 37 in Chautaqua and 29 in Ulster to 100 in Albany, Nassau, Putnam, Rensselaer, Schoharie, and Schuyler counties.[45] In recognition of the fact that the mere *distribution* of information is insufficient for adequate preparedness on an individual level, the 57 local health departments outside of New York City were required to conduct "community engagement activities" to gather information *from* the community and incorporate their findings into their preparedness plans.[46] Among other particular issues, responding to the needs of the elderly was one important specification that was focused on during these studies for incorporation into future plans.[47] This is both a positive indication that the elderly are being considered as a distinct population with unique characteristics and unique needs that must be accounted for during an emergency, as well as a considerable shift towards actually addressing their needs, both in times of emergency and every day.

Despite the careful evaluation and planning now being done, necessity acted as the mother of invention at a time when adequate preparedness measures were not in place for large numbers of displaced elderly. Following Hurricane Katrina, evacuees were transferred to the Reliant Astrodome Complex (RAC) in Houston where they received shelter, food, medical services, clothing, and access to benefits.[48] However, there was no formal mechanism in place to ensure that frail elders received the assistance they needed with functions such as eating, bathing, toileting, medical treatment and administration of medication.[49] Many of these elderly evacuees were unable to voice their needs and did not have family members present to advocate for them.[50] Eight professionals (nurses, social workers and physicians) who served the geriatric community in Houston devised a rapid treatment plan to address these problems.[51] The "SWiFT" (Seniors Without Families Triage) tool was devised to make a quick determination as to who needed help, how quickly, and what type.[52] These professionals walked through the astrodome and engaged the seniors in conversation, asking questions from an assessment outline and filling out a form.[53] Pulse and blood pressure readings were taken for emergency treatment.[54] After two hours, the professionals reconvened to discuss what worked, modified the instrument and implemented the plan.[55] A local public-private partnership of groups involved in elder care was contacted to volunteer, and the SWiFT tool was up and running.[56]

As implemented, a doctor or a nurse would be paired with a social worker and they would identify seniors who seemed to be alone.[57] Following assessment, the senior would be placed into one of three categories.[58] Seniors who could not perform one or more activity of daily life were placed in Level One. These individuals were immediately transferred to a location able to provide skilled or personal care. Seniors who had trouble with only instrumental activities of daily life such as accessing resources, benefits, or handling finances, were assigned Level Two

status and were connected with local case managers. Seniors in Level Three simply needed to be reconnected with their family or had problems that could be solved by the Red Cross or other volunteers. These seniors were put in touch with a rescue organization service.[59]

Because of its success during the Katrina aftermath, adoption the SWiFT tool has been advocated for inclusion in other emergency plans.[60] By focusing on individuals without families, SWiFT sought to avoid separation, and to address the most vulnerable individuals and focus resources on the people most in need.[61] This tool embodied a practical strategy in the prioritization of patient's needs during a time with scarce resources. The level designations would be a valuable assessment tool for future disasters and could be made in advance of an emergency. Seniors could be placed in the appropriate level by a family member, home health nurse or physician/clinician *each year*. The three SWiFT levels could act as a universal language, and would allow needs of the elderly to be identified and treated as "swiftly" as possible. Employing SWiFT as a tool would allow nurses who are charged with emergency response to direct their attention to the patients who need nursing and/or medical care, while allowing social workers and volunteers to address other issues. Thus seniors would have better, and more appropriate, care and any mismanagement of valuable staff resources would be avoided.

Staff Shortages and Volunteer Liability

Problems with a potential shortage of staff can be addressed through deployment of a pre-established volunteer force.[62] Both non-clinical staff as well as community volunteers can assist during an emergency.[63] However, a policy should be in place ahead of time which addresses issues surrounding liability as well as measures to ensure that volunteers are equipped and trained to deal with the challenges posed by emergency situations. Liability concerns are heightened when dealing with the frail elderly, as death rates are higher.[64] Concerns are further exacerbated when a health care worker or volunteer is acting in an unfamiliar environment or performing an unfamiliar procedure, out of necessity.

Under common law tort principles, a volunteer acting in good faith can still face liability by undertaking a duty to rescue. However, statutes have been enacted at the state and federal level that address these liability issues so that individuals are no longer discouraged from rendering aid. The liability faced, and protection offered for a volunteer, depend on what type of volunteer the individual is acting as.[65] Community volunteers who are affiliated with a government or organization are generally protected by statute.[66] The Volunteer Protection Act of 1997 (VPA) generally limits volunteer liability to gross negligence when the volunteer is affiliated with an organization.[67] Accordingly, pursuant to this federal law, if a volunteer is acting with ordinary care while rendering medical treatment at the scene of an accident or emergency, he or she may not be liable in negligence for any act or omission that occurs during the rescue. This act preempts state law to the extent that additional liability cannot be placed *on* a volunteer covered under the VPA; however, greater *immunity from* liability can be provided for under state law.

Liability for "Good Samaritans," volunteers who are largely unaffiliated and acting independently, can be reduced or eliminated by a Good Samaritan statute. New York's Good Samaritan law limits the liability that an unaffiliated rescuer can face to instances of gross negligence and in effect extends the VPA to rescuers who are not working under an organization.[68] In New York, a "Good Samaritan" includes a health care professional who acts outside of a medical office and without proper and necessary medical equipment.[69] It is also important to note that the "Good Samaritan" must be a true volunteer, and acting without expectation of monetary compensation.[70]

Other classes of volunteer, such as trained groups that are organized and deployed as emergency responders receive protection from emergency management statutes such as the Emergency Management Assistance Compact.[71] The Emergency Management Assistance Compact (EMAC) was the first national disaster relief compact to be ratified by Congress since 1950.[72] EMAC provides for mutual cooperation between the states in the management of an emergency or disaster such that the compact is activated when a governor calls a state of emergency and its provisions govern the assistance given by other states.[73] New York's Emergency Management Assistance Compact exists in within Article 2-B of the Executive Law.[74] All fifty states, Washington, D.C., Puerto Rico and all United States territorial possessions have adopted the compact and the provisions are consistent throughout.[75] The liability section of the law provides that officers/employees of the rendering state who are in another state pursuant to the compact are treated as agents of the requesting state for the purposes of tort liability and immunity and acts and omissions in good faith do not subject the agent to liability.[76]

Additionally, New York has enacted an intrastate mutual assistance program which provides the same type of cooperation as EMAC between municipalities within the state.[77] Respecting liability, an agent of a local government is provided with the same immunities and privileges as if such duties were performed within his or her home jurisdiction, and a providing local government is liable for the negligence of its employees in accordance with their home jurisdiction. [78]

The most serious liability issues fall on emergency volunteers who are unaffiliated but organized, as well as non-governmental organizations that assist spontaneously during a disaster.[79] New York's Good Samaritan law alleviates some liability issues by the inclusion of physicians, dentists, nurses, physical therapists and registered physicians assistants.[80] Additionally, the New York State Department of Health has endorsed the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standard that allows privileges to be granted to medical staff in disaster situations.[81] This standard provides for credentialing when an emergency plan has been activated in the hospital, which allows medical staff to volunteer at other facilities with decreased or eliminated concerns over liability and licensure portability.[82] The ServNY program, under the NYSDOH, allows medical personnel to register in advance of an emergency for volunteer service.[83] By virtue of their enrollment in this state-sponsored volunteer program, if they are called upon during an emergency the protections provided under the law for indemnification of state officers and officials apply to them.[84]

Making Difficult Choices Before They Need to Be Made: The Importance of Planning to Avoid Ethical Dilemmas

Ethical considerations also occur with greater frequency during an emergency. Allocation of scarce resources can pose ethical predicaments for providers. Times of emergency and disaster are generally accompanied by shortages in staff, equipment and medications. The elderly require a disproportionate share of resources and also are the least resilient, and the least capable of going without care and medications that are in short supply. While steering resources towards the neediest patients is one school of thought, the opposing argument advances the position that these same resources should be directed towards the patients who have a greater chance of survival.[85] It is not formally advocated that caregivers consider age in these appropriations; it is likely that age discrimination does occur.[86] It is therefore wise to establish strategies and protocols ahead of time that deal with these issues. Prioritizing patient care, even in the hypothetical, is a formidable task that evokes much debate. However, it is preferable that these difficult decisions be made when the decision-makers have clear heads and are able to engage in thoughtful debates and reach compromises, which is unlikely in the frenzied environment following a disaster.

Other ethical considerations that would benefit from advance examination are those surrounding life-sustaining measures. The New York Court of Appeals has held that decisions to withhold life-sustaining treatment are subject to a "clear and convincing" standard, which requires "proof sufficient to persuade the trier of fact that the patient held a firm and settled commitment to the termination of life supports under the circumstances like those presented."[87] This is an exacting standard, and the wishes of the patients should be unequivocally declared while they have capacity to avoid ambiguity.

The New York State Health Law provides for a hierarchy of surrogate decision makers with respect to "do not resuscitate" orders.[88] This allows a statutorily enumerated list of people to consent to withholding cardiopulmonary resuscitation for an incapacitated patient.[89] Even though the list is exhaustive, naming "a close friend" as the last surrogate, during an emergency it could be difficult to track relatives and friends, especially for an elderly patient who presented alone.[90]

Respecting other treatments, the New York Health Law provides several conditions which when met allow a surrogate to decide whether to withhold treatment for an incapacitated patient.[91] One of these two conditions must be met to satisfy the statute: (1) the treatment must be a substantial burden for the patient *and* either the patient is not expected to live longer than six months with or without treatment or the state of unconscious is permanent, or (2) the treatment would be extraordinarily burdensome or inhumane.[92] These conditions are not clear-cut and do not ease the process of determining whether to sustain the patient or withhold treatment. This hardship is necessarily worsened when hospitals are dealing with the large influx of patients that occurs during a disaster. Health Care Proxy forms are encouraged so that these decisions can be made by a designated agent with capacity and the burden on the health care provider is lifted.[93] Hospitals should also have policies in place that accurately interpret the law in order to legally and efficiently deal with situations where there is no health care proxy, or the agent cannot be located.

Ventilator allocation is an additional consideration. Due to a shortage in ventilators, as well as a shortage in staff members who are able to administer ventilators, hospitals could be forced to decide which patients will receive ventilator support and which patients will not.[94] The New York State Task Force on Life and the Law has undertaken the responsibility of drafting uniform guidelines on this issue to lessen the burden on hospitals in making these choices.[95] The Task Force's report is currently in the public comment phase and is expected to be revised based on input from the health care community and the general population.[96] While not expressly age-based, current guidelines do include exclusion criterion that account for certain end-stage illnesses such as dementia.[97] The task force, chaired by the New York State Commissioner of Health, Nirav Shah, M.D., M.P.H., is composed of experts and leaders in all applicable fields

including nursing, bioethics, religion, law, medicine and philosophy.[98] The comprehensive makeup of the task force allows considerations and concerns to be viewed from many, sometimes conflicting, angles. This diverse group is also qualified to take all interests into account in formulating the guidelines, which enables difficult debates to be settled fairly.

Conclusion

This article only scratches the surface of this multifarious issue. As life expectancies increase, the senior and frail elderly populations rise. Accounting for the needs of this population involves constant modifications to ensure that they receive the care they need, as well as considerations of the impact that their care has on others, including availability of resources for the non-elderly, as well as the treating nurses and other health care workers and volunteers. Natural disasters and other emergencies catch everyone off guard and inherent vulnerabilities in certain populations are exacerbated and can be difficult to navigate. The old adage "prevention is the best medicine" is particularly appropriate here. While we may not be able to prevent emergency situations, we can have plans in place at all levels of government, within hospitals, and at home—that serve to prevent additional complications and unfavorable outcomes. Nurses play a vital role in developing plans to address the unique needs of the elderly in disaster situations. We must learn from each disaster what measures worked and what went wrong, therefore improving disaster planning and saving the most vulnerable elderly from preventable morbidity and even death in these stressful situations.

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69. *Id*.
70. *Id*.
71. Emacweb.org, EMAC Legislation, http://www.emacweb.org/ (accessed December 27, 2012).
72. *Id*.
73. *Id*.
74. N.Y. EXEC. LAW §29(e) (McKinney).
75. *See* Emacweb.org, *supra* note 71.
76. N.Y. EXEC. LAW. §29(e) (McKinney).
77. N.Y. EXEC. LAW §29-h(10) (McKinney).
78. *Id*.
79. VOLUNTEER LIABILITY GUIDE, *supra* note 65.
80. N.Y. PUB. HEALTH LAW §3000-a (McKinney).
81. Letter from the Greater New York Health Association to New York State Hospital Chief Executive Officers, (July 13, 2004), *available at* www.gnyha.org/344/File.aspx (accessed Dec. 15, 2012).
82. *Id*.
83. N.Y.S. DEP'T OF HEALTH, SERVNY- NEW YORK STATE'S VOLUNTEER PROGRAM, *available at https://apps.nyhealth.gov/vms/appmanager/vms/public* (accessed Dec. 15, 2012).
84. N.Y. PUB. OFF. Law §17 (McKinney).
85. UMIAMI ETHICS PROGRAMS, GERIATRICS: ACCESS TO CARE AND ALLOCATING SCARCE RESOURCES, *available at* http://Miami.edu/index.php/ethics/projects/…/access_to_care_and_allocating_scare_resources/ (accessed Dec. 13, 2012).
86. AHRONHEIM, et al., *supra* note 14 at 105.
87. Matter of Westchester County Medical Center on Behalf of O'Connor, 72 N.Y.2d 517, 531 (1988).
88. N.Y. PUB. HEALTH LAW §2965 (McKinney).
89. *Id*.
90. *Id*.
91. N.Y. PUB. HEALTH LAW §2994-d(5) (McKinney).
92. *Id*.
93. AHRONHEIM, et al., *supra* note 14 at 11.
94. N.Y.S. DEP'T OF HEALTH, FREQUENTLY ASKED QUESTIONS – PROPOSED POLICY ON ALLOCATION OF VENTILATORS IN AN INFLUENZA PANDEMIC, *available at* http://www.health.ny.gov/diseases/communicable/influenza/pandemic/ventilators/faq.htm (accessed Dec. 16, 2012).
95. N.Y.S. DEP'T OF HEALTH, TASK FORCE ON LIFE IN THE LAW, *available at* http://www.health.ny.gov/regulations/task_force/ (accessed Dec. 16, 2012).
96. *Id*.
97. AHRONHEIM, et al., *supra* note 14 at 106.
98. *Id*.

Ms. Casey is an associate attorney in the law firm of Thuillez, Ford, Gold, Butler & Monroe, LLP in Albany, NY.

Nurse Practitioner Practice in New York State

By Melissa M. Zambri and Margaret Surowka Rossi

Introduction

Over 17,000 nurse practitioners provide valuable primary care services all across New York State.[1] The rules which govern services provided by nurse practitioners can be complex and counterintuitive. This article seeks to highlight some of those rules and explain the framework by which nurse practitioners may practice in New York State.

Scope of Practice

The scope of practice of a nurse practitioner is provided in Article 139, section 6902(3)(a) of the Education Law as follows:

> The practice of registered professional nursing by a nurse practitioner, certified under section six thousand nine hundred ten of this article, may include the diagnosis of illness and physical conditions and the performance of therapeutic and corrective measures within a specialty area of practice, in collaboration with a licensed physician qualified to collaborate in the specialty involved, provided such services are performed in accordance with a written practice agreement and written practice protocols. The written practice agreement shall include explicit provisions for the resolution of any disagreement between the collaborating physician and the nurse practitioner regarding a matter of diagnosis or treatment that is within the scope of practice of both. To the extent the practice agreement does not so provide, then the collaborating physician's diagnosis or treatment shall prevail.

As such, while a nurse practitioner in New York State may only actively practice once a collaborative agreement with a physician is in effect, a nurse practitioner is not under the supervision of the collaborator. Thus, while not completely independent, due to the collaborative agreement requirement, nurse practitioners are responsible for their own diagnoses and other service provision. They can be sued and can have professional disciplinary actions brought against their licenses, independent of physician involvement.[2]

While nurse practitioners can diagnose illness and prescribe treatment, their practice is limited to a specialty area that is determined by their educational preparation and stated on their State-issued certificate to practice. Similar to any other health care provider, nurse practitioners may not undertake a particular procedure unless there has been adequate training and competence in the procedure. Nurse practitioners face potential tort liability under the same rules as other health care providers. The law continues to evolve as the standards of patient care continue to develop, expert witnesses become more heavily used, and courts attempt to determine the standards of care for collaboration, consultation and referral.[3]

The Collaborative Agreement

A nurse practitioner must have a collaborative agreement with one physician prior to beginning practice and maintain that agreement in the practice setting(s) where it must be available for inspection by the New York State Education Department. New practitioners are also required to submit Form 4NP-Verification of Collaborative Agreement and Practice Protocol only once to the New York State Education Department's Office of the Professions no later than 90 days after beginning professional practice. The collaborative agreement must include provisions for referral and consultation, coverage for absences of either the nurse practitioner or the collaborating physician, resolution of disagreements between the nurse practitioner and the collaborating physician regarding matters of diagnosis and treatment, the review of a representative sample of patient records every three months by the collaborating physician, record keeping provisions and any other provisions jointly determined by the nurse practitioner and the physician to be appropriate.[4] The name of the nurse practitioner and the collaborating physician must be clearly posted in the practice setting of the nurse practitioner.[5] Physicians are limited to entering into collaborative agreements with no more than four nurse practitioners who are not located on the same physical premises as the collaborating physician.[6]

For nurse practitioners participating in Medicaid, the collaborating physician must also be enrolled in the New York State Medicaid Program and not be excluded from participation in Medicare or Medicaid. "If the collaborating physician becomes excluded from Medicaid, the collaborative agreement is considered terminated for purposes of the Medicaid Program."[7] When a collaborative agreement is terminated with the physician, the nurse practitioner and the collaborating physician must notify the Medicaid Program of the effective date of termination

and the nurse practitioner must advise the Medicaid Program of any new agreement and effective date.[8]

Collaborative physicians are responsible for chart reviews which seek to ensure that the practice of the nurse practitioner reflects accepted standards of medical practice within the appropriate scope of specialty practice. Patient records must be reviewed by a nurse practitioner's collaborating physician according to Section 6902(3)(c) of the New York State Education Law, which states that:

> Each practice agreement [between a nurse practitioner and physician] shall provide for patient records review by the collaborating physician in a timely fashion but in no event less often than every three months.

The law does not specify ratios or numbers of charts that must be reviewed by the collaborating physician, but instead leaves such issues to the professional judgment of the parties. Guidance from the New York State Education Department advises that the number may vary depending on a number of variables such as: the nurse practitioner's level of experience; the collaborating physician's knowledge of the nurse practitioner's abilities and judgment; specialty; patient mix; the nature of the practice setting; and other factors. Regulators expect that the physician will have readily available a system that will permit retrospective, quarterly verification of documentation indicating that these elements of practice have been satisfied.[9] It is important that the nurse practitioner and the physician determine the appropriate terms of the collaboration through negotiation and agreement. The appropriateness of the process of patient record review might be considered in professional discipline, malpractice litigation, or in institutional internal reviews, for example, those in an Article 28 facility.[10]

The requirements make for some interesting questions surrounding the necessity of a collaborative physician. For example, the New York State Education Department has offered guidance on a number of issues related to the death of a collaborator, vacations and illnesses of a collaborator and the necessity of a collaborator signing orders and charts.[11] Plaintiffs have made attempts to sue physicians for a failure to adequately collaborate with a nurse practitioner.[12]

Compensation of a collaborating physician has been the subject of much confusion and discussion. Part 29 of the New York State Education Regulations describes a variety of circumstances that may be considered professional misconduct. 8 NYCRR § 29.1(b)(3) states that unprofessional conduct shall include kickbacks, "directly or indirectly offering, giving, soliciting, or receiving or agreeing to receive, any fee or other consideration to or from a third party for the referral of a patient or client or in connection with the performance of professional services." The New York State Education Department Office of the Professions has interpreted this rule, within the context of nurse practitioner practice, to mean that a nurse practitioner may pay a collaborating physician the fair market value of services legitimately provided, such as chart review and consultation. Says the Department, "However, there is no compulsion for the nurse practitioner to enter into such an arrangement, nor is it appropriate to include such terms within the written collaborative agreement." Given that referrals could potentially go in either direction, we would recommend fair market value, flat fee payments. When a payment agreement does exist, the payment may not influence the nature of the chart review nor result in any exclusive arrangement between the nurse practitioner and physician for patient referrals in exchange for the services rendered. It is understood that in certain instances nurse practitioners may refer patients to their collaborating physicians when medically necessary. Such instances would not automatically be considered professional misconduct unless a nurse practitioner binds himself or herself into an exclusive arrangement for referrals to the collaborating physician or otherwise gives or receives compensation for such referrals.[13]

Part 29 of the New York State Education Regulations also considers fee-splitting to be professional misconduct. 8 NYCRR § 29.1(b)(4) states that "unprofessional conduct shall include permitting any person to share in the fees for professional services, other than: a partner, employee, associate in a professional firm or corporation, professional subcontractor or consultant authorized to practice the same profession, or a legally authorized trainee practicing under the supervision of a licensed practitioner. This prohibition shall include any arrangement or agreement whereby the amount received in payment for furnishing space, facilities, equipment or personnel services used by a professional licensee constitutes a percentage of, or is otherwise dependent upon, the income or receipts of the licensee from such practice." As such, we recommend that the compensation for a collaborating physician be a flat monthly amount based on the services provided and not be in any way related to a percentage of the fees paid for professional services provided by the nurse practitioner.

Structure of Practice

The means by which health professionals can independently or jointly practice in New York State often frustrate nurse practitioners trying to structure their independent practice. In New York, an individual practitioner, professional partnership, professional corporation, professional limited liability partnership, and professional limited liability company are all authorized to offer

professional services. In certain circumstances, such as in the New York Partnership Law[14] and Article 15 of the Business Corporation Law covering Professional Corporations,[15] the owners must practice in the same profession. Professional Limited Liability Companies, in certain cases, may offer multi-disciplinary services with certain exceptions, one being the practice of medicine.[16] As such, a physician and nurse practitioner cannot co-own a practice. These rules, combined with laws prohibiting fee splitting,[17] often make the structure of physician/nurse practitioner arrangements confusing for providers, as in many cases they would involve two separate practices, a lease or sublease and payments that must satisfy fair market value requirements,[18] kickback safe harbors[19] and regulatory guidance regarding leases of space.[20]

In addition, sometimes the simple act of choosing a name for a practice can prove difficult. The proposed name of the corporation must appropriately describe the profession or professions practiced and the services to be provided and may not be false, fraudulent, deceptive or misleading.[21] Names must be approved by the New York State Department of Education, who has in numerous cases required the name of a nurse practitioner practice to include the phrase "nurse practitioner" or "NP." In addition, in some instances, the Education Department has required the nurse practitioner to indicate the approved specialty area in the name itself.

Conclusion

Nurse practitioners provide valuable health services in many specialties across New York State. The laws which govern practice of this important profession oftentimes discourage nurse practitioners from entering private practice. However, there are many successful private nurse practitioner practices across New York State and with research and careful consideration, nurse practitioners will find that they indeed can work through much of the legalese to work toward a successful practice.

Endnotes

1. N.Y. State Educ. Dep't Office of the Professions, *License Statistics*, NYSED.GOV (July 2, 2012), http://www.op.nysed.gov/prof/nurse/nursecounts.htm.
2. N.Y. STATE EDUC. DEP'T OFFICE OF THE PROFESSIONS, NURSING GUIDE TO PRACTICE, 45 (Apr. 2009) [hereinafter "NURSING GUIDE TO PRACTICE"], *available at* http://www.op.nysed.gov/prof/nurse/nurse-guide-april09.pdf.
3. *See* Hanson-Turton, Ware & McClellan, *Nurse Practitioners in Primary Care*, 82 TEMP. L. REV. 1235, 1251 (2010).
4. N.Y. COMP. CODES R. & REGS. Tit. 8, § 64.5(b) (2012) [hereinafter NYCRR].
5. N.Y. EDUC. LAW § 6902(3)(c).
6. *Id.* § 6902(e).
7. N.Y. STATE MEDICAID PROGRAM, NURSE PRACTITIONER MANUAL POLICY GUIDELINES 3 (2006), *available at* http://www.emedny.org/ProviderManuals/NursePractitioner/PDFS/Nurse_Practitioner_Policy_Guidelines.pdf.
8. *Id.* at 3-4.
9. NURSING GUIDE TO PRACTICE, *supra* note 2, at 45.
10. NURSING GUIDE TO PRACTICE, *supra* note 2, at 47.
11. NURSING GUIDE TO PRACTICE, *supra* note 2, at 19-20.

    Can a Nurse Practitioner (NP) continue working when the collaborating physician is on vacation or out due to a prolonged illness? Answer: Yes. The collaborator can designate a resource person to be available to the nurse practitioner as needed during the collaborator's absence. It is best if the resource person is named in the collaborative agreement if the absence is prolonged. **Can a Nurse Practitioner (NP) who has a collaborative agreement with a collaborator continue working if the collaborator dies? Answer:** No. The law requires that there be an active collaborative agreement in place for the Nurse Practitioner to practice. If there is already a designated resource physician for vacations and illness, that physician could agree to become the official collaborator. **Must the collaborating physician co-sign the Nurse Practitioner's (NP) orders and charts? Answer:** No. Nurse practitioners (NPs) do not function under the supervision of physicians—they function in collaboration with physicians. Nurse practitioners are independently responsible for the diagnosis and treatment of the patients that they serve. We do not recommend co-signatures as it transfers responsibility of the care from the NP to the physician.
12. Hytko v. Hennessey, 62 A.D.3d 1081, 1084 (3d Dep't 2009).
13. NURSING GUIDE TO PRACTICE, *supra* note 2, at 46.
14. N.Y. P'SHIP LAW § 121-1500.
15. N.Y. BUS. CORP. LAW § 1503.
16. N.Y. LTD. LIAB. CO. LAW § 1203.
17. N.Y. EDUC. LAW § 6509-a; 8 NYCRR § 29.1(b)(4).
18. *See* N.Y. PUB. HEALTH LAW § 238(2).
19. 42 C.F.R. 1001.952(b).
20. Publication of OIG Special Fraud Alert on Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer, 65 Fed. Reg. 37,9274 (Feb. 24, 2000), *available at* https://oig.hhs.gov/authorities/docs/fraudalert.pdf.
21. 8 NYCRR § 29.1(b)(12)(i)(a).

Ms. Zambri is a partner in the Albany Office of Hiscock & Barclay, LLP and the Chair of the Firm's Health Care and Human Services Practice Area, focusing her practice on enterprise development and regulatory guidance for the health care industry. She is also an Adjunct Professor of Management at the Graduate College of Union University, teaching Legal Aspects of Health Care.

Ms. Rossi is counsel in the Albany Office of Hiscock & Barclay, LLP, focusing her practice on regulatory guidance and defense of health care practitioners in disciplinary matters. She also represents health care clients on employment and personnel matters and lectures on the professional and ethical obligations of health care providers.

The Role of Nurses in Securing Patient Informed Consent

By Daisy Ford Paglia

The doctrine of informed consent is a fundamental principle underlying the delivery of health care. In 1914, Judge Benjamin Cardozo declared in *Schloendorff v. Society of the New York Hospital* that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body."[1] Since 1975, the cause of action for lack of informed consent has been codified in New York.[2] Therefore, all health care providers, including nurses, should be aware of their obligations with respect to securing patient informed consent.

Analysis begins with the text of the informed consent statute:

> Lack of informed consent means the failure of *the person providing the professional treatment or diagnosis* to disclose to the patient such alternatives thereto and the reasonably foreseeable risks and benefits involved as *a reasonable medical, dental or podiatric practitioner* under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation (emphasis added).[3]

The cause of action for lack of informed consent "is limited to those cases involving either (a) non-emergency treatment, procedure or surgery, or (b) a diagnostic procedure which involved invasion or disruption of the integrity of the body."[4] In these situations, the statute places the responsibility to obtain informed consent on "the person providing the professional treatment or diagnosis." The statute requires the disclosure of risks and benefits that "a reasonable medical, dental or podiatric practitioner under similar circumstances would have disclosed." Thus, the statute clearly makes doctors, dentists and podiatrists liable for providing professional treatment or diagnosis without informed consent.

The statute does not expressly refer to nurses, and there is relatively little case law in New York examining the role of nurses in obtaining informed consent. In *Hoffson v. Orentreich*, the plaintiff alleged that a nurse employed at her dermatologist's office negligently, and without informed consent, performed an incision and drainage of three acne cysts and removal of blackheads on plaintiff's face.[5] The jury found that the nurse did not obtain informed consent, but that a reasonable person would not have refused to consent if the risks and benefits had been properly disclosed. The plaintiff moved to set aside this finding on the ground that a physician had not attempted to obtain informed consent. The court denied this portion of the plaintiff's post-trial motion, reasoning that "[n]othing in Public Health Law § 2805-d expressly precludes the use of an agent to provide information to a patient and to obtain the patient's consent."[6]

The court in *Hoffson* noted that there was no New York case law directly on point. However, the court read *Brandon v. Karp* to suggest "that if a nurse were to provide improper information in the course of obtaining the necessary consent, the result would be to make her principal liable under the statute."[7] In *Brandon*, the plaintiff was admitted to the hospital for spinal meningitis, an ear infection and hearing loss.[8] She was transferred to the care of Dr. Harrison M. Karp, an ear, nose and throat specialist, who told her that he would perform a sinus wash. A nurse employed by the hospital obtained and witnessed the plaintiff's signature on a consent form. In error, the nurse informed the plaintiff that the sinus wash would be performed via her ear. However, when Dr. Karp came to the plaintiff's room to perform the procedure, he advised her that the procedure would be performed through her nose, and she voiced no objections. The court dismissed the plaintiff's action against the hospital for lack of informed consent, which was premised on the nurse's provision of incorrect information when obtaining written consent. The court reasoned that the statute "makes only 'the person providing the professional treatment or diagnosis' liable for his failure to make proper disclosure."[9] Here, Dr. Karp provided the professional treatment, and he was not a hospital employee.

The sparse case law does not definitively resolve whether a nurse can be held liable under Public Health Law § 2805-d for lack of informed consent. Based on the statutory definition of the practice of nursing, a nurse could theoretically be identified as "the person providing the professional treatment or diagnosis." Education Law § 6902(1) defines the practice of a registered professional nurse as:

> diagnosing and treating human responses to actual or potential health problems through such services as casefinding, health teaching, health counseling, and provision of care supportive to or restorative of life and well-being, *and executing medical regimens prescribed by a licensed physician, dentist or other licensed health care provider* legally authorized under this title and in accordance with the commissioner's regulations (emphasis added).[10]

The practice of nursing by a nurse practitioner is more expansive and may include:

> the diagnosis of illness and physical conditions and the performance of therapeutic and corrective measures within a specialty area of practice, in collaboration with a licensed physician qualified to collaborate in the specialty involved, provided such services are performed with a written practice agreement and written practice protocols.[11]

Moreover, a nurse practitioner may issue "[p]rescriptions for drugs, devices and immunizing agents."[12] Under New York law, a claim for lack of informed consent can be premised on the prescription of medication.[13]

Regardless of their potential direct liability under Public Health Law § 2805-d, nurses and nurse practitioners have a vital role to play in securing patient informed consent. Frequently, they will be called upon to witness their patients' signatures on consent forms. (The statute does not mandate written consent, but documentation of consent, especially for major procedures, is prudent.) In a hospital or office setting, patients may turn to nurses when they have lingering questions about a procedure or treatment for which consent is required. Such questions may prompt a nurse to advise the treating physician that additional discussion of risks and benefits with the patient is warranted. Thus, all nurses and nurse practitioners should be aware of the following basic principles underlying the doctrine of informed consent:

When Is Consent Required?

The statute provides that a claim for lack of informed consent (which is a species of medical malpractice) "is limited to those cases involving either (a) non-emergency treatment, procedure or surgery or (b) a diagnostic procedure which involved invasion or disruption of the integrity of the body."[14] Thus, informed consent is not required in emergency situations.[15] Moreover, a cause of action for lack of informed consent will not lie unless "the wrong complained of arose out of some affirmative violation of plaintiff's physical integrity."[16]

The statute identifies four other situations in which a medical provider is not required to obtain the patient's informed consent:

> (a) the risk not disclosed is too commonly known to warrant disclosure; or
>
> (b) the patient assured the medical, dental or podiatric practitioner he would undergo the treatment, procedure or diagnosis regardless of the risk involved, or the patient assured the medical, dental or podiatric practitioner that he did not want to be informed of the matters to which he would be entitled to be informed; or
>
> (c) consent by or on behalf of the patient was not reasonably possible; or
>
> (d) the medical, dental or podiatric practitioner, after considering all of the attendant facts and circumstances, used reasonable discretion as to the manner and extent to which such alternatives or risks were disclosed to the patient because he reasonably believed that the manner and extent of such disclosure could reasonably be expected to adversely and substantially affect the patient's condition.[17]

Capacity to Consent

New York law presumes that adults are competent to make decisions about their medical treatment.[18] However, situations will arise in which a patient is not capable of giving informed consent for treatment. Health care providers must then determine who is authorized to consent on behalf of the patient. Some patients will have planned for their incapacity by executing a health care proxy. A health care proxy appoints an agent to make health care decisions for an individual when he or she no longer has capacity to do so.[19] The determination that a patient lacks capacity to make health care decisions, which triggers the agent's authority, is made by the attending physician.[20] Although they cannot independently make the official determination of incapacity, nurses certainly could provide the physician with valuable information about the patient's condition to assist in the determination. Moreover, the statute expressly states that the agent shall make health care decisions after consulting with one of several health care providers, including a registered nurse.[21]

Nurses should be aware of other statutory commands with respect to patients who have executed a health care proxy. Any health care provider who is provided with a health care proxy must arrange for the document to be inserted in the patient's medical record.[22] Health care providers are also required to comply with health care decisions made in good faith by the agent.[23] Moreover, a competent adult may revoke a health care proxy by notifying a health care provider, and "[a]ny member of the staff of a health care provider informed of or provided with a revocation of a health care proxy…shall immediately notify a physician of such revocation."[24]

A relatively new statute, the Family Health Care Decisions Act,[25] authorizes surrogates (family members and close friends) to make health care decisions for patients who lack decision-making capacity, did not execute a health care proxy and did not previously indicate their treatment wishes. The law applies to patients in hospitals and nursing homes, as well as to decisions regarding hospice care, regardless of where the decision is made or the care is provided.[26] In these situations, the initial determination that an adult patient lacks decision-making capacity is made by the attending physician.[27] Sometimes, a concurring determination that a patient lacks decision-making capacity by "a health or social services practitioner"—a term which includes a registered professional nurse and a nurse practitioner—is required.[28] For example, in nursing homes, all such determinations are subject to an independent concurring determination by a health or social services practitioner formally affiliated with the facility.[29] In general hospitals, a concurring determination is required only if the surrogate's decision concerns the withdrawal or withholding of life-sustaining treatment.[30]

Process for Informed Consent

The process involves two steps: (1) providing sufficient information so that the patient can make an informed decision and (2) obtaining consent. With respect to a particular treatment, the statute requires disclosure of "such alternatives thereto and the reasonably foreseeable risks and benefits involved as a reasonable medical, dental or podiatric practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation."[31] Thus, the law calls upon the person providing the treatment to make a reasoned judgment as to what information is required to enable to patient to make an informed decision. The scope of disclosure will vary with the complexity of the procedure and the patient's level of understanding. It is important for health care providers to carefully document the information provided prior to obtaining the patient's consent.

Nurses are frequently called upon to witness the patient's signature on a consent form. Although a nurse acting as a witness is not legally obligated to disclose risks and benefits with the patient, nurses should be attuned to any indication that the patient is not fully informed. They have to judge whether it should be brought to the treating provider's attention that the patient requires more information.

As outlined above, nurses play a critical role in securing patient informed consent. All nurses and other allied health professionals should be thoroughly trained in the law of informed consent and provided with policies and procedures. This proactive approach protects the right of patient self-determination and can also reduce health care providers' liability under the informed consent statute.

Endnotes

1. 211 N.Y. 125, 129 (1914).
2. *See* Public Health Law § 2805-d.
3. *Id.* § 2805-d(1).
4. *Id.* § 2805-d(2).
5. 144 Misc. 2d 411, 412-413 (Sup. Ct., N.Y. County 1989).
6. *Id.* at 414.
7. *Id.*
8. 112 A.D.2d 490, 491 (3d Dep't 1985).
9. *Id.* at 492-493.
10. A "nursing diagnosis" should not be confused with a medical diagnosis.
11. Education Law § 6902(3)(a).
12. Education Law § 6902(3)(b).
13. *See Kuperstein v. Hoffman-Laroche, Inc.*, 457 F.Supp.2d 467, 472 (S.D.N.Y. 2006).
14. Public Health Law § 2805-d(2).
15. *See, e.g., Connelly v. Warner*, 248 A.D.2d 941, 942 (4th Dep't 1998) ("The surgery herein was of an emergency nature, and thus there is no cause of action based on lack of informed consent.").
16. *Iazzetta v. Vicenzi*, 200 A.D.2d 209, 213 (3d Dep't 1994).
17. *See* Public Health Law §2805-d(4).
18. *See* Public Health Law §§ 2994-c(1), 2981(1)(b).
19. *See* Public Health Law § 2981(4).
20. *See* Public Health Law § 2983(1).
21. *See* Public Health Law § 2982(2).
22. *See* Public Health Law § 2984(1).
23. *See* Public Health Law § 2984(2).
24. Public Health Law § 2985(1)(a), (2)(b).
25. *See* Public Health Law Article 29-CC.
26. *See* Public Health Law § 2994-b(1).
27. *See* Public Health Law § 2994-c(2).
28. *See* Public Health Law §§ 2994-c(3), 2994-a(17).
29. *See* Public Health Law § 2994-c(3)(b)(i).
30. *See* Public Health Law § 2994-c(3)(b)(ii).
31. Public Health Law § 2805-d(1).

Ms. Paglia is of counsel to the law firm of Thuillez, Ford, Gold, Butler & Monroe, LLP in Albany, NY.

New Officers Elected

At the Section's Annual Meeting, the following officers were elected for one-year terms beginning June 1, 2013:

Chair:	**Kathleen M. Burke** NY Presbyterian Hospital
Chair-Elect:	**Margaret J. Davino** Kaufman Borgeest & Ryan, LLP
Vice- Chair:	**Kenneth R. Larywon** Martin Clearwater & Bell, LLP
Secretary:	**Raul A. Tabora, Jr.** Bond Schoeneck & King
Treasurer:	**Lawrence R. Faulkner** ARC of Westchester

Kathleen Burke is Vice President—Board Relations, Secretary and Counsel to New York Presbyterian Hospital, and has been with that institution since 1998. Previously, Ms. Burke was Secretary and Counsel to New York Hospital. Ms. Burke is a longstanding member of the Health Law Section. She chaired the Committee on Ethical Issues in Health Care for several years, and organized several of the Section's programs.

Upcoming Events

- *Fall 2013 Section Retreat:* The Section's Executive Committee is in the process of planning its Fall 2013 Retreat. For more information about upcoming events, go to nysba.org and click on Events.

Recent Events

- *Annual Meeting (January 23, 2013, NYC):* The program at the Annual Meeting covered a range of current health law topics, including:
  - Health IT Update: Key Impediments to HITECH implementation and the View Ahead towards 2014
  - Two Currrent Issues in Legal Ethics: Rules for Internal Investigations and a Template for Avoiding Conflict
  - New York Health Planning, Certificate of Need and Governance Reforms
  - New York State Limits on Executive Compensation and Proposed Regulations
  - Accountable Care Organizations (ACOs): Regulatory and Strategic Issues and Implementation Challenges
  - Medical Indemnity Fund Update and Impact on Settlements
  - New York's Health Insurance Exchange and Its Impact on Providers, Payers, and Employers.

The program was co-chaired by Kathleen Burke of NY Presbyterian Hospital, Margaret Davino of Kaufman, Borgeest & Ryan, and Julia Goings-Perrot of Tarshis Catania.

- *HITECH for Lawyers*. This program on the Health Information Technology for Economic and Clinical Health (HITECH) Act was held on Dec. 7. Program Chair: Raul A. Tabora, Jr. of Bond Schoenbeck & King, Albany.

Further information about upcoming programs is always available at www.nysba.org/health. Just click on "Events."

Section Committees and Chairs

he 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.

E-Health and Information Systems
Raul A. Tabora Jr.
Bond, Schoeneck & King PLLC
111 Washington Avenue, 5th Floor
Albany, NY 12210
rtabora@bsk.com

Ethical Issues in the Provision of Health Care
Lawrence R. Faulkner
Arc of Westchester
265 Saw Mill River Road, 3rd Floor
Hawthorne, NY 10532
lfaulkner@westchesterarc.org

Fraud, Abuse and Compliance
Melissa M. Zambri
Hiscock & Barclay LLP
80 State Street
Albany, NY 12207-2207
mzambri@hblaw.com

Robert A. Hussar
Manatt Phelps & Phillips
30 South Pearl Street
Albany, NY 12207
rhussar@manatt.com

Health Professionals
Barbara A. Ryan
Aaronson Rappaport Feinstein & Deutsch, LLP
600 3rd Avenue, 6th Fl.
New York, NY 10016
baryan@arfdlaw.com

Inhouse Counsel
Reginald Bullock Jr.
North Shore-Long Island Jewish Health System
145 Community Drive
Great Neck, NY 11021
rbullock@nshs.edu

Institutional Providers
David A. Manko
Rivkin Radler LLP
926 RexCorp Plaza
Uniondale, NY 11556-0926
david.manko@rivkin.com

Legislative Issues
James W. Lytle
9 Fernbank Ave.
Delmar, NY 12054
jlytle@manatt.com

Medical Research and Biotechnology
Alexander C. Brownstein
Bioscience Communications
250 Hudson Street
New York, NY 10013
alex.brownstein@bioscicom.net

Samuel J. Servello
Moses & Singer LLP
405 Lexington Avenue, 12th Floor
New York, NY 10174-0002
sservello@mosessinger.com

Membership
Karen L. I. Gallinari
15 Wilcox Avenue
Yonkers, NY 10705
kgallina@montefiore.org

Hon. James F. Horan, ALJ
New York State Health Department
Bureau of Adjudication,
Riverview Center
150 Broadway, Suite 510
Albany, NY 12204-2719
jfh01@health.state.ny.us

Mental Hygiene and Developmental Disabilities
Hermes Fernandez
Bond, Schoeneck & King, PLLC
111 Washington Avenue
Albany, NY 12210-2211
hfernandez@bsk.com

Carolyn Reinach Wolf
Abrams, Fensterman, Fensterman, Eisman, Greenberg, Formato & Einiger, LLP
1111 Marcus Avenue, Suite 107
Lake Success, NY 11042
cwolf@abramslaw.com

Publications and Web Page
Robert N. Swidler
St. Peter's Health Partners
2212 Burdett Avenue
Troy, NY 12180
swidlerr@nehealth.com

Public Health
Julia C. Goings-Perrot
Tarshis Catania Liberth Mahon & Milligram PLLC
1 Corwin Court
Newburgh, NY 12550
jgoings-perrot@tclmm.com

Reimbursement Issues
Ross P. Lanzafame
Harter Secrest & Emery LLP
1600 Bausch and Lomb Place
Rochester, NY 14604
rlanzafame@hselaw.com

Harold N. Iselin
Greenberg Traurig, LLP
54 State Street
Albany, NY 12207
iselinh@gtlaw.com

Web Blog Director/Webmaster
Paul Ashway Gillan, Jr.
Capital District Physicians' Health Plan, Inc.
500 Patroon Creek Blvd.
Albany, NY 12206-1057
pgillan@cdphp.com

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