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Health Law Journal

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of the New York State Bar Association

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THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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A Message from the Outgoing Section Chair

Regulatory Agenda

(1) *DOH Solicitation of Comments on Physician Mega-Practices and the Corporate Practice of Medicine prohibition*. On February 25, 2013, the Department of Health ("DOH") solicited comments on, among other things, whether it should expand or modify the criteria set forth in its regulations at section 600.8, which define the difference between a physician practice (that is not subject to licensure under Article 28 of the Public Health Law) and a diagnostic and/or treatment center ("DTC") that is subject to such licensure. DOH also solicited comments on whether New York State should modify its approach to the corporate practice of medicine. Our Section submitted comments on these important issues, which are published in this edition of the *Journal* and are also located on our website at http://www.nysba.org/health.

(2) *Executive Compensation*: Our Section submitted a third set of comments to DOH on its revised proposed regulations on Executive Compensation. Many thanks to Ed Kornreich of Proskauer for preparing this latest set of comments. The Section's comments are listed on our website at http://www.nysba.org/AM/Template.cfm?Section=Comments.

CLE Programs and Fall Meeting

Antitrust CLE Program—Our Section co-sponsored a program with the Antitrust Law Section of the NYSBA in Rochester on May 9, 2013. The program was entitled: "An Apple a Day: What you need to know about Antitrust and Healthcare."

Fall Meeting: Our Section will hold its Fall Meeting on Friday, October 25, 2013 in Albany. *Please hold the date.*

Membership Reception

On June 11, 2013, our Section held a membership reception, together with the Food, Drug and Cosmetic Law Section of the NYSBA, at the offices of Hodgson Russ in New York City, at 1540 Broadway, 24th floor from 5-7 pm. It was great to see all who attended.

Committees

We have reorganized several of the committees and their missions. The committees, their chairs and member rosters are listed at: http://www.nysba.org/AM/Template.cfm?Section=Health_Law_Committees&Template=/CustomSource/SectionCommitteeList.cfm&Sect=HLS.

Many thanks to my fellow Officers, the Committee Chairs and other members of the Executive Committee for assisting me during the past year.

Ellen V. Weissman, Chair
Health Law Section

In the New York State Courts

By Leonard M. Rosenberg

2d Circuit Asks New York Court of Appeals Whether Ultra Vires Disclosure of Confidential Patient Information by Non-Physician Employee Gives Rise to Private Right of Action Against Medical Corporation

Doe v. Guthrie Clinic, Ltd., 2013 WL 1188933 (2d Cir., March 25, 2013). Plaintiff was treated at the Clinic for a sexually transmitted disease. A nurse who worked at the Clinic disclosed Plaintiff's treatment to Plaintiff's girlfriend, for reasons unrelated to his care. Plaintiff learned of the disclosure and complained to the Clinic, which fired the nurse. Plaintiff sued the Clinic, asserting eight causes of action under New York statutes and common law. The Court granted Defendant's motion to dismiss the entire complaint. 2012 WL 531026 (W.D.N.Y., Feb. 17, 2012). The Second Circuit Court of Appeals affirmed dismissal, except as to Plaintiff's cause of action for common law breach of fiduciary duty to maintain the confidentiality of personal health information.

The Court noted that Plaintiff's claim was premised on the Clinic's liability for the nurse's actions under respondeat superior. Under New York law, an employer is liable for the actions of an employee if those actions were foreseeable and if the employee acted within the scope of employment. However, an employee's conduct cannot be attributed to the employer if the conduct was motivated by personal reasons unrelated to the furtherance of the employer's business. The Court found that because the complaint alleged that the nurse was motivated by purely personal reasons that had nothing to do with Plaintiff's treatment and care, the nurse's actions could not be attributed to the Clinic on the basis of respondeat superior.

The Court, however, noted Plaintiff's reliance on *Doe v. Cmty*

Health Plan–Kaiser Corp., 268 A.D.2d 183, 709 N.Y.S.2d 215 (3d Dep't 2000) ("*Kaiser*"), in which a medical records clerk disclosed information about a patient's treatment by a psychiatric social worker. In *Kaiser*, the Appellate Division held that the corporation could be held liable for its employee's breach. It reasoned that because a corporation can act only through its agents or employees, and the wrongful disclosure of confidential information would never be within the scope of its employees' employment, an "outside the scope" analysis would render meaningless the corporation's duty of confidentiality.

Noting that New York common law recognizes a cause of action against a physician who improperly discloses confidential medical information, the Court viewed the Appellate Division's decision in *Kaiser* as expansion of that claim to include a direct right of action against a medical corporation for breach of confidentiality by a non-physician employee. Further noting that two justices dissented from the majority's decision in *Kaiser*; that *Kaiser* "cited no statutory authority or caselaw to support its analysis," and that a corporation can be held liable for improper disclosure by an employee where the employee acts within the scope of her employment (e.g., by disclosing information to another provider without the patient's consent), the Court found that "the broad theory of medical corporate tort liability announced in [Kaiser] is subject to question."

In deciding whether to certify a question to the New York State Court of Appeals under Second Circuit Local Rule 27.2, the Court considers (1) the absence of controlling state law; (2) the importance of the issue to the state and whether state public policy is implicated; and (3) whether certification will resolve the litigation.

The Court found existing state case law on the issue to be "extremely sparse," that medical privacy and the confidentiality of medical records is of concern to New York, in that the disclosure of personal health information is governed by a number of New York statutes; and that the resolution of the question may end the litigation. Accordingly, the Court certified the following question:

> Whether, under New York law, the common law right of action for breach of the fiduciary duty of confidentiality for the unauthorized disclosure of medical information may run directly against medical corporations, even when the employee responsible for the breach is not a physician and acts outside the scope of her employment?

The New York State Court of Appeals accepted the certified question on April 25, 2013.

Appellate Division Vacates Jury Verdict for Defendant; Rules That Physician Breached the Implied Covenant of Trust and Confidence Inherent in the Patient-Physician Relationship by Disclosing Information to Patient's Estranged Spouse About the Patient's Potential for Violent Behavior

Juric v. Bergstraesser, 2013 N.Y. Slip Op. 02808, 2013 WL 1759909 (3d Dep't April 25, 2013). Plaintiff brought an action against his family physician, alleging that she breached

the implied covenant of trust and confidence inherent in the patient-physician relationship when physician disclosed Plaintiff's confidential information to his estranged wife. Specifically, physician disclosed the details of Plaintiff's visit to an emergency room for a medical condition, including that Plaintiff was reported by the emergency room physician as "exhibiting bizarre behavior, likely due to a major psychiatric pathology," and that he was carrying a "large stack of gun magazines."

Approximately three months earlier, Plaintiff's wife had reported to Defendant an escalating pattern of verbal abuse and controlling behavior by Plaintiff, which resulted in physician concluding that Plaintiff possibly suffered from a "severe, undiagnosed mental illness." At that time, physician attempted to discuss Plaintiff's marriage with him, but he became offended and refused to see physician again. Thereafter, Plaintiff's wife told physician that, pursuant to physician's advice, she had left Plaintiff after he threatened to physically assault her and her father, and to take their daughter out of the country.

Plaintiff then commenced this action, alleging that physician's disclosure of information to Plaintiff's wife breached the implied covenant of trust and confidence inherent in the patient-physician relationship, and resulted in him losing visitation with his daughter for several months. Physician admitted that she breached her duty, but raised the affirmative defense that such disclosure was justified because Plaintiff posed a danger to himself or others. To carry her burden, physician had to show that she had a "reasonable basis to believe and did believe, in fact, that Plaintiff posed an actual and current threat to himself or to a third-party." After a trial, the jury returned a verdict in physician's favor, and the trial Court denied Plaintiff's motion to set aside the verdict.

Plaintiff appealed and the Appellate Division, Third Department set aside the jury verdict, finding that it was against the weight of the evidence at trial, and that "no valid line of reasoning and permissible inference…could possibly lead rational [people] to the conclusion reached by the jury…." In so holding, the Court noted that physician had no knowledge that Plaintiff had ever harmed his wife or anyone else, and that physician had not witnessed, and had no knowledge of any details of, any threats by Plaintiff towards his wife. Moreover, physician admitted that Plaintiff was not violent or threatening while in the emergency room, and physician had consented to Plaintiff's release from the hospital because there was insufficient evidence to involuntarily admit Plaintiff for a psychiatric evaluation; further, physician did not notify law enforcement. In fact, physician testified that although she believed Plaintiff was "a potential danger" and there was a "possibility" that his wife would be harmed, it was likely that nothing would have happened because Plaintiff was not "a danger at that moment." Thus, the Appellate Division found that there was insufficient evidence to support physician's affirmative defense of justification, and that the jury's conclusion otherwise was not based on a reasonable or fair interpretation of the evidence.

Health Care Workers Who Misrepresented Their Intention Not to Strike Placed Patients at Risk of Foreseeable Imminent Harm, Are Not Entitled to Protection of Collective Bargaining Laws

National Labor Relations Board v. Special Touch Home Care Services, 708 F.3d 447 (2d Cir. 2013). The National Labor Relations Board (NLRB) petitioned for enforcement of a final decision and order finding that the respondent health care provider, Special Touch Home Care Services, Inc. (Special Touch), had engaged in unfair labor practices for its refusal to reinstate 48 aides who participated in a strike. Special Touch subcontracts with nursing and health-related services to provide home health aides for patients who require special assistance. The Court identified four characteristics in common amongst all of Special Touch's patients: (1) a physician ordered home health services; (2) their illness prevents them from normal functioning and daily living activities; (3) they are "homebound"; and (4) they are receiving skilled nursing, physical, occupational or speech therapy. Given the nature of the services, Special Touch had a call-in rule requiring aides who are unable to get to their patients' homes for any reason to notify Special Touch. Special Touch used an automated call-in service, requiring the aides to call in to report at the beginning of their shift. Any aide who had not called in would trigger a call to his or her patient's home to see if the aide had reported for work.

In May 2004, New York's Health and Human Service Union, 1199SEIU, AFL-CIO, CLC (the Union), notified Special Touch of its intention to strike between Monday June 7 and Wednesday, June 10. Supervisors at Special Touch contacted the approximately 1,400 aides then scheduled to work and asked whether they intended to miss any work during that period, whether to strike or for any other reason. Approximately 75 aides responded that they would miss work during that period, and Special Touch made arrangements to cover their patients. On June 7, 48 aides who had not previously conveyed their intention to be absent from work failed to appear for their assigned patients, and Special Touch had difficulty finding replacements. The Union, unbeknownst to Special Touch, had advised those aides at a meeting prior to the strike that they did not need to notify Special Touch that they intended to strike, because the Union had done so already. At the end of the strike, the 75 aides who had previously notified Special Touch of their intention to be absent from work were reinstated to their prior assignments. The 48 aides who did not notify Special Touch were not terminated, given that the Union had told them that it was unnecessary to report, but they were told not to report to their assigned patients until further notice. They were

reassigned over the next few months, but not always to prior patients or similar work schedules.

The Union filed charges against Special Touch, and the NLRB issued a complaint, charging Special Touch with violating the National Labor Relations Act by failing and refusing to reinstate all 48 of the aides who participated in the strike unexpectedly. An ALJ found in favor of the NLRB, holding that Special Touch's call-in rule did not alter the aides' status as protected workers, and that the statute requiring the Union to give ten days' notice to a health care facility before its workers strike applies to the Union only, not to individual employees. Finally, the ALJ rejected Special Touch's contention that some type of individual notice was required because of the imminent danger to its patients that could result otherwise. The NLRB moved the Court to enforce the ALJ's order, but the Court remanded the case back to the NLRB for consideration of the "plant rule" doctrine, and to better balance the interests of the employer and employees in issue.

The NLRB re-affirmed its prior ruling that Special Touch had violated the law by refusing to promptly reinstate the 48 aides. While the "plant-rule" doctrine permits an employer to enforce neutral, reasonable rules covering the conduct of employees on company time, the NLRB reasoned that the cases articulating the plant-rule doctrine had no application to this matter. As a threshold matter, the plant-rule doctrine had only been previously applied where the employer had no notice of the impending strike—here, Special Touch received the requisite ten-day notice from the Union. In addition, the NLRB held that the plant-rule doctrine applies only to the conduct of employees who are on company time. The employees in question in this matter were not on company time—Special Touch's call-in rule, however, focused specifically on conduct occurring outside of working hours by requiring employees to provide advance notice of an intention to miss work.

Special Touch next argued to the NLRB that the aides' activity was not protected, because they ceased work without taking reasonable measures to protect Special Touch's patients from "foreseeable imminent danger due to sudden cessation of work." The NLRB found that the aides had not triggered the "imminent danger" exception that would render their activity unprotected because the Union had given notice of the strike, coverage was found for all but five of the 48 aides who walked off the job unannounced, and no actual harm to patients had resulted.

Upon application to the Court to affirm the NLRB's decision of the matter on remand, the Court, analyzing the "plant-rule" cases, agreed with the NLRB that Special Touch's call-in rule was not a "plant-rule" of the type sufficient to override the clear Congressional mandate that individual employees need to provide notice to a health care employer of their intention to strike, which notice was required of and provided by the Union. The Court held that "it is apparent that Congress specifically weighed the interests of employers and employees, in light of the 'special considerations' relevant in the health care industry, in adopting a union notice rule but not an individual employee notice rule. Notably, Congress balanced these interests… after the plant rule doctrine had been established.

The Court, however, found that the aides had nonetheless engaged in non-protected behavior by striking after representing to Special Touch, in its pre-strike poll, that they would, in fact, report to work. These uncorrected affirmative misrepresentations, held the Court, placed 48 of Special Touch's patients in foreseeable danger of imminent harm. Disagreeing with the NLRB's characterizations of the nature of the aides' services to Special Touch's patients, the Court held that sufficient evidence existed in the record to support a finding that all of Special Touch's patients were subject to "nursing plans that prescribe some measure of supervision and assistance. The primary reason for the aides to be present in patients' homes in prevention. The Special Touch aides are the primary link between the nursing agency and the patients and their job is to observe the patients and ensure their safety."

While re-iterating that the individual aides were not required to give notice to Special Touch of their intention to strike, they did have a duty not to misrepresent their intention to be at work, once they were asked. The Court held "[w]hat an employee cannot do is mislead their employer into expecting their presence when the lack thereof will result in foreseeable imminent danger." The Court further held that actual harm was not a requirement, rendering irrelevant the fact (recognized by the ALJ) that none of the 48 affected patients sustained any actual injury. As a result, the aides were engaged in unprotected activity when they failed to appear for work the day of the strike, and the Court denied the NLRB's petition for an order enforcing its decision in the aides' favor.

Second Circuit Court of Appeals Affirms Dismissal of FLSA Collective Action and RICO Claims; Clarifies Pleading Standard Under FLSA

Lundy v. Catholic Health System of Long Island, Inc., 711 F.3d 106 (2d Cir. 2013). Plaintiffs appealed from the district Court's dismissal of their claims under the Fair Labor Standards Act (FLSA), 29 U.S.C. 201 et seq., the Racketeer Influenced and Corrupt Organizations Act (RICO), 18 U.S.C. §§ 1961-1968, and the New York Labor Law (NYLL). The case was brought as a putative class and collective action by employees who worked at Good Samaritan Medical Hospital Medical Center, one of many health care defendants in the suit. The employees originally asserted several federal and state law causes of action, although on appeal the only claims addressed were the employees' overtime and gap-time claims under the

FLSA and NYLL, and claims under RICO. All the employees' causes of action were based on allegations that their employer failed to compensate them for time worked during meal breaks, before and after scheduled shifts, and during required training sessions. After prolonged litigation, ultimately involving four amended complaints, the district Court dismissed all claims.

Prior to *Lundy*, the Second Circuit had not previously considered the degree of specificity needed to plead an FLSA overtime claim. In *Lundy*, the Court held that "to state a plausible FLSA overtime claim, a plaintiff must sufficiently allege 40 hours of work in a given workweek as well as some uncompensated time in excess of the 40 hours." But the Court opined that determining whether a plausible claim has been pleaded is "a context-specific task," and acknowledged that "under a case-specific approach, some courts may find that an approximation of overtime hours worked may help draw a plaintiff's claims closer to plausibility."

The Second Circuit Court affirmed dismissal of the employees' FLSA and NYLL overtime claims because "Plaintiffs have not alleged a single workweek in which they worked at least 40 hours and also worked uncompensated time in excess of 40 hours." Instead, Appellant only alleged in the most general of senses that she occasionally worked through unidentified lunch periods for undetermined amounts of time. The Second Circuit found that these allegations were "nothing but low-octane fuel for speculation, not the plausible claim that is required." Further, the complaint merely alleged that employees "typically" worked uncompensated pre- and post-shift time and mandatory training time, "typically" missed or experienced interrupted meal breaks, and "occasionally" worked additional shifts. Plaintiff, however, did not allege any instances where such "typical" and "occasional" occurrences resulted in uncompensated time for hours worked over 40 hours in a particular week.

The Court also affirmed dismissal of claims for gap-time wages under the FLSA, holding that "[s]o long as an employee is being paid the minimum wage or more, [the] FLSA does not provide recourse for unpaid hours below the 40-hour threshold, even if the employee also works overtime hours in the same week." "Gap time" is time worked under 40 hours in a week that is allegedly uncompensated. Thus, only hours worked over 40 hours in a given week are subject to FLSA scrutiny.

The Court also affirmed dismissal of Plaintiff's RICO claim, agreeing with the District Court that it was legally insufficient because Plaintiff failed to plead the alleged mail fraud with particularity, and to establish that the mailing of employee paychecks were in furtherance of a fraudulent scheme. In particular, the Second Circuit Court held that "the mailing of pay stubs cannot further the fraudulent scheme because the pay stubs would have revealed (not concealed) that Plaintiffs were not being paid for all of their alleged compensable overtime." In sum, in affirming the dismissal of Plaintiff's RICO claims, the Second Circuit explained that "Plaintiffs here have not alleged what any particular Defendant did to advance the RICO scheme. Nor have they otherwise pled particular details regarding the alleged fraudulent mailings. Barebones allegations do not satisfy Rule 9(b)."

Attorney General's Medicaid Fraud Control Unit Has Power to Prosecute Criminal Cases of Medicaid and Medicare Fraud; State Law Authorizing Prosecution of Medicare Fraud Not Preempted by Federal Law

People v. Miran, ___ N.E.2d ___, ___ A.D.2d ___, Slip Op. 02910, 2013 WL 1777715 (4th Dep't April 26, 2013). Defendants Michael Miran, a clinical Psychologist, Esta Miran, Michael's wife, and Michael Miran, Ph.D. Psychologist, P.C., a corporation formed by Mr. and Mrs. Miran, were indicted for various criminal charges arising out of allegations that the Mirans, through their corporation, fraudulently billed the state Medicaid program and the federal Medicare program. Specifically, the fraud was alleged to have occurred in the context of billing for so-called "dual eligible" patients—patients who were eligible for coverage by both Medicaid and Medicare. The indictment charged 25 counts of Medicaid fraud and 6 counts of Medicare fraud, and the case was prosecuted by the Medicaid Fraud Control Unit of the New York State Attorney General's Office (MFCU). Defendants challenged the indictment before the trial Court, arguing that the Attorney General lacked authority to prosecute allegations of Medicare Fraud, and that, even if the prosecution was authorized under state law, such authorization conflicted with a federal statute governing prosecution of Medicare-related fraud by state MFCUs, and state law was therefore preempted by the federal statute. County Court (Marks, J.) denied defendants' motions. Judge Marks found that New York Executive Law § 63(3) authorized the prosecution, and he rejected the defendants' preemption argument. The defendants all subsequently entered pleas of guilty in Supreme Court, Monroe County (Dolinger, J.). Under the terms of the plea agreements all defendants preserved their right to raise the issues regarding the scope of Executive Law § 63(3) and federal preemption on appeal.

On the defendants' appeal to the Appellate Division, Fourth Department, the Court unanimously affirmed the determination below that the prosecutions were authorized by Executive Law § 63(3), and rejected the defendants' claims of federal preemption. The Court began by noting that the Attorney General has no inherent authority to investigate and prosecute criminal activity, absent a specific statutory authorization. In addition, the Court of Appeals has held that unauthorized prosecutorial

participation by the Attorney General requires dismissal of any resulting indictment. However, the Court explained, Executive Law § 63(3) provides that "[u]pon request of the… head of any…department, authority, division or agency of the state, [the Attorney General shall] investigate the alleged commission of any indictable offense or offenses in violation of the law which the office making the request is especially required to execute…and to prosecute the person or persons believed to have committed the same and any crime or offense arising out of such investigation or prosecution or both, including but not limited to appearing before and presenting all such matters to a grand jury."

On April 26, 2002, years before the MFCU's investigation of the defendants began, the Commissioner of Health requested, pursuant to Executive Law § 63(3), that the Attorney General investigate and prosecute Medicaid fraud, and prosecute "any person or persons believed to have committed…any crime or offense arising out of your investigation or prosecution or both, or properly joinable with the foregoing offenses in such prosecution." Relying on this "referral" from the Department of Health, the Court found that the Attorney General has the power to investigate and prosecute Medicaid fraud. Moreover, the Court concluded that the language in Executive Law 63(3) and the referral's language extending the Attorney General's authority to prosecution of "any crime or offense arising out of such investigation or prosecution," was more than adequate to support the Attorney General's further prosecution of the Medicare fraud charges.

The defendants also advanced two theories of federal preemption of Executive Law § 63(3): "express" preemption and "conflict" preemption. Express preemption is established only where "Congress has explicitly mandated preemption in the statute's language." Conflict preemption "occurs when compliance with both state and federal law is impossible (impossibility preemption), or when the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objective of Congress'" ("impediment" preemption) (citing *United States v. Locke*, 527 U.S. 89, 109, quoting *California v. ARC Am. Corp.*, 490 U.S. 93, 100-101). The Court rejected defendants' express preemption and conflict preemption arguments.

The statute which the defendants asserted preempted state law, 42 U.S.C. § 1396b, contains no express preemption provision. Rather the statute specifically authorizes prosecution of Medicare fraud "if the suspected fraud or violation of law… is primarily related to the State [Medicaid] plan." The Court readily found that such language did not demonstrate express preemption of any state laws, even if those laws authorized prosecution beyond the scope specifically authorized in 42 U.S.C. § 1396b (which the defendants claimed was the case with respect to Executive Law § 63(3) and the 2002 referral from the DOH). According to the Court, the provision defendants cited created, at best, a "negative implication" that states lacked such power, and "cannot be deemed an explicit mandate with respect to Executive Law § 63(3)."

The Court also rejected the defendants' arguments that Executive Law § 63(3) was preempted by 42 U.S.C. § 1396b under a theory of conflict preemption. Specifically, with respect to "impossibility" preemption, the Court concluded that the Attorney General's MFCU actually complied with both state and federal law, and thus demonstrated that it was not "impossible" to do so. The Executive Law specifically authorized the MFCU to prosecute crimes or offenses "arising out of" MFCU's investigation or prosecution of matters properly referred to it, including Medicaid fraud. MFCU's prosecution also complied with the provision of 42 U.S.C. § 1396b(q)(3), which authorized State MFCUs to investigate and prosecute Medicaid fraud, and related Federal health care fraud where the underlying investigation case or investigation is primarily of alleged fraud against the State (25 of the indictment's 31 counts related to Medicaid fraud). Accordingly, since the investigation and prosecution at issue complied with both federal and state law, it was plainly not "impossible" to do so, and the "impossibility" form of conflict preemption was not established.

Finally, the Court dismissed the defendants' argument that Executive Law § 63(3) was preempted under an "impediment" preemption theory, because it "stands as an obstacle to the accomplishment and execution of the full purposes and objective of Congress." The Court concluded that Executive Law § 63(3) appears to support, not impede, the objectives of the federal statute, rendering "impediment" preemption inapplicable.

Federal Court Permits Antitrust Claims to Proceed Against Provider of Outpatient Dialysis Services

IHS Dialysis Inc., et al. v. DaVita, Inc., 2013 WL 1309737 (S.D.N.Y. March 31, 2013). The Court denied in part and granted in part Defendant DaVita Inc.'s (DaVita) motion to dismiss anti-trust claims by IHS Dialysis Inc. (IHS). IHS alleged that DaVita engaged in anticompetitive conduct in the provision of outpatient dialysis services in New York and Massachusetts. IHS, through its affiliates, operates outpatient kidney dialysis facilities in the Bronx and Flushing, New York and Quincy/South Shore and southern parts of Boston, Massachusetts. DaVita is based in Denver, Colorado, and is the second largest provider of outpatient dialysis services in the United States. It operates more than 1,800 outpatient dialysis clinics in 42 states and the District of Columbia, at which approximately 125,000 end-stage renal disease patients regularly receive treatment.

In this suit, IHS alleged that in many local markets throughout the United States, DaVita wields significant market and, in some cases, monopoly power, and also creates significant barriers to entry into these

markets. Specifically, IHS claimed that DaVita entered into long-term exclusive contracts with nephrologists and other referrals sources for dialysis services and that DaVita had negotiated contracts with pharmaceutical companies to purchase supplies at favorable and, in some cases, predatory prices, and that DaVita disparaged IHS and threatened referral sources, patients, and employees against using or working for other dialysis providers. IHS also alleged that DaVita conspired to restrain trade in the provision of outpatient dialysis services in these areas by entering into long-term exclusive and predatory contracts with nephrologists, health plans, and pharmaceutical companies, among others.

IHS alleged that this anticompetitive conduct has had significant, adverse effects upon competition in the relevant markets, which effects have included the exclusion of actual and potential providers of outpatient diagnostic imaging services, prices above competitive levels, output below competitive levels, and price discrimination or predatory pricing. IHS also alleged that due to DaVita's overwhelming market control in many geographical locations, "DaVita has:

> (a) permitted the patient quality care at its facilities to decline below acceptable levels; (b) failed to update and upgrade their facility amenities, such as televisions, radios, internet access, and equipment; (c) made unnecessary wage cuts and cuts to employee benefits; (d) violated state laws, including without limitation, disability laws; and (e) improperly demanded employees to sign non-compete restrictive covenants through threats of termination." IHS's complaint asserted claims against DaVita for monopolization, attempted monopolization, and conspiracy to monopolize outpatient dialysis services in specific geographic locations in New York and Massachusetts in violation of Sherman Act § 1 and § 2.

The Court denied DaVita's motion to dismiss IHS' claims of monopolization and attempted monopolization. The Court found that DaVita's attempt to attack the individual details of the pleading, rather than focusing on the overall anticompetitive scheme, failed to "squarely and clearly address…the essential elements of the four causes of action" and that "DaVita]'s arguments are deficient in a number of other respects." For example, DaVita argued it did not have market power by trying to show that it had a small share of the number of outpatient facilities in the relevant areas. The Court rejected DaVita's argument on this point, finding that IHS had properly alleged the relevant markets in the Bronx and Flushing, New York and Massachusetts areas and also because DaVita's arguments improperly required the consideration of extrinsic evidence on a motion to dismiss.

The Court also rejected DaVita's arguments that the pleading failed to properly allege anticompetitive conduct or monopoly power. The Court found that DaVita's attack on a single incident or category of alleged conduct did not require dismissal because the conduct alleged in the Complaint was pled in the aggregate, and that the alleged conduct is considered as a whole in the context of the relevant market and parties' respective roles therein.

The Court, however, dismissed IHS' conspiracy claims, without prejudice, and granted IHS the right to replead these claims. [Editorial Note—Garfunkel Wild, P.C. represents Plaintiff IHS Dialysis, Inc. in this matter.]

Under Primary Jurisdiction Doctrine Administrative Review by Public Health and Health Planning Council Is Not Required Where Physician's Patient Care and Medical Skills Are Not in Issue

Varughese v. Mount Sinai Medical Center, No. 12 Civ. 8812, 2013 WL 1385015 (S.D.N.Y. Apr. 3, 2013). Plaintiff, a medical resident, sued a hospital and various physicians for terminating her medical residency. The Complaint asserted twenty-one causes of action alleging violations of anti-discrimination and anti-retaliation laws, tortious interference with business relations, defamation, and breach of contract and other claims. The defendants moved to dismiss the complaint on the grounds that the New York State Public Health and Health Planning Council ("PHC") has primary jurisdiction over plaintiff's claims.

The Southern District of New York (McMahon, J.) denied the defendant's motion, finding that the defendants' reasons for terminating the plaintiff did not relate to the plaintiff's patient care or medical skills so as to implicate the application of the doctrine of primary jurisdiction.

Primary jurisdiction applies when the enforcement of a claim requires the resolution of issues which have been placed within the special expertise of an administrative body, such as the PHC. Section 2801-b(1) of the Public Health Law provides that it is an "improper practice" for a hospital to "curtail, terminate or diminish in any way a physician's… professional privileges in a hospital, without stating the reasons therefor, or if the reasons stated are unrelated to standards of patient care, patient welfare, the objectives of the institution or the character or competency of the applicant." Under Section 2801-b(1), an aggrieved physician or medical resident alleging such an improper practice may file a complaint with the PHC, which is authorized

to determine whether an improper practice has occurred.

The Court acknowledged case law in the Second Circuit holding that under the primary jurisdiction doctrine, a physician is required to obtain administrative review by the PHC prior to seeking judicial relief in Federal Court. The case law provides an exception to this rule: (i) "where the physician alleges that his or her privileges have been terminated for reasons unrelated to medical care and therefore do not require the particular expertise of the PHC" and (ii) "where the physician seeks damages, but not reinstatement and where the presence or absence of a proper medical reason for terminating the plaintiff's privileges is not dispositive of the plaintiff's claims."

The Court found that the defendants' reasons for terminating the plaintiff did not involve deficiencies in plaintiff's patient care or medical skills but instead were solely related to interpersonal disputes. Reviewing the disciplinary incidents that precipitated plaintiff's termination, the Court concluded that although the plaintiff's patient care and medical skills were tangentially involved in some of these incidents, the real issue behind these incident reports was the plaintiff's lack of professionalism, which did not necessitate the PHC's expertise.

Based on these findings, the Court concluded that the doctrine of primary jurisdiction did not apply, and denied the defendants' motion to dismiss the complaint on that basis.

Second Department Holds That Part C of the Medicare Act Preempts New York General Obligations Law § 5-335, and Therefore Medicare Secondary Payors May Seek Reimbursement From Medicare Beneficiaries Who Receive Settlements in Personal Injury Actions.

Trezza v. Trezza, 104 A.D.3d 37, 957 N.Y.S.2d 380 (2d Dep't 2012). The plaintiff brought a personal injury claim against the driver of a vehicle involved in an accident from which she sustained injuries. After plaintiff settled the litigation, nonparty appellant The Rawlings Company, on behalf of Oxford Health Plans, the plaintiff's Medicare secondary payor organization ("Oxford"), sought reimbursement for amounts Oxford had paid for the plaintiff's medical care, pursuant to the plaintiff's membership contract. Part C of the federal Medicare Act expressly permits, but does not require, benefit providers such as Oxford to contract for such reimbursement rights.

Plaintiff moved to extinguish Oxford's reimbursement claim, relying upon New York General Obligations Law § 5-335. Section 5-335 provides that unless there is a statutory right to reimbursement, a settlement for personal injuries is presumed not to include the costs of health care, to the extent that such cost is obligated to be paid by a benefit provider. Therefore, the benefit provider is expressly prohibited from recovering portions of such settlements, "[e]xcept where there is a statutory right of reimbursement." N.Y. Gen. Ob. § 5-335(a). The plaintiff claimed that Oxford's right to reimbursement was contractual, not statutory, and therefore preempted by § 5-335. The plaintiff also claimed that § 5-335 was not preempted by federal law. Oxford claimed that it had a statutory right to reimbursement under the Medicare Act, and further that it was unnecessary to determine whether § 5-335 is preempted by federal law, because § 5-335 expressly permits reimbursement when a statutory right exists.

The Supreme Court, Kings County, concluded that Congress did not create a private cause of action when passing the Medicare Act, and therefore the Act did not create a statutory right of reimbursement—rather, it permitted benefit providers to include subrogation rights in their contracts. Because the Medicare Act was permissive, as opposed to mandatory, there was no statutory right of reimbursement, and § 5-335 was not preempted. And because § 5-335 created a presumption that settlement costs do not include reimbursement for covered health services, Oxford did not have a claim for subrogation.

The Appellate Division reversed. It agreed with the lower Court in holding that because the language in the Medicare Act was permissive, Oxford did not have a statutory right to subrogation. However, the Court held that the Medicare Act preempted § 5-335.

Preemption is determined by Congressional intent, which can be discerned from express language; where legislation is so comprehensive as to occupy an entire field of regulation; or when federal law conflicts with state law. The Court noted that in 1997, the Medicare Act generally stated that state laws and regulations "inconsistent" with federal regulations were preempted. However, in 2003, Congress stated explicitly that the statutes and regulations pertaining to Part C of the Medicare Act "shall supersede" state laws and regulations that would otherwise apply to Part C, with the exception of state licensing laws and laws relating to plan solvency. The legislative history accompanying this change stated that the change was intended to clarify that the Medicare Act was a federal program operated under federal rules, and that state laws should not apply.

In addition, federal regulations provided that state law could not take away a Medicare plan's right under federal law and regulations to bill for services for which Medicare is not the primary payor. And Part C itself stated that plans could bill members for services "notwithstanding any other provision of law."

Given these clear indications that Congress did not intend for Part C of the Medicare Act to be subject to state override, the Court concluded that § 5-335 would impermissibly prohibit Medicare plans from obtaining reimbursement which they were entitled to seek under federal law, and accordingly was preempted. The Court also rejected the lower Court's emphasis on a private right of action, which it

found to be irrelevant. Accordingly, the Court reversed the lower Court's order and denied the plaintiff's motion to extinguish Oxford's claim for reimbursement.

Judicial Subpoena or Court Order Is Required to Obtain Notes and Records of Minor Child's Psychotherapist; HIPAA Release Signed by Parent Is Insufficient

Liberatore v. Liberatore, 37 Misc.3d 1034 (Sup. Ct. Monroe County 2012). In the context of a child custody battle within a matrimonial proceeding, the father obtained the records of the minor child's treating psychologist and psychiatrist. The father obtained those records based solely on a release that he signed pursuant to a Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The Court held that communications between the child and her therapist may not be disclosed to the parties or their counsel without judicial process sufficient to allow the Court to exercise its obligation as *parens patrie* to determine the best interests of the child, and to permit the child's attorney to assert the statutory privilege against disclosure.

CPLR §§ 4504 (psychologist) and 4507 (psychiatrist) protect against disclosure of confidences to a psychotherapist. The father argued that he had put the child's attorney on notice by telephone that he intended to request the records, and the attorney did not object. The father also argued that as the child's parent he had an absolute right under HIPAA to obtain the records. The Court rejected both arguments. First, informal notice cannot supplant the Court's *parens patriae* authority and discretion to determine whether assertion or waiver of the privilege is in the child's best interest. Second, the child's attorney had a reasonable expectation that a formal process would be used, thus providing sufficient information to evaluate whether to assert the privilege.

Third, the father did not have an absolute right to the records under HIPAA. Under 45 CFR § 164.502(g), a health care provider may not disclose protected health information about an unemancipated minor to a parent if doing so is "prohibited by an applicable provision of State or other law," including case law. In New York, both CPLR § 4504 and 4507, as well as case law, prohibit such disclosure. Further, § 164.502(g) permits the provider to withhold information from a parent, even if such disclosure is not prohibited, if the provider, in the exercise of professional judgment, decides that it is not in the best interest of the child to treat the parent as the child's personal representative.

Based on hearing testimony from the child's psychologist and psychiatrist, the Court found that disclosure of the child's confidences would destroy the therapeutic relationship. Accordingly, the Court ordered that the records be returned to the providers or given to the child's attorney for immediate destruction.

Second Department Dismisses Malpractice Claim Based Solely on Emotional Harm

Nadal v. Jaramillo, 959 N.Y.S.2d 505 (2d Dep't 2013). Plaintiff brought a medical malpractice action against a physician seeking damages solely for emotional distress. The claim was based on the physician's decision to conduct a CT scan without informing her that she was pregnant. The patient did not assert that either she or her child suffered any physical injury. The trial Court denied physician's motion to dismiss the complaint. The Appellate Division, Second Department reversed.

The Court noted the judiciary's reluctance to recognize claims grounded in negligence when the harm is solely emotional. The Court acknowledged some instances where New York has recognized a valid cause of action for negligence based solely on emotional damages, but never on a theory of recovery as broad as alleged. The Court characterized the emotional damages as "fear that [the plaintiff's] unborn child might be harmed," which was too broad to be recognized as valid emotional damages under New York law.

Consulting Firm and Fiscal Intermediary Did Not Violate the False Claims Act by Receiving Medicare Outlier Payments Based on Out-of-Date Cost-to-Charge Ratios

U.S. v. Huron Consulting Group, No. 09 Civ. 1800, 2013 WL 856370 (S.D.N.Y. Mar. 5, 2013). Plaintiff, Associates Against Outlier Fraud, brought a qui tam action under the False Claims Act against a hospital's consulting firm and fiscal intermediary for allegedly submitting excessive outlier payment reimbursement claims to Medicare that were based on an out of date cost-to-charge ratio. The consulting firm and fiscal intermediary moved for summary judgment. The Southern District of New York (Rakoff, J.) granted the defendants' motions for summary judgment finding that neither party submitted false claims to the government.

Under Medicare, providers are reimbursed for inpatient procedures based on certain billing categories for which Medicare usually reimburses providers at fixed rates. Occasionally, however, providers are reimbursed certain add-on payments. As the Court explained, although Medicare reimburses providers at fixed rates, the provider nevertheless includes its own stated charge for the service when submitting its bill to Medicare. An automated system created by the Center for Medicare and Medicaid Services ("CMS") takes these submitted charges and calculates its own estimate of the provider's costs using a provider-specific cost-charge ratio. The cost-charge ratio is calculated based on a provider's overall report of its total services and charges. When the automated system determines that a provider's submitted charge, adjusted for cost, is higher than the usually applicable fixed price and loss amounts, the provider will automatically receive what is called an outlier payment.

Given that the calculation of an outlier payment is based upon a current charge adjusted by a historical cost-to-charge ratio, a provider that implements "across the board" price increases to the services it charges Medicare can immediately increase the "charge" component of the outlier calculation before the provider's retrospective cost-to-charge ratio has had a chance to catch up. Because Medicare pays individual outlier claims as they are submitted even though the cost-to-charge ratios may take several years to be settled, such providers may receive artificially inflated reimbursements. These reimbursements represent only temporary windfalls to the provider, however, because CMS implemented a reconciliation process that retroactively recoups excessive outlier payments once the applicable cost reports are settled.

These Medicare reimbursements are facilitated by "fiscal intermediaries," which act as administrative contractors to CMS by paying claims, processing cost reports, and auditing provider's cost reports. To implement the outlier reconciliation program, CMS instructed these fiscal intermediaries to flag providers when their outlier payments exceeded certain thresholds.

Plaintiff brought suit against Huron, a consulting firm, and Empire, a fiscal intermediary, for allegedly submitting bills for a hospital's outlier costs based on stale cost-to-charge ratios. In 2003, the hospital retained Huron's predecessor to provide consulting services to help it return to profitability. The consulting firm found that the hospital was charging below-market rates and failing to bill for certain services. As a result, the hospital increased its pricing approximately thirty-three percent, elevating its pricing to the 75th percentile of the market. Nevertheless, nearly a year later, the hospital filed for bankruptcy protection. For the next several years, the hospital continued to receive outlier payments based upon the cost-to-charge ratio that was in place before it instituted an overall price increase. Toward the end of 2006, the hospital notified Empire that its cost-to-charge ratio should be adjusted to reflect its price increases and submitted its final cost report for 2005.

As is custom in the industry, Empire's multi-step review process can take several years before a cost report is finally settled. After the hospital emerged from bankruptcy in 2007, Empire updated the hospital's prospective cost-to-charge ratio. Empire also notified CMS that the hospital met the criteria for outlier reconciliation but, pursuant to CMS instruction, did not take any further steps to reconcile outlier payments until specifically instructed to do so by CMS. CMS did not issue guidance for conducting outlier reconciliation until 2011, at which time Empire began the outlier reconciliation process.

Based on this factual backdrop, the plaintiff alleged that Heron knowingly submitted charges that would "take advantage of the time lag in updating the hospital's cost-to-charge ratio in order to 'game the outlier system,'" and by doing so falsely certified to the Government that the hospital was in compliance with applicable statutes. The plaintiff also alleged that Empire violated the False Claims Act when it authorized payment of Huron's claims in contravention of its contractual obligations to CMS.

The Court held that Huron did not violate any law, rule or regulation by submitting the hospital's claims. Reviewing the various CMS regulations proffered by the plaintiff, the Court held that the regulations merely serve as a warning against the dangers of overcharging when a facility's cost-to-charge ratio is outdated, and that the charges should reasonably relate to costs. The Court concluded that the requirement that charges reasonably relate to costs does not render Huron's submissions false. As the Court explained, at the time of the hospital's price increases, the hospital's prior charges were found to be so poorly aligned with costs that they were often below actual costs. This necessitated the hospital's program pricing increases, that, of necessity, were "related to" actual costs.

For those same reasons, the Court held that the plaintiff's claims against Empire also fail. In addition, the Court found that the CMS regulations only required Empire to flag potential excesses in outlier reimbursements but not to suspend payments or sua sponte adjust cost-to-charge ratios. Given that Empire did just that until it received specific instructions from CMS to begin the reconciliation process, the Court held that Empire did not submit false claims to the government in violation of its contractual duties.

Based on the above, the Court concluded that no reasonable juror could find that either defendant submitted a false claim under the False Claims Act and dismissed the plaintiff's complaint.

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

The NYS Legislature's 2013 session ended just as this edition went to print. Here is a summary of the status of key health-related bills by the Healtcare Association of NYS, reprinted here with permission.

Healthcare Association of New York State

HANYS

2013 State Legislative Summary

Bills that Passed Both Houses

The following provides a summary of selected health care legislation that passed both houses of the legislature during the 2013 legislative session. It does not include health care issues that may have been debated but did not pass both houses.		
BILL/SPONSOR	**BILL SUMMARY**	**STATUS**
A.2691-B (Gottfried)/ S.5834 (Hannon)	**Managed Care Reform.** Reforms managed care practices by requiring utilization review agents to substantiate pre-authorizations electronically, except where not practicable, and extends the provider external appeal timeframe from 45 days to 60 days. Current law requires plans to pay for all pre-authorized care and require notification of such authorization within three business days.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.8072 (Brennan)/ S.5845 (Ranzenhofer) Attorney General Bill #5	**Not-for-Profit Governance.** Makes various changes to the laws governing charities and not-for-profit organizations to require that a not-for-profit develop and implement a conflict of interest policy, establish an audit committee, and closely scrutinize transactions between a "related party" and the not-for-profit organization. This bill also streamlines many outdated provisions of law.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.433 (Dinowitz)/ S.2157 (Valesky)	**NY Connects Contact Information.** Requires the Department of Health (DOH) to create a list of contact information for the NY Connects: Choices for Long Term Care program and other local social service agencies to be organized by county, and to provide that list to health care providers and practitioners, who will then provide that information to patients determined to be in need of long-term care services.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.490-A (Paulin)/ S.2287-A (Ball)	**Hannah's Law.** Enacts Hannah's Law to require insurance coverage of enteral formulas, whether administered orally or via tube feeding. Current law requires coverage of enteral formulas, but does not specifically reference coverage for oral administration.	Passed Assembly and Senate, awaiting delivery to the Governor.

A.526-B (Magnarelli)/ S.5353-A (DeFrancisco)	**Perfusionist Licensure.** Establishes a licensure process through the State Education Department for perfusionists.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.717-A (Braunstein)/ S.3469-A (Griffo)	**Substituted Cathinones ("Bath Salts").** Classifies substituted cathinones, commonly referred to as "bath salts," as Schedule I controlled substances.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.826 (Lifton)/ S.3145 (Krueger)	**Clinical Nurse Specialist Certification.** Establishes a certification process through the State Education Department for clinical nurse specialists.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.857 (Weinstein)/ S.2534 (Hannon)	**Uniform Guardianship and Protective Proceedings Jurisdiction Act.** Provides a mechanism and process for resolving multi-state jurisdictional disputes related to adult guardianships and other protective proceedings.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.878-A (Bronson)/ S.697-A (Grisanti)	**Central Service Technicians.** Requires certification of central service technicians and imposes continuing education requirements. Individuals employed as a central service technician for a cumulative period of one year within the four years prior to the effective date of this proposal would not be required to attain certification. Hospitals and ambulatory surgery centers would be able to hire individuals without the certification, as long as they attain it within 18 months of employment. This proposal would take effect 18 months from being signed into law.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.962-A (Kellner)/ S.2186-A (Robach)	**CHP Coverage of Blood Clotting Factor Products.** Requires Child Health Plus (CHP) outpatient coverage for blood clotting factor products and other treatments and services furnished in connection with the care of hemophilia and other blood clotting protein deficiencies.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.989-B (Rosenthal)/ S.4422-B (Golden)	**Health Proxy Information on State Web Sites.** Requires state agencies with a significant public interaction in the field of public health to include a link on their home page to the health care proxy information on the DOH Web site.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.1101-B (Gunther)/ S.3944-B (Hannon)	**Safe Disposal of Unused Controlled Substances Program.** Last year's I-STOP law (Chapter 447 of 2012) required DOH to establish the safe disposal of unused controlled substances program to provide consumers with appropriate disposal sites, to be operated by law enforcement agencies. This bill requires DOH to establish regulations that would authorize pharmacies to become disposal sites.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.1115-A (Jaffee)/ S.1987-A (Martins)	**Smoking on Health Care Facility Grounds.** Prohibits smoking on the grounds of hospitals and nursing homes. This bill would not prohibit smoking by a nursing home resident or a visitor/guest of a nursing home resident if there is a separately designated smoking area on the grounds of the nursing home, as long as the designated area is not within 30 feet of any building structure.	Passed Assembly and Senate, awaiting delivery to the Governor.

A.1286-A (Zebrowski)/ S.2750-A (Hannon)	**Hepatitis C Virus Testing.** Requires a hepatitis C virus (HCV) screening test to be offered to patients born between 1945 and 1965 who are receiving health services as a hospital inpatient or receiving primary care services in an outpatient department, clinic, or from a physician, physician assistant, or nurse practitioner. A health care provider can refer a patient who receives a positive screening test to another provider to receive confirmatory testing and follow-up care and treatment. This testing requirement would expire on January 1, 2020.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.1347 (Cymbrowitz)/ S.910 (Parker)	**OASAS Programs for Veterans.** Requires the Office of Alcohol and Substance Abuse Services (OASAS) to review its programs to ensure that the needs of veterans are met and, in collaboration with the Office of Mental Health, make recommendations to improve programs that provide treatment, rehabilitation, relapse prevention, and recovery services to veterans who have a co-occurring mental health and alcoholism or substance abuse disorder.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.1713 (Gunther)/ S.882 (Bonacic)	**Task Force on Adults with Autism.** Creates the Task Force on Adults with Autism within the Office for People with Developmental Disabilities (OPWDD) to evaluate and recommend specific actionable measures to support and meet the needs of adults with autism who are residents of the state.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.1989 (Gottfried)/ S.2080 (Hannon)	**Accountable Care Organization (ACO) Workgroup.** Legislation was enacted last year (Chapter 461 of 2012) to make permanent the ACO demonstration program authorized in the 2011-2012 state budget. Additionally, that law required DOH to convene a workgroup to "develop a proposal whereby an ACO may serve in place of a managed care plan." This bill amends the workgroup's charge to say it will "consider whether an ACO should be enabled to serve in place of a managed care plan."	Signed by the Governor, Chapter #6.
A.2316-B (Gunther)/ S.270-B (Larkin)	**Pulse Oximetry Screening for Newborns.** Requires hospitals and birthing centers to perform on each newborn a pulse oximetry screening for critical congenital heart defects. This test is added to the list of newborn screening requirements.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.4099 (Thiele)/ S.1604 (Grisanti)	**Leave of Absence for Volunteer Emergency Responders.** Following a governmental declaration of emergency, this bill requires an employer to grant an excused leave of absence to an employee, upon the employee's request, if that employee is a volunteer firefighter or an enrolled member of a volunteer ambulance service.	Passed Assembly and Senate, awaiting delivery to the Governor.

A.4100 (Weisenberg)/ S.3802 (Carlucci)	**Jonathan's Law.** Clarifies Jonathan's Law to authorize the sharing of records/reports with a health or behavioral health care provider, law enforcement, or the recipient's attorney. Jonathan's Law was enacted in 2007 to allow parents/guardians to retrieve records/reports related to the care of family members in OPWDD facilities.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.6124-A (Magnarelli)/S.4097-A (DeFrancisco)	**Clinical Laboratory Limited Licensure Extension.** Extends for three years, through September 1, 2016, the current limited licensing provisions of the Clinical Laboratory Technology Practice Act.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.6692-C (Weisenberg)/ S.4777-D (Golden)	**OPWDD Budget Cut Restoration.** This year's budget included a $90 million funding reduction to OPWDD service providers and tasked a workgroup with developing recommendations to mitigate the impact by finding alternatives. This bill is an agreement between the Legislature and Administration on alternative options to achieve the savings and, if these alternatives do not achieve the full $90 million, the balance would be made up by the state's General Fund.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.6724-B (Gottfried)/ S.5539 (Hannon)	**Optometrists Perform Clinical Laboratory Tests.** Adds optometrists to the list of health care professionals who may conduct certain clinical laboratory tests without a permit, as long as the tests do not use an invasive modality and the tests are solely as an adjunct to the treatment of their patient.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.6838-A (Gottfried)/ S.4493-A (Hoylman)	**Study of Health Care Delivery Models.** Directs DOH to conduct a study of health care entities that are not subject to the state Certificate of Need process, including clinics operating in pharmacies, urgent care centers, and major physician practices.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.6963-B (Morelle)/ S.4862-B (Fuschillo)	**Applied Behavior Analysis.** Establishes a licensure process for applied behavior analysts and a certification process for applied behavioral analyst assistants. Applied behavior analysis is a behavioral health service for people with autism and autism spectrum disorders that implements and evaluates environmental modifications, using behavioral stimuli and consequences, to produce socially significant improvements in human behavior.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.7257-A (Peoples-Stokes)/S.3926-A (Hannon)	**Notice of Observation Services.** Requires hospitals to provide patients who are placed into observation services with oral and written notice within 24 hours of such placement that the patient is in observation status and not admitted to the hospital. DOH will develop guidance to hospitals for the written notice, which must include a statement that observation status may impact the patient's coverage and the patient should contact his or her insurance plan to get more information.	Passed Assembly and Senate, awaiting delivery to the Governor.

A.7324-A (O'Donnell)/ S.4881-A (Hoylman)	**Pharmacist Administer Meningococcal Vaccine.** Authorizes pharmacists, upon a non-patient specific (standing) order from a physician or certified nurse practitioner, to administer immunizations to prevent meningococcal disease.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.7419-A (Cahill)/ S.5185-A (Savino)	**Surgical Technologists.** Requires surgical technologists working in hospitals and ambulatory surgery centers to complete a nationally accredited surgical technologist educational program, maintain the certified surgical technologist credential, and meet annual continuing education requirements. Individuals employed as a surgical technologist for a cumulative period of one year within the four years prior to the effective date of this proposal would not have to meet these requirements. Facilities could only hire surgical technologists that have completed the educational program, but then the individual would have one year from the date of hire to attain the certified surgical technologist credential. This proposal would take effect 18 months from being signed into law.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.7500-A (Steck)/ S.4668-B (Carlucci)	**Electronic Death Registry.** Authorizes and directs DOH to design, implement, and maintain an electronic death registration system.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.7636 (Gottfried)/ S.3912-A (Hannon)	**Oversight of MLTC Transition.** Requires DOH to provide oversight of individuals transitioning to managed long-term care (MLTC), including ensuring appropriate notification of changes, access to enrollment assistance, and choice of plans.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.7667-B (Gottfried)/ S.3137-C (Krueger)	**Maternal Depression Education.** Requires DOH, with the Office of Mental Health (OMH), to establish evidence-based guidelines for maternal depression screening for use by maternal health care and pediatric primary care providers. Current law requires hospitals and birthing centers to provide maternity patients with an informational leaflet designed by DOH. This bill requires DOH to make this information available on its Web site and requires information regarding maternal depression in the maternity leaflet, in addition to the currently required information on post-partum depression.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.7734-A (Paulin)/ S.4528-A (Hannon) DOH Departmental Bill #31	**Statewide Immunization information System.** Provides medical research centers, institutes of higher education, and other institutions engaged in epidemiological or public health research with access to de-identified registrant information in the statewide immunization information system or the city-wide immunization for research purposes. Also provides access to the statewide immunization information system to certain colleges, professional and technical schools, and children's camps to verify immunization status.	Passed Assembly and Senate, awaiting delivery to the Governor.

A.7755 (Gottfried)/ S.5096 (Golden)	**Assisted Living Program Admissions.** Authorizes assisted living programs to admit and retain individuals who are chairfast. Current law prohibits assisted living programs from admitting individuals who are chronically bedfast or chairfast.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.7758 (Lifton)/ S.5534-A (Hannon)	**Hospice Residences.** Increases from eight to 16 the number of allowable beds in a hospice residence and permits these hospice residences to have dually-certified hospice inpatient beds up to 25% of the residence's patient capacity.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.7835-A (Gottfried)/ S.5628-A (Hannon)	**Streamlined Application Process for Adult Care Facilities and Assisted Living Programs.** Requires DOH to develop a streamlined application and approval process for existing operators of adult care facilities and assisted living programs who are in good standing.	Passed Assembly and Senate, awaiting delivery to the Governor.
A.7866 (Glick)/ S.5757 (Hannon)	**Dental Hygienist Collaborative Arrangement.** Authorizes a registered dental hygienist working for a hospital to practice pursuant to a collaborative arrangement with a licensed dentist. Current law requires dental hygienists to work under the supervision of a licensed dentist.	Passed Assembly and Senate, awaiting delivery to the Governor.

This summary was prepared for HANYS by Nicholas Henley, Director of Governmental Affairs, HANYS.

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In the New York State Agencies

By Francis J. Serbaroli

Nursing Home Reserved Bedhold

Notice of Emergency Rulemaking. The Department of Health amended section 86-2.40(ac) of Title 10 NYCRR to revise the rate of payment for reserved bed days billed for temporary hospitalizations. Filing date: January 2, 2013. Effective date: January 2, 2013. *See* N.Y. Register January 23, 2013.

Financial Reporting for Providers of OPWDD Services

Notice of Adoption. The Office for People With Developmental Disabilities amended 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. Filing date: January 15, 2013. Effective date: February 1, 2013. *See* N.Y. Register January 30, 2013.

Provider Requirements for Insurance Reimbursement of Applied Behavior Analysis

Notice of Emergency Rulemaking. The Department of Financial Services added Part 440 (Regulation 201) to Title 11 NYCRR to establish standards of professionalism, supervision, and relevant experience for providers of Applied Behavior Analysis. Filing date: January 28, 2013. Effective date: January 28, 2013. *See* N.Y. Register February 13, 2013.

Reduction to Statewide Base Price

Notice of Emergency Rulemaking. The Department of Health amended section 86-1.16 of Title 10 NYCRR to continue a reduction to the statewide base price for inpatient services. Filing date: January 24, 2013. Effective date: January 24, 2013. *See* N.Y. Register February 13, 2013.

Statewide Pricing Methodology for Nursing Homes

Notice of Emergency Rulemaking. The Department of Health added section 86-2.40 to Title 10 NYCRR to establish a new Medicaid reimbursement methodology for Nursing Homes. Filing date: January 24, 2013. Effective date: January 24, 2013. *See* N.Y. Register February 13, 2013.

Episodic Pricing for Certified Home Health Agencies (CHHAs)

Notice of Emergency Rulemaking. The Department of Health amended section 86-1.44 of Title 10 NYCRR to exempt services to a special needs population from the episodic payment system for CHHAs. Filing date: January 25, 2013. Effective date: January 25, 2013. *See* N.Y. Register February 13, 2013.

Authority to Collect Pharmacy Acquisition Cost

Notice of Adoption. 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: January 29, 2013. Effective date: February 13, 2013. *See* N.Y. Register February 13, 2013.

Orthodontic Screening

Notice of Adoption. The Department of Health repealed section 85.45 of Title 10 NYCRR and amended section 506.4 of Title 18 NYCRR to change Orthodontic Screening Provider Qualifications and Recipient Eligibility Criteria. Filing date: January 29, 2013. Effective date: February 13, 2013. *See* N.Y. Register February 13, 2013.

Audits of Institutional Cost Reports (ICR)

Notice of Adoption. 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: January 29, 2013. Effective date: February 13, 2013. *See* N.Y. Register February 13, 2013.

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

Notice of Proposed Rulemaking. The Department of Health proposed amending sections 2.59, 405.3, 415.19, 751.6, 763.13, 766.11 and 793.5 of Title 10 NYCRR to require hospital DT&Cs, nursing home, home care and hospice personnel to wear a surgical or procedure mask if not vaccinated for Influenza. *See* N.Y. Register February 13, 2013.

Hospital Pediatric Care

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 405 of Title 10 NYCRR to amend pediatric provisions and update various provisions to reflect current practice. *See* N.Y. Register February 13, 2013.

Limits on Administrative Expenses and Executive Compensation

Notice of Revised Rulemaking. The Office of Alcoholism and Substance Abuse Services revised its proposal to add 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 March 13, 2013.

Unauthorized Providers of Health Services

Notice of Emergency / Proposed Rulemaking. The Department of Financial Services added Subpart 65-5 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: February 25, 2013. Effective date: February 25, 2013. *See* N.Y. Register March 13, 2013.

Limits on Administrative Expenses and Executive Compensation

Notice of Revised Rulemaking. The Office of Mental Health revised its proposal to add Part 513 to Title 14 NYCRR to implement Executive Order No. 38 to limit administrative expenses and executive compensation of providers of services. *See* N.Y. Register March 13, 2013.

Limits on Administrative Expenses and Executive Compensation

Notice of Revised Rulemaking. The Office for People With Developmental Disabilities revised its proposal to add Part 645 to Title 14 NYCRR to curb abuses in executive compensation and administrative expenses and ensure that taxpayer dollars are used to help persons in need. *See* N.Y. Register March 13, 2013.

Repeal of Outdated Forms and Conforming Amendments

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Appendix 1 and amended section 15.1(c) of Title 14 NYCRR to eliminate antiquated and irrelevant forms. Filing date: March 5, 2013. Effective date: March 20, 2013. *See* N.Y. Register March 20, 2013.

NYS Medical Indemnity Fund

Notice of Emergency Rulemaking. The Department of Health amended Part 69 of Title 10 NYCRR to provide the structure within which the NYS Medical Indemnity Fund will operate. Filing date: March 5, 2013. Effective date: March 5, 2013. *See* N.Y. Register March 20, 2013.

Adverse Event Reporting Via NYPORTS System

Notice of Revised Rulemaking. The Department of Health revised amendments to sections 405.8 and 751.10 of Title 10 NYCRR to update current provisions to conform with current practice. *See* N.Y. Register March 20, 2013.

Transfer of Involuntary Patients to Authorized Secure Facilities

Notice of Emergency / Proposed Rulemaking. The Office of Mental Health amended Part 57 of Title 14 NYCRR to allow for the transfer of an involuntary patient from an OMH hospital to one of its regional forensic units. Filing date: March 5, 2013. Effective date: March 5, 2013. *See* N.Y. Register March 20, 2013.

Repeal of Outdated Forms and Conforming Amendments

Notice of Adoption. The Office of Mental Health repealed Appendix 1 and amended section 15.1(c) of Title 14 NYCRR to eliminate antiquated forms. Filing date: March 5, 2013. Effective date: March 20, 2013. *See* N.Y. Register March 20, 2013.

Repeal of Outdated Forms and Conforming Amendments

Notice of Adoption. The Office for People With Developmental Disabilities amended Parts 15 and 17 and repealed Appendix 1 of Title 14 NYCRR to eliminate antiquated forms. Filing date: March 5, 2013. Effective date: March 20, 2013. *See* N.Y. Register March 20, 2013.

Erratum

A Notice of Revised Rule Making, I.D. No. ASA-22-12-00014-RP, pertaining to Limits on Administrative Expenses and Executive Compensation, published in the March 13, 2013 issue of the State Register contained the incorrect assessment of public comment. The correct assessment is published in the March 27, 2013 issue of the N.Y. Register.

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: March 7, 2013. Effective date: March 7, 2013. *See* N.Y. Register March 27, 2013.

Language Assistance and Official New York State Prescription Form Requirements

Notice of Adoption. The Department of Health amended 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. Filing date: March 12, 2013. Effective date: March 27, 2013. *See* N.Y. Register March 27, 2013.

Electronic Prescribing, Dispensing and Recordkeeping of Controlled Substances

Notice of Adoption. The Department of Health amended Part 80 of Title 10 NYCRR to allow practitioners to issue prescriptions electronically for controlled substances. Filing date: March 12, 2013. Effective date: March 27, 2013. *See* N.Y. Register March 27, 2013.

Rent Allowance Offset (SSI Update) for IRAs & Community Residences and Annual Increase Percentage for Leases for Real Property

Notice of Adoption. The Office for People With Developmental Disabilities amended sections 635-6.3 and 671.7 of Title 14 NYCRR to update the rent allowance offset for IRAs and Community Residences and the annual increase percentage for leases for real property. Filing date: March 12, 2013. Effective date: March 27, 2013. *See* N.Y. Register March 27, 2013.

Medicaid Managed Care Programs

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

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

Notice of Emergency Rulemaking. The Department of Health amended sections 505.14 and 505.28 of Title 18 NYCRR to establish definitions, criteria and requirements associated with the provision of continuous PC and continuous CDPA services. Filing date: March 21, 2013. Effective date: March 21, 2013. *See* N.Y. Register April 10, 2013.

Limits on Executive Compensation and Administrative Expenses in Agency Procurements

Notice of Revised Rulemaking. The Department of Health revised the addition to Addition of 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 April 10, 2013.

Medicaid Eligibility

Notice of Adoption. The Department of Health amended section 360-2.4 of Title 18 NYCRR to clarify time frames for issuance of Medicaid Eligibility determinations. Filing date: April 3, 2013. Effective date: April 24, 2013. *See* N.Y. Register April 24, 2013.

Sepsis Protocols

Notice of Adoption. The Department of Health amended sections 405.2 and 405.4 of Title 10 NYCRR to require hospitals to implement evidence-based protocols for the early recognition and treatment of patients with sepsis. Filing date: April 16, 2013. Effective date: May 1, 2013. *See* N.Y. Register May 1, 2013.

Conforming Amendments to Chapter 498 of the Laws of 2012

Notice of Adoption. The Office for People With Developmental Disabilities amended section 624.8(c)(3) of Title 14 NYCRR to extend the deadline for requests for release of records pertaining to allegations of abuse. Filing date: April 16, 2013. Effective date: May 1, 2013. *See* N.Y. Register May 1, 2013.

Compiled by Francis J. Serbaroli. Mr. Serbaroli is a shareholder in the Health and 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

New York State Department of Health OMIG Audit Decisions

Compiled by Eugene M. Laks

Saratoga County Maplewood Manor (DOH administrative hearing decision dated January 16, 2013, William J. Lynch, Administrative Law Judge). This was an audit of the facility's December 1, 2002 through 2006 Medicaid reimbursement in which the OMIG determined that inclusion of both capital cost reimbursement for a cogeneration project, based upon an approved rate appeal, and continued reimbursement for energy costs as part of the operating cost component of the Medicaid rate constituted an overpayment. The OMIG sought to recover the added capital cost reimbursement. The Department of Health Administrative Law Judge reversed the audit finding, holding that approval of the rate appeal had been a discretionary policy determination by the Department in support of cogeneration projects and the OMIG did not have authority to change the Department's reimbursement methodology. Various other audit adjustments relating to capital costs were sustained by the ALJ.

New York State Attorney General Press Releases

Compiled by Charles Z. Feldman

Amgen, Inc. Settles for $19 Million Related to Claims That It Inflated the "Average Wholesale Price" Benchmark That New York Uses to Set Pharmaceutical Reimbursement Rates—April 29, 2013—Amgen, Inc. resolved a multistate investigation into its pricing of drugs used to treat kidney disease and cancer.

The Attorneys General charged that in reporting to Medicaid, Amgen inflated the "Average Wholesale Price" and "Wholesale Acquisition Cost" for these drugs which caused the States to increase reimbursement rates for these drugs.

Self Reporting Leads to Arrest of North Country Duo Involved in a Fraudulent Respite Care Scheme—April 25, 2013—In Massena, a respite worker hired by the Cerebral Palsy Association of the North Country (CPNC) entered into an agreement with a patient's father whereby the respite worker would file false time sheets and the patient's father would falsely verify the same, and the two would share all proceeds. After the false records were discovered by the CPNC, both the worker and the patient's father were arrested and charged with stealing $9,000 from Medicaid.

LPN from Watertown Arrested for Falsification of Business Records—April 25, 2013—A licensed practical nurse (LPN) working in a rehabilitation center in Watertown is alleged to have failed to provide medications to residents and then falsified records to indicate that she had in fact dispensed the drugs. She faces up to four years in prison.

Dentist Sentenced for Offering Kickbacks for Patient Recruiting—April 4, 2013—A Brooklyn Dentist who paid recruiters to solicit business from homeless Medicaid patients was sentenced to 1 to 3 years in prison and ordered to pay restitution of almost $700,000 to Medicaid and to the State Department of Taxation.

Personal Care Assistant Swipes Check from House of an Elderly Resident in Her Care—April 3, 2013—A personal care assistant (PCA) at a Long Island Senior Center admitted to forging a check written from a checkbook of an 88-year-old resident in her care. The PCA forged the check and attempted to deposit it when the resident was temporarily admitted to the hospital. She faces up to seven years in prison.

Six Arrests in Hudson Valley Oxycodone Trafficking Operation—March 21, 2013—MFCU announced the arrests of six people in connection with the trafficking of Oxycodone in the Hudson Valley. The ring leader supplied the others with forged prescriptions, a van ride to different pharmacies across New York and enough cash to pay to fill the prescriptions. After the prescriptions were filled, the ring leader paid the accomplices $150 to $400 per pill and then sold the pills in bulk to street drug dealers.

Texting of Picture of a Patient's Genitalia Leads to Arrest of CNA From Long Island—March 8, 2013—A Certified Nurses Aide (CNA) faces 1 1/3 to 4 years in prison after texting an inappropriate picture of a patient in his care to a nurse aide student without permission from the patient. MFCU seized the CNA's cell phone and located the incriminating picture.

Elmira Area Pharmacist Pleads Guilty to Billing Medicaid for Drugs and Supplies That Were Never Dispensed—March 8, 2013—An Elmira Pharmacist pled guilty to defrauding Medicaid of more than $93,000 through fraudulent billings for

medications that were not dispensed. Between January 2005 and January 2007, the pharmacy billed Medicaid for 18 different drugs, treatments and supplies that were never purchased or dispensed.

Caught on Surveillance Tape—Assault of An Elderly Nursing Home Resident Leads to Arrest of Nurse's Aide—February 27, 2013—An 83 year old resident of a Rochester nursing home suffered personal injuries when the Nurse's Aide on duty slammed the resident's wheelchair into a door. The incident was captured on surveillance video and the Nurse's Aide faces up to one year in jail.

LPN from Rome Arrested for Theft of Prescription Drugs—February 19, 2013—An LPN working in various rehabilitation centers in Rome was arraigned for taking prescription drugs from her patients and consuming them herself. The LPN was also charged with falsifying business records to cover up her theft. She faces up to four years in prison.

Caught on Hidden Camera—Assault of An Elderly Nursing Home Resident Leads to Arrest of Nurse's Aide—February 27, 2013—A grandchild of an elderly resident of a Bronx nursing home, concerned for her grandmother's care, placed a hidden video camera in her grandmother's room. Over the course of three days, the camera showed a Certified Nurse Assistant (CNA) snap the resident's arm back, push her into the metal railing on the bed and strike the resident on her side. She faces up to one year in jail.

A Rockland County Based Physician Is Indicted for Selling Prescriptions for Pain Medications—February 11, 2013—A Rockland County psychiatrist sold prescriptions for Oxycodone and other painkillers for profit from his offices in Manhattan and Nyack. The Doctor charged up to $300 per prescription and wrote the prescriptions to either fictitious persons or to persons who had no knowledge that he was doing so. Since the Doctor did not report sales of these prescriptions on his tax return, the charges against him include filing fraudulent tax returns by underreporting his income by $500,000.

Hospital That Double Billed Medicaid and Medicare for Services at Mental Health Clinics Settles Whistleblower Action for $2.3 Million—February 7, 2013—After charging the hospital with violations of the state and federal false claims acts, MFCU and the whistleblower entered into a settlement where the Hospital agreed to pay a total of $2.3 million in restitution. The whistleblower alleged that the hospital billed outpatient psychiatric services as a rate-based service to Medicaid, while at the same time billing the federal government for the same care on a fee-for-service basis.

Brooklyn Psychiatrist Arrested for Fraudulent Billing Practices and for Allegedly Writing Prescriptions for Anti-Depressant Seroquil to Patients Who Sought to Sell the Drug on the Street—February 7, 2013—A Brooklyn Psychiatrist billed Medicaid for the "hour code" when his sessions with patients lasted less than ten minutes. During one 24-hour period, the Doctor billed the hour code 30 times. MFCU seeks $230,000 in restitution for services not provided. MFCU is also investigating the Doctor's practice of frequently prescribing Seroquil. The Doctor was one of the top prescribers of Seroquil in the state, a drug with a street value among addicts.

New York State Office of the Medicaid Inspector General Update

Compiled by the Editor

OMIG Audit Leads to Arrest of Man Who Faked Credentials—April 26, 2013—The individual allegedly falsified credentials to obtain his position as a Medicaid Service Coordinator. Auditors from the Office of the Medicaid Inspector General discovered this when the provider self-disclosed this information during the course of a routine audit. OMIG contacted the New York State Office of the Attorney General's Medicaid Fraud Control Unit, which then arrested him for Medicaid fraud—http://www.omig.ny.gov/latest-news/670-omig-audit-leads-to-arrest-of-man-who-faked-credentials.

OMIG Excludes Individuals and Facilities Involved in Bribery Scheme—April 22, 2013—In a two-part announcement, the Office of the Medicaid Inspector General has taken administrative action against two individuals and an Assemblyman for their role in an alleged bribery scheme involving two social adult day care centers. All five have been excluded from participating in New York's Medicaid program. The Office also took action against two facilities. These facilities have also been excluded from the Medicaid program—http://www.omig.ny.gov/latest-news/667-omig-excludes-individuals-and-facilities-involved-in-bribery-scheme.

Medicaid Inspector General and Health Commissioner Send Joint Letter to Nursing Home Administrators Regarding Appropriate Use of Antipsychotic Medications for Nursing Home Residents—April 9, 2013—http://www.omig.ny.gov/images/stories/provider_misc/antipsychotics-4-9-13.pdf.

OMIG Posts its New Work Plan for Fiscal Year 2013-14—April 8, 2013—http://www.omig.ny.gov/images/stories/work_plan/2013_2014_workplan.pdf.

OMIG Identifies Millions in Bad Dental Payments: Double-Billings, Errors in Restorative Work for Toothless Patients Discovered—March 18, 2013—http://apps.cio.ny.gov/apps/mediaContact/public/preview.cfm?parm=E47A29DC-5056-9D2A-103381FA2CA33E29.

OMIG Audit Recovers $1.6 Million in Overpayments From Queens Nursing Home—March 12, 2013—Although the nursing home's use of outdated and inflated reimbursement rates represented a majority of the audit findings, among other disallowed costs were expenses for a Lexus automobile operated by the facility's administrator—http://www.omig.ny.gov/images/stories/press_releases/elmhurstlexus-jz-v23813.pdf.

OMIG Audit Protocols Posted to the OMIG Website as of May 2, 2013—Certified Home Health Agency, Hospital Outpatient Department (OPD) Emergency Room/Clinic, Hospital Outpatient Department (OPD) Laboratory, Hospital Outpatient Department (OPD) Ordered Ambulatory Other Than Laboratory, OPWDD Day Habilitation, OPWDD Day Treatment, OPWDD IRA Residential Habilitation, OMH Rehabilitation Adult Services, Pharmacy, Transportation Ambulette, Transportation Taxi/Livery.

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- The Politics Of Obamacare: Health Care, Money, And Ideology, Richard Kirsch
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De-Gendering Health Insurance: A Case For A Federal Insurance Gender Nondiscrimination Act, Kate Walsham, 24 Hastings Women's L.J. 197 (2013).

Don't Let Go Of The Rope: Reducing Readmissions By Recognizing Hospitals' Fiduciary Duties To Their Discharged Patients, Thomas L. Hafemeister and Joshua Hinckley Porter, 62 Am. U.L. Rev. 513

Effective Defenses Of Hospital Mergers In Concentrated Markets, By Jeffrey H. Perry and Richard H. Cunningham, 27 Antitrust ABA 43 (2013).

Health Care And The Illegal Immigrant, Patrick Glen, 23 Health Matrix 197 (2013).

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For Your Information

By Claudia Torrey

Items of interest:

Plaintiff's complaint in the case of *Varughese v. Mount Sinai Medical Center, et al.*[1] has been described as a "kitchen sink" pleading, but the decision re-articulates when the New York State Public Health Council ("PHC") has primary jurisdiction ("PJ") over an alleged cause of action. In this recent employment discrimination case, the United States District Court for the Southern District of New York, via Judge McMahon, denied defendants' motion to dismiss and gave plaintiff (a pathology resident) leave on her cross-motion to amend her complaint.

In general, defendants assert that the PHC has PJ over plaintiff's claims because her dismissal from the Residency Program concerns issues of patient care and patient welfare. Section 2801-b(1) of the Public Health Law governs this situation, and the Court points out that applying PJ is discretionary; to wit, the Second Circuit has acknowledged two scenarios wherein PJ is **not** applicable: the first—where the physician alleges that his or her privileges have been terminated for reasons unrelated to medical care and thus do not require the expertise of the PHC, and the second—where the physician seeks damages with no reinstatement, and the presence or absence of a proper medical reason for terminating plaintiff's privileges is not dispositive of the plaintiff's claims.[2]

Plaintiff claims a number of **non-medical care reasons** for her alleged discrimination by the defendants (gender, national origin, race, turning in fellow residents for drinking on the job, etc.); in fact, the summary of plaintiff's work submitted by the defendants' states that in some rotations the plaintiff's work was considered superior…in the areas of patient care and medical knowledge.[3] Plaintiff was not seeking reinstatement, and the Court determined that the defendants' purported reasons for terminating plaintiff were essentially non-medical (nothing to do with patient care, medical skills, or anything that uniquely fell within the purview of the PHC). Thus, a determination of whether there was or was not a proper medical reason for terminating plaintiff's privileges would be superfluous and not dispositive of plaintiff's claims.[4] Judge McMahon concludes that the PJ Doctrine is not applicable, and his Court indeed has subject matter jurisdiction over the complaint.*

* * *

This column is being written in April 2013, one year after the death of 12-year old Rory Staunton from sepsis in New York State. In the Summer / Fall 2012 issue of the *Health Law Journal* ("HLJ"), this author highlighted the North Shore-Long lsland Jewish Health System ("Health System") for being named an award winning "Sepsis Hero" by the Sepsis Alliance.[5] Sepsis is akin to blood poisoning—the body's deadly response to infection or injury.[6]

On January 29, 2013, nine months after Rory's death and about three days after the 2013 NYSBA Annual Meeting, Gov. Andrew M. Cuomo announced proposed regulations by the State Department of Health ("DOH") making New York State the first in the nation to require all hospitals to adopt best practices / evidence based protocols for the early identification and treatment of sepsis.[7] The governor also announced that the DOH would put forth regulations to reform pediatric care to improve both the quality and the oversight, including requiring hospitals to post a "Parents' Bill of Rights."[8] The Governors sepsis announcement was a "down payment" on his 2013 commitment in the State-of-the State speech regarding New York State setting a gold standard for patient care.

Health System president and CEO Michael Dowling worked with Rory's parents on the proposed Parents' Bill of Rights, sharing with them how the Health System has reduced sepsis mortality by 35% since 2008![9] The proposed DOH regulations took effect in May 2013, with hospitals to submit protocols for DOH review before July 1, 2013. The protocols are to be implemented no later than 45 days post DOH approval.

Endnotes

1. No. 12 Civ. 8812(CM) (S.D.N.Y. Apr. 3, 2013).
2. *Id.*
3. *Id.*
4. *Id.*
5. NYSBA Health Law Journal, Vol.17, #3 (Summer / Fall 2012), p. 25.
6. *Id.*
7. www.governor.ny.gov.
8. *Id.*
9. *Id.*

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***Ironically, on June 24, 2013, as the galley for this column was being reviewed, the United States Supreme Court decided a pair of cases concerning the Equal Employment Opportunity Commission and the concepts of workplace supervisor harassment ("*Vance v. Ball State University*," Slip Op. No. 11-556; 570 U.S. __ [2013]) and illegal retaliation ("*University of Texas Southwestern Medical Center v. Nassar*," Slip Op. No. 12-484; 570 U.S. __ [2013]); to wit, in proving employer retaliation a plaintiff must establish that the employer conduct was a direct result of plaintiff's complaint. Lawsuits claiming sexual and/or racial discrimination shift the burden to the employer to prove valid business reasons existed for its actions.**

Clinical Ethics Training for Members of New York Ethics Review Committees (ERCs)

By Bruce D. White, DO, JD

> [W]hat is essential to the proper functioning of the ethics review committees under the Family Health Care Decisions Act, particularly in view of their newly expanded responsibilities, is comprehensive education for ethics committee members in a number of critical areas. (Morrissey, 2011)

Introduction

With the passage of the Family Health Care Decisions Act (FHCDA) in 2010, the New York State Legislature went farther than any other U.S. state legislative body had ever gone with respect to creating statutory roles for hospital and nursing home ethics review committees (ERCs) (Miller, 2011). Under the statute, New York ERCs have binding decision making authority in at least three conflict situations, and are to be involved in several other cases through referral when disagreements arise in patient care. (Editorial Board, New York State Bar Association Family Health Care Decisions Act Infomation Center, 2011) (Holley & Otto, 2011).

Since 1986, the New York State Task Force on Life and the Law has encouraged institutions to have and use ERCs to assist in the resolution of patient care dilemmas (New York State Task Force on Life and the Law, 1986). The Joint Commission for the Accreditation of Healthcare Organizations has required that accredited institutions have an ethics "mechanism" to deal with ethical dilemmas that arise in patient care since the early 1990s. (Pope, 2009). This may have been trendy at the time (particularly with the growing concern about family conflicts over interventions, such as do-not-resucitate orders and artifical feeding), but medical-moral committees had been functioning effectively in Catholic hospitals for several decades (Kelly & McCarthy, 1984).

There are other states that mandate that hospitals have ethics committees, either expressly (as in Maryland, New Jersey, Colorado, and Texas) or by implication (as in Florida) (Pope, 2009). But until enactment of the FHCDA, no jurisdiction had permitted an ERC to have a clear decision-making role that was to be binding on parties; heretofore, except perhaps for Texas, ERC participation in a case and any resultant recommendations had been advisory only (Fine & Mayo, 2003).

> Ethics [Review] Committees have a clear obligation to seek the training, expertise, and information they need. At a minimum, training should include broadly accepted ethical principles for treatment decisions, committee members' obligations and committee procedures, and the requirements of the FHCDA [New York's 2010 Family Health Care Decisions Act] and other related laws such as the health care proxy law. (Miller, 2011)

Illustrative Case

The chair of the hospital's Ethics Review Committee (ERC) called an emergency meeting to be held about six hours after the notice was circulated, at 5 p.m. later that day. One of the patient's adult daughters had objected to the patient's spouse acting as his surrogate under authority of the Family Health Care Decisions Act (FHCDA) and hospital policy. Because the daughter had formally objected, the matter was referred to the ERC, again as specified in the FHCDA and a hospital policy.

The hospital's clinical ethicist had been involved in the case for several days. The clinical ethicist had met with the family and team members at least twice during the last 48 hours; each meeting continued for over an hour-and-a-half. The patient had been in the hospital's surgical intensive care unit for over 20 days; he had been transferred in from an outlying hospital with life-threatening traumatic injuries, including a potentially fatal injury to the head. Immediately after transfer the patient went to the operating room for several procedures. He had been in a coma since the accident; his Glasgow Coma Scale score had been recorded as 3 with no change during the entire hospialization. He was intubated at the accident scene and had afterwards remained on assisted ventilation. The neurology service had been involved from admission. The neurology team told the family—should he survive—that his best possible outcome would be a minimally functional state, in which he would require 24 hour long-term nursing care. The neurology service told the family that—again, should he survive—it was entirely probable that he would progress to a persistent vegetative state (PVS) and no longer have any awareness of his condition or surroundings.

The meetings with the clinical ethicist had been primarily to discuss what the patient's preferences might be under the circumstances so that the surrogate could participate in the medical decision-making process using either a substituted judgment standard or a best interests standard. The team asked for a clinical ethics consultation service intervention at this time because it had not

been making much progress in discussions with the family: the team felt that it was now time to discontinue the respirator and move to a palliative care plan, or take the patient to the operating room for a tracheostomy for prolonged ventilatory support and placement of a gastrostomy tube for long-term artificial nutrition and hydration. The team felt that further day was not an option since it could not possibly be in the patient's best interests clinically. All of the family members who attended the meetings were in agreement that the patient "would not want to be in this [current] state indefinitely." However, the patient's daughters believed that "stopping life sustaining treatment now is giving up too soon," and, as an extension of this belief, requested that the patient undergo tracheostomy and gastrostomy tube placement. The patient's spouse and the patient's siblings believed that he would prefer—given the clinical situation—that medical treatments be discontinued and that organ procurement services become involved to harvest any available donations should death occur immediately after removing the ventilator.

In conversation with the family members, the clinical ethicist learned that the family dynamics are in flux. The patient is a 49-year-old male and currently estranged from his wife, the person now acting as his surrogate under the FHCDA and hospital policy. The patient and his wife have been living apart for the past several months. The two have a six-year-old daughter. He was divorced several years ago from his first wife; she had just been released from prison. His former wife had not visited the patient in the hospital, but was in communication with the patient's oldest daughter. For the past several months, the patient had been living with a girlfriend. Both his wife and his girlfriend have been at the patient's bedside almost every day since the accident. However, the girlfriend has not participated in the medical desision making, nor has she made any effort to do so. (In conversation with the unit social worker about medical decisions, she said, "I know my place here.")

The patient is unemployed and has no health insurance. The patient's one natural daughter from his previous marriage is in her early 20s. There is another young woman at the bedside who introduces herself as the patient's daughter; however, she was never formally adopted by the patient. All family members agree, though, that the patient treated her as a daughter and had raised her as his own child, and that she should be involved in the conversation to the same extent as she were his natural or adopted child. Both the natural adult daughter and the adult common-law daughter have been at the patient's bedside continually. The patient has several brothers and sisters, and sisters- and brothers-in-law, who have visited the patient regularly during the intensive care unit stay. Several of the patient's siblings and siblings-in-law attended the family meetings with the clinical ethicist. (Relevant relationships are illustrated as a family tree in **Figure 1**.)

At the meeting of the ERC to review the daughters objection, the group elected to limit the discussion to the surrogacy issue. There was some preliminary conversation about the role of the ERC at this stage: (1) To identify the most appropriate surrogate at this point; (2) to review the team's earlier decision to recognize the spouse; or (3) to suggest other ideas that may help the team with the surrogate identification and scope of authority issues.

One should recall that in mandating the referral to the ERC, the FHCDA is silent regarding the substantive and procedural aspects of the committee's involvement. This lack of legislative direction is not uncommon for statutes of this type (for example, the sections of the Texas Advance Directives that mandate an ethics committee review in disputed medical futility cases) (Fine & Mayo, 2003). The ERC has relatively broad discretion in the matter. Consistent with the traditional advisory role of ethics committee interventions, in this case the ERC elected to review the appropriateness of the team's identification of the patient's spouse as surrogate. The ERC met for about two hours. During this time, the ERC reviewed the facts as described in the medical record and the unit social worker's extensive notes, was told about the clinical ethics consultant meetings and conversations, and debated the relevant provisions of the FHCDA and hospital policies. At the conclusion of the meeting the committee entered the following note in the patient's chart:

> [Date, time redacted]
>
> **Clinical Ethics**
>
> The Ethics Review Committee met in a special called meeting to discuss an objection to the designated surrogate identification and her participation in the decision making process.
>
> After consideration, we concluded that the team appropriately identified surrogate [name redacted], the patient's spouse, with due diligence in accord with accepted medical practice and hospital policy. It appears the [name redacted] has: (1) been making decisions in accordance with the patient's best interests; (2) has been in regular contact with the patient; (3) has been showing care and concern for the patient; (4) has been available to visit; and (5) has engaged in face-to-face contact with the providers.
>
> We find that all family members who attended the meeting with [name redacted] this morning agreed that the patient's previously expressed wishes apply to this

> situation. We also agree that the patient's surrogate is participating in the medical decision making process with the team in a manner consistent with the patient's previously expressed wishes.
>
> [Chair's signature redacted]

In follow-up, the ERC learned that the team continued to recognize the patient's spouse as the surrogate. There were no further objections. The morning following the meeting, the team removed the ventilator and instituted a palliative care plan. After withdrawal, and until he died two days later, the patient appeared comfortable and in no distress.

> [T]he vast majority of HEC [hospital ethics committee] members probably have little academic training or formal background in the field of healthcare ethics. Yet their position on the HEC implies that they are prepared to help others resolve ethical problems. Thus they feel the need for some education to give them confidence in their ability to help, and to give them credibility in the eyes of their colleagues who might turn to them. (Hackler & Hester, 2008)

Minimum Ethics Review Committee Training

Without question, there are a vast number of material facts and issues—some medical, some legal, some psycho-social, some others; some facts relatively simple, others far more complex—presented in this case with which the ERC must be familiar. Even if the ERC limits its involvement in the illustrative case to only reviewing the objection to the identification and authority of the patient's surrogate—the triggering event here that mandated referral—to competently study the concerns, the committee must understand the underlying ethical, medical, legal, psycho-social, economic, theological, and health system facets implicated.

The American Society for Bioethics and Humanities (ASBH) first published its *Core Competencies for Healthcare Ethics Consultation* in 1998; it is now in its second edition (Core Competency Task Force, 2011). The core knowledge areas recognized in the ASBH report include: moral reasoning and ethical theory; common bioethical issues and concepts; health care systems and clinical context; the local health care institution and its policies; relevant codes of ethics and professional conduct; guidelines of accrediting organizations; and relevant health law. The illustrative case shows how important an understanding of the core knowledge areas are in real-life patient care. There should be no disagreement that the ERC be adequately prepared—trained—to meet its responsibilities under the FHCDA and hospital policies credibly and effectively.

The ASBH *Core Competencies* were drafted as a guide for ethics committees who are invited to participate in clinical cases via a consultation request. (Under the FHCDA, some cases will come to the ERC by referral, as in the illustrative case, rather than through a request from a patient, a family member, or a member of the institution's staff). The ASBH *Core Competencies* accept that consultations may be offered by: (1) individual health care ethics consultants, (2) small groups of individuals or a sub-set of an ethics committee, or (3) the ethics committee as a whole. However, the *Core Competencies* also stresses that an advanced working understanding of all the core knowledge areas is essential if a consultation or review is provided appropriately, by whatever manner or mechanism. That is, if one person provides the consultation service, then that one individual should have an advanced knowledge level of the core knowledge areas and the adequate skills to offer the consultation alone. Alternatively, whether a small group or the entire committee provides the consultation service, then that group collectively should together have an advanced understanding of all the core knowledge areas and a similarly adequate skills set. Moreover, some may argue that under the FHCDA, ERC involvement should be through a committee structure, particularly in those few instances in which the statute specifies that the committee has binding decisional authority or in which an issue should be referred to the ERC.

The *Core Competencies* is a pragmatic document. The expert authors understood that the consultation service for each institution would necessarily reflect a unique clinical and societal culture and fabric. However, the *Core Competences* is also interested in consultation standards and focuses on participation and reviews being offered to meet minimum levels of expertise. The Task Force could not be clearer: if a consultation is provided, the work should be done competently.

A few years after the first edition of the *Core Competencies* was published, the Society's Clinical Ethics Task Force issued its *Improving Competencies in Clinical Ethics Consultation: An Education Guide* (American Society for Bioethics and Humanities Clinical Ethics Task Force, 2009). This document has topical subject matter and content suggestions for those interested in learning the educational core competencies. Absent other nationally endorsed or peer-consensus standards for clinical ethics consultation services or a widely accepted curriculum for ethics committee members or health care ethics consultants, one might reasonably argue that these booklets should be considered definitively in developing educational topics and materials for ERC training. Moreover, the national standards expressly endorse the notion that

local institutional policies and relevant health care laws must be part of the training.

ERC member education may take several forms. (See **Table 1**.) And of course, it is not critical that all ERC members individually develop an advanced level of understanding of each of the core knowledge areas identified, so long as that expertise is otherwise represented on the committee by a member with that advanced core knowledge of the area (Core Competency Task Force, 2011). But is does seem reasonable that all ERC members have some basic understanding in each of the target areas. That too is an idea endorsed by the ASBH *Core Competencies* (Core Competency Task Force, 2011). By implication, a physician through medical training alone may lack the basic understanding of the core knowledge elements described in the *Core Competencies*. The same may be said of every discipline that is represented on ERCs. The FHCDA drafters must have given this idea of interdisciplinary expertise due consideration because the statute specified that for each institutional ERC there must be at least one physician, one nurse, and another individual who has no relationship to the facility (a "public" or "lay" member, are common terms used to discribe this person) (Editorial Board, New York State Bar Association Family Health Care Decisions Act Infomation Center, 2011). However, these individuals alone—absent some level of expertise in the ASBH core knowledge and skills competencies—will clearly not be enough for the committee to meet its responsibilities.

Of course it will be the task of each institutional ERC to determine local educational standards absent some state or national authority mandate. It would seem, though, that the *Core Competencies* recommendations do set the bar. The extent to which these the core knowledge and skills compentenices are met or exceeded locally may depend on the number of persons who serve on the ERC. This is the way in which many ethics committees have operated nationally for many years (Post, Blustein, & Dubler, 2007).

So to the direct question, how much training is required? The answer is simple: "enough." It may not be sufficient, for example, if the lawyer who serves on the committee is a corporate attorney who knows little about relevant health law topics (such as informed consent, shared decision making, do-not-resuscitate orders, terminal sedation, palliative care, double effect, the process for the identification and authority of the surrogate, substituted judgment, and best interests standard), unless there is another member of the ERC that understands these topics at the advanced level. Again, each local ERC will need to establish its own criteria as compared to national standards. There are many bioethics and clinical ethics training options that are readily available to ERC members (several are listed in **Table 1**). Moreover, the ERC will need to design some method for continuing education over time. One-time educational programs—even to train ERC members initially—will not be enough. As technology and approaches change, so too must the ERC be prepared to deal with new challenges (Post, Blustein, & Dubler, 2007).

> [If one approaches] any endeavor as an amateur activity, you will get, in the end an amateurish version of the activity. Without a sufficient commitment of personnel, time, support, and financial resources, a healthcare organization will get the "ethics" program…it set out to create: an inept unskilled, inefficient, and highly risky "program" in healthcare ethics and bioethics. (Hoffmann, Tarzian, & O'Neil, 2000 [quoting D. Blake, Vital Signs, 2000:75:1-2).

Conclusion

By enacting the FHCDA, the New York Legislature placed great faith in the integrity and professionalism of ERCs and their individual members. The legislature did so with the understanding that now, with the recognition of what had been before a purely advisory role to improve the care of patients, ERCs can perhaps play a greater role as an extra-judicial safeguard to speed and better reinforce traditional medical decision making processes, particularly in times of stressful and emotionally charged conflicts. Moreover, the legislature bolstered that belief that the ERCs would meet their duties competently by preemptively providing statutory immunity to institutions and committee members who act in good faith in carrying out their responsibilities under the law (Editorial Board, New York State Bar Association Family Health Care Decisions Act Infomation Center, 2011).

But, "with great power comes great responsibility" (Lee, Ditko, & Koepp, 2002). Now is the time for ERCs to prepare—with sufficient education and training—to meet present and future challenges they will confront.

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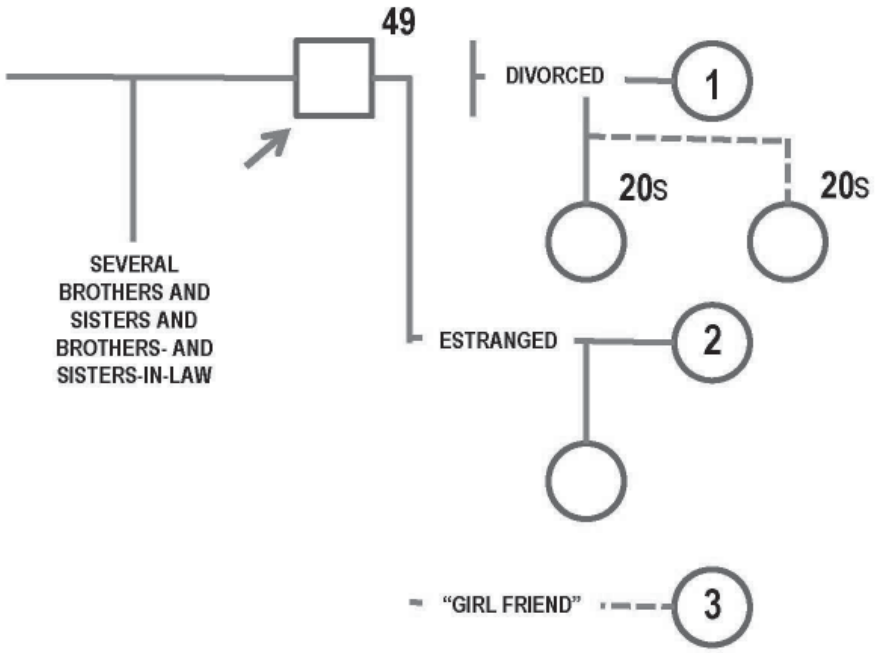
Figure 1. Patient's Family Tree



The patient is indicated by the square with the arrow point; the patient's first wife is represented by the circle with the number 1; the patient's second wife is represented by the circle with the number 2; the patient's girlfriend is represented by the circle with the number 3; the circle labeled with 20s are the patient's natural and common law adult daughters from his first marriage; the unlabeled circle represents the patient's six-year-old daughter from his second marriage.

Table 1. Typical Clinical Ethics Training Options[1]

Type	Typical Format, Style	Example(s)	Contact Hours	Goals, Objectives	Credit Awarded	Typical Fee, Tuition
Institutional orientation (usually on-site)	Readings; organized group discussion or self-study; typically coordinated topically (systematic)	Flannigan R. *Ethics Committee Handbook—For New Member Orientation*. Available at: http://www.practicalbioethics.org/documents/guidelines/18-Ethics-Committee-Handbook-Flanigan-2008.pdf (accessed January 11, 2013).	Typically less than 5 hours	Varies; typically an introduction to terms, functions, operations focusing on institutional specifics	Typically no credit	None
Institutional manual (usually on-site)	Readings; organized group discussions or self-study; typically coordinated topically (systematic)	Thompson R. *So You're on the Ethics Committee: A Primer & Practical Guide for 21st Century Clinical Ethics*, 2nd ed. Chicago: American College of Physician Executives, 2012 [Kindle Edition]. Available at: http://www.amazon.com/Youre-Ethics-Committee-2nd-ebook/dp/B009HH8UYK (accessed January 11, 2013).	Typically less than 10 hours	Varies; typically an introduction to terms, functions, operations focusing on institutional specifics	Typically no credit	None
Institutional ethics grand rounds presentation or case consultation review (on-site)	Lecture or group discussion; typically uncoordinated topically with other presentations (sporadic)	Tenenbaum E. *Revitalizing Informed Consent to Protect Patient Autonomy*. Albany Medical Center Ethics Grand Rounds, January 17, 2013. Available at: http://www.amc.edu/Academic/bioethics/documents/Ethics_Grand_Rounds_-_011713.pdf (accessed January 11, 2013).	Typically 1 hour per session	Varies; instruction typically focuses on a single issue or case	Typically 1 CEU[2] per session	None
Institutional mentorship	Patient encounters, on-the-job mentoring (sporadic)	Acre CA, Prager K, Hardart GE, Fins JJ. *Credentialing the clinical ethics consultant: an academic medical center affirms professionalism and practice*. Journal of Clinical Ethics. 2012;23(2):156-164.	Varies; typically about 5 hours per consult	Varies; mentoring typically focuses on a single set of issues within a case context	None	None

Type	Typical Format, Style	Example(s)	Contact Hours	Goals, Objectives	Credit Awarded	Typical Fee, Tuition
Intensive or emersion program (usually on-site)	Lectures, group discussions, seminars, standardized patient encounters, rounds; typically coordinated topically (systematic)	Mokwunye NO, DeRenzo EG, Brown VA, Lynch JJ. *Training in clinical ethics: launching the clinical ethics immersion course at the Center for Ethics at the Washington Hospital Center.* Journal of Clinical Ethics. 2012;23(2):139-146.	About 25 hours per seminar over five consecutive days	Structured, coordinated topical instruction (systematic)	Typically either CEUs or graduate course credit	About $2,500 per participant (expenses additional)
Series of coordinated seminars (usually on-site)	Lectures, group discussions, seminars, standardized patient encounters, rounds; typically coordinated topically (systematic)	White BD, Zaner RM. *Clinical ethics training for staff physicians. designing and evaluating a model program*. Journal of Clinical Ethics. 1993;4(3):229-235.	About 6 hours per seminar; or, about 25 hours for an entire series	Structured, coordinated topical instruction (systematic)	Typically either CEUs or graduate course credit	About $100 per participant per seminar within the series; about $400 for an entire series
Graduate course (such as a course in clinical ethics on-site or online)	Lectures, group discussions; typically coordinated topically (systematic)	AMBI[3] 503. Clinical Ethics. Information, available at: http://www.amc.edu/Academic/bioethics/educational_programs/graduate_programs/course_info/course_descriptions.cfm (accessed January 11, 2013).	About 100 hours per course	Structured, coordinated topical instruction (systematic)	Typically graduate course credit (about 3 credits per 100 contact hours)	About $2,500 per course
Certificate in clinical ethics (typically a series of college courses on-site or online)	Lectures, group discussions; typically coordinated topically (systematic)	AMBI Graduate Certificate in Clinical Ethics. Information available at: http://www.amc.edu/Academic/bioethics/educational_programs/graduate_programs/degrees_certificates/certificate_program.cfm (accessed January 11, 2013).	About 400 hours per program	Structured, coordinated topical instruction (systematic)	Typically graduate course credit (about 12 credits per 400 contact hours)	About $10,000 per program

Type	Typical Format, Style	Example(s)	Contact Hours	Goals, Objectives	Credit Awarded	Typical Fee, Tuition
Graduate degree (such as a master of science in bioethics on-site or online)	Lectures, group discussions; typically coordinated topically (systematic)	AMBI Comprehensive Master of Science in Bioethics. Information available at: http://www.amc.edu/Academic/bioethics/educational_programs/graduate_programs/degrees_certificates/master_science_bioethics.cfm (accessed January 11, 2013).	About 1000 hours per program	Structured, coordinated topical instruction (systematic)	Typically graduate course credit (about 30 credits per 1000 contact hours)	About $25,000 per program
Fellowship in clinical ethics (on-site or through some distance learning and mentoring arrangement)	Lectures, group discussions, seminars, rounds, patient encounters, on-the-job mentoring; typically coordinated topically (systematic)	Clinical Ethics Fellowship, Albany Medical Center. Information available at: http://www.amc.edu/Academic/bioethics/documents/AMBI_Ethics_Fellow_2012-2013.pdf (accessed January 11, 2012); Cleveland Fellowship in Advanced Bioethics, Cleveland Clinic. Information available at: http://my.clevelandclinic.org/about-cleveland-clinic/ethics-humanities-care/bioethics/advanced-fellowship.aspx (accessed January 11, 2013); MacLean Center Fellowships in Clinical Medical Ethics, University of Chicago Medical Center. Information available at: http://medicine.uchicago.edu/centers/ethics/fellowship.html (accessed January 11, 2013).	About 2000 hours (on-site full-time for one year)	Structured, coordinated topical instruction (systematic)	Typically a non-accredited fellowship certificate or graduate course credit	No-site, typically associated with an employee stipend of about $40,000

Endnotes

1. For complete education at the institutional level, these options must be coupled with training in local policies and practices.
2. CEU means a "continuing education unit" from an accredited professional continuing education provider.
3. AMBI is an acronym for the Alden March Bioethics Institute at Albany Medical College, Albany, New York 12208.

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An Innovation in Continuing Medical Education: Online, Remedial Education for Physicians Following a Professional Violation or Incident

By Wayne Shelton, PhD, Bruce D. White, DO, JD and Evelyn Tenenbaum, JD

Introduction

Each year approximately 3% of all practicing physicians in the United States are referred to state medical conduct boards. Most referrals originate from patient or surrogate complaints, although some come from health care colleagues including fellow physicians and staff. The most common complaints seem to revolve around quality of care concerns, that may include medication / prescription violations, fraudulent practices, and other inappropriate behaviors.[1] Patients may express concerns about the actions of a physician in a particular case such as making a medical mistake or some untoward activity. But many other issues may come to light from colleagues and system audits, or from incidents such as misuse of medications, writing prescriptions inappropriately, fraudulent insurance claims, misrepresenting or fabricating information about a patient that could have some adverse impact on the patient's welfare, engaging in harassing or inappropriate sexual behavior toward a patient or co-worker, or using alcohol or drugs that impair the physician's practice of medicine. In all such cases, some basic ethical and professional violation has taken place, which throws into question the professional integrity of the individual physician and threatens the integrity of the medical profession itself.

Recent Emphasis on Professionalism in Medical Education

Professional violations in medicine are serious matters because of the high expectations of physicians upon their entrance into the medical profession. These high expectations are often symbolized at the beginning of medical school by a kind of professional initiation ritual commonly called the "White Coat Ceremony," which was developed by Dr. Arnold P. Gold in 1993 at the Columbia University College of Physicians and Surgeons in New York.[2] Like many medical educators, Dr. Gold believed that medical professionalism begins on the first day of medical school, not at some future date. The very fact that one enters the medical profession entails a commitment to uphold the ethical standards of the profession. Fortunately, this high expectation of all entering medical students has become the norm throughout medical schools in the United States.

Medical education has given greater attention in recent years to the professional character of the physician as reflected in the 1998 Medical School Objectives Project (MSOP) as issued by the American Association of Medical Colleges (AAMC).[3] The very first learning objective in this document is the bold claim that "Physicians Must Be Altruistic." This is interpreted to mean that physicians must be "compassionate," "empathic," "trustworthy" and "truthful" in all of their professional dealings. Specifically, the MSOP asserts that physicians must "bring to the study and practice of medicine those character traits, attitudes, and values that underpin ethical and beneficent medical care. They must understand the history of medicine, the nature of medicine's social compact, the ethical precepts of the medical profession, and their obligations under law." In addition to the standard expectations such as being "Knowledgeable" and "Skillful" that relate to being competent to practice medicine for the best interests of their patients, the MSOP also asserts that physicians must be "Dutiful." This means physicians must be attentive to the responsibilities of work in a community of fellow professional colleagues, work in a helpful and respectful manner and promote the welfare of patients, particularly the underserved. These are the now common types of professional value orientations in contemporary medical education.

In addition to the standard courses on the basic medical sciences and clinical medicine, for the past two decades medical educators have broadened the scope of the medical curriculum to include topics such as professionalism, ethics and a range of concerns that permeate medical care such as death and dying, spirituality and effective communication. These courses reflect many of the broader learning objectives set by professional organizations such as the AAMC and also organizations like the American Board of Internal Medicine (ABIM) which, in 2002, produced the document entitled "Medical Professionalism in the New Millennium: A Physician's Charter."[4] The Preamble to this document states: "Professionalism is the basis for medicine's contract with society." This means the physicians must dedicate themselves to high standards of personal integrity and patient well-being and must embody the high expectations of the medical profession. Physicians must be honest, truthful and dedicated to patient welfare by respecting their patients and maintaining their professional competence. Moreover, they must recognize appropriate professional boundaries between themselves and their patients as well as their coworkers. Society grants to physicians a high social standing and the right to set standards within the medical profession. This means that the members of the profession of medicine

must self-regulate, that is, accept the responsibility to ensure that the standards of professionals are met in the daily practice of medicine.

Challenges in Contemporary Medical Practice

The expectation of self-regulation is challenging to say the least in the context of contemporary medicine where we see a continual explosion of knowledge and technology, serious problems in the health care delivery system and changing market conditions and uncertainties. Along with these challenges, there is the growing expectation throughout medical practice for physicians to see more and more patients. In this setting, there are at times lapses in individual judgment and behavior. For some who commit professional violations, the incident represents a pattern of behavior that is reflected in past experiences and may continue in the future. In some cases, a serious professional violation may mean the end of a medical career. But for most individuals, it does not.

For the majority of physicians who have committed a professional violation, there is the hope that they will fully realize the breach of their professional responsibilities, make meaningful amends and return to practice. This group may have gaps in their understanding of the standards and expectations of medical professionalism and/or not have fully come to grips with what those standards and expectations entail for them in daily practice. For most of these individuals, second chances are possible. But further education is essential, combined with serious soul searching and reflection. The remainder of this article will describe a new, online course called *Better Doctoring* provided by the Alden March Bioethics Institute specifically for such physicians seeking remedial education in medical ethics and professionalism.

The Alden March Bioethics Center (AMBI)

The Alden March Bioethics Institute (AMBI) of Albany Medical College is a multidisciplinary center deeply involved in academic medical and graduate bioethics education, research and clinical consultation.

All instructors for the Better Doctoring seminar focusing on medical ethics and professionalism are Albany Medical College faculty or staff. One has served as a consultant to the Office of Professional Medical Conduct, has experience prosecuting professional misconduct cases, and is now a law school professor; another is an attorney with experience defending health care professionals accused of professional misconduct. Three are practicing physicians. Two are recognized thought leaders and consultants in providing education with standardized patient scenarios and interviews. All are medical school professors who have been involved in educating medical students and residents about professionalism and ethics for many years.

Why Better Doctoring?

The name *Better Doctoring* was selected to emphasize that physicians who may be good doctors in most ways may still have deficiencies they need to address to make themselves better doctors. Thus, the course is designed to help those enrolled become better doctors with respect to understanding and being better able to embrace the standards of professionalism expected of them as physicians. Moreover, *Better Doctoring* sends the message that professional and ethical violations and concerns need not mean the end of a medical career. If approached properly, such occasions may offer an opportunity for professional growth and renewal. Because the faculty members of AMBI are dedicated medical educators, our hope is that *Better Doctoring* will serve patients and physicians by helping physicians achieve their aspirations to meet high standards of quality, professional patient care.

Finally, *Better Doctoring* was created as an online course because some of the physicians who are in need of remedial education in professionalism and ethics are working full time and trying to salvage their professional careers. They may find the expense and time of traveling long distances to sites for 2-3 days of full time instruction too burdensome to pursue. The *Better Doctoring* online course enables the learner to find the most convenient times to participate and generally makes the course more practicable. The online, distance-learning format is a type of education the AMBI faculty has used successfully for a long time. *Better Doctoring* is an extension of AMBI's broad array of online educational courses and provides those that complete it 25 hours of AMA PRA Category 1 Continuing Medical Education (CPE) credits. This course is unique in that it combines a personal, tailored approach to ensure a participant's specific needs are met, with a general approach to the field of medical professionalism and misconduct, all in a distance learning format.

What Is Better Doctoring?

The learning outcome objectives are designed to enable learners in this course to better understand their professional responsibilities as members of the medical profession and to address the particular reasons they came to this course. Specifically, the objectives of the course are as follows:

- Demonstrate knowledge of prevailing standards of professionalism arising from professional organizations, codes of conduct and medical ethics.
- Identify some of the major failures of physicians to act as professionals or good doctors towards patients, colleagues, and staff, and to fulfill obligations to the community.
- Exercise sound reasoning skills and judgment in reaching viable solutions to cases involving potential violations of medical professionalism.

- Engage in reflective writing about professional infractions or violations.
- Participate openly and respectfully in discussions with peers and mentors about professional infractions.
- Give and receive feedback thoughtfully and constructively when interacting with mentors and peers.
- Formulate a precise, personal plan for renewed commitment to professional values, norms and service, medical ethics, and professionalism.

The course is divided into five modules through which learners must proceed in a tightly scheduled time frame and pass each one successfully in order to get credit for the full course. The learner either receives a "pass" at the end of the course and receives full credit, or receives a "fail" and receives no credit. Partial credit for this course is not given. However, sections may be repeated a second time if learners fail to receive a "pass" the first time.

The course begins in Part I with a personalized one-on-one introduction to the course either by phone or Skype, which allows each learner to describe the reasons that brought him or her to the course and the particular goals he or she wishes to achieve. Learners will then be asked to describe, in no more than 2-3 pages, their stories and reasons for enrolling in the course. Those stories will be posted on the Forum discussion board to share with fellow learners with the clear understanding all stories are to be held in strict confidence and used for learning purposes only. Finally, the participant will be informed of the specific expectations of the course and that each segment of the course must be completed successfully to get full credit for the whole course. At this point, the heart of the course can begin, which consists of the main modules covered in the Forum discussion. Because the Forum is such a critical part of an online course, it is important to describe its function fully.

The Forum, or discussion board, is an online, distance learning tool comparable to the classroom in an on site course. It is where the class is held—where lectures are given, critical questions are asked and discussed at length and where most of the learning takes place. It is where students spend most of their time in the course. After doing the required writing, reading or viewing of online videos, the course will have discussion questions for those enrolled in the class, which commonly results in an extended class discussion. Although one of the course instructors will orchestrate the discussion and participate when needed to provide critical information and clarification of issues, what seems obvious from years of teaching online is that learners learn immensely from one another. Because learners are usually seasoned professionals, they have much experience and knowledge from which to draw. Participation is also expected of everyone, so those who may be reticent to speak up in class will readily speak up in the Forum discussion. Because learners are using the written word to express their ideas, writing is highly emphasized and allows learners to refine their thoughts and views on each topic being considered. This is also the setting where the learners come to know each other and a sense of online community often develops.

Part II is devoted to readings and questions on those readings that highlight the standards and expectations of what we call "good doctoring" and medical professionalism. The "good doctor" is an age-old term that applies to those physicians who fully embody those standards and expectations in their daily medical practice. Physicians have an image of such an individual from their medical education and training. Historical iconic images of the good doctor bring to mind the likes of William Osler who said, "The good physician treats the disease; the great physician treats the patient who has the disease."[5] Topics in this section of the course include the normative meaning of medical professionalism, the importance and meaning of respect and honesty in the physician-patient relationship, the role of moral courage in medical practice, the art of healing, and the basis of medical morality in well-established professional codes.

In Part III, the course turns to an examination of the types of acts of medical misconduct that interrupt professional careers and require some type of redress. Actual professional misconduct cases that were litigated in court have been adapted for this course and are representative of the types of cases that result in disciplinary consequences. Specifically, the topics include:

- Impairment
- Quality of care—Malpractice: excusable versus inexcusable practice
- Professional boundaries
- Sexual misconduct—harassment—appropriate personal boundaries
- Honesty—gaming the system—cutting corners—billing insurers
- Disruptive, unprofessional behavior

Six real cases, taken from public legal records, are adapted for this course and are discussed in light of the content learned from Part II. Learners are expected to respond to written questions concerning the nature of the violations that occurred in each case and the professional standard that was violated.

In Part IV, scenarios raising ethical issues are presented by actors posing as patients. Medical misconduct will be discussed in an online Discussion Forum using the same topics as in Part III.

On each of these topics, there is an online video produced at the Patient Safety and Clinical Competency Center at Albany Medical College using patient actors to demonstrate what the characters in each of these six scenarios are going through. The actors in each of these videos give voice and personal identity to a problematic situation in which a possible professional violation is occurring. The task of the learner is to watch each video and then be able to critically discern the particular type of professional violation that is raised in each one. The key question asked for each scenario is: "Based on what you learned in Modules II and III, and from how you now understand professional obligations, what would you do as the physician in this situation? Be sure to fully explain why what you propose to do is, professionally, the right thing to do." The goal here is to ensure that the learners are now to the point where they not only have basic and specific knowledge about professional standards and expectations in specific situations that they encounter but are also able to critically assess what steps they, as fully functioning professionals, would take to rectify the situation. Each learner will share his or her own personal perspective and also read the responses of others and then discuss as a class all the various options.

Finally in Part V, to wrap up the course, each student will have an exit interview and write a final paper. The paper is the culmination of each learner's experience in the course. The specific task is to rethink in a short, final paper, the concerns that prompted each learner to take this course. Learners are asked to precisely identify the professional standards they may have violated or encountered in the past, and most importantly to describe how they plan to deal in the future with similar situations. Then, they are asked to describe any new insights they have had into their past practices as health care professionals and formulate in detail new professional goals for becoming the kind of professional they wish to become. A final phone call or Skype teleconference between the learner and faculty mentor will center on discussing this paper and any final reactions to the course. During the phone call, the faculty member will also deal with any remaining concerns and wrap up the course. If the learner so desires, and if he or she has successfully passed all parts of the course, a letter will be written by the AMBI faculty course director on the learner's behalf to any third party to confirm successful completion of the course.

Conclusion

With regularity each year, for whatever reason, some physicians fail to meet their professional responsibilities and therefore risk being removed from professional practice. For those who genuinely wish to redeem themselves and seek to become well grounded in professional and ethical standards in medical practice, a second chance is warranted. *Better Doctoring* is a new offering in the field of professional and medical ethics that gives physicians this chance.

Endnotes

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Tube Feeding in Advanced Dementia Should Not Be Classified as Life-Sustaining Treatment

By James Zisfein, Howard J. Finger, and Nancy Neveloff Dubler

New York's Family Health Care Decisions Act (FHCDA), enacted in 2010, establishes the legal right of surrogates (family members and close friends) to make health care decisions for adults who lack decision-making capacity. For decisions that do not involve life-sustaining treatment (LST), surrogates are given broad authority to make decisions that are in accord with the patient's known wishes, values, and beliefs, or if the wishes are not known, in the patient's best interest.

For decisions involving withholding or withdrawing of LST, however, surrogate authority is restricted:

> Decisions by surrogates to withhold or withdraw life-sustaining treatment shall be authorized only if the following conditions are satisfied, as applicable: (i) Treatment would be an extraordinary burden to the patient and an attending physician determines, with the independent concurrence of another physician, that, to a reasonable degree of medical certainty and in accord with accepted medical standards, (A) the patient has an illness or injury which can be expected to cause death within six months, whether or not treatment is provided; or (B) the patient is permanently unconscious; or (ii) The provision of treatment would involve such pain, suffering or other burden that it would reasonably be deemed inhumane or extraordinarily burdensome under the circumstances and the patient has an irreversible or incurable condition, as determined by an attending physician with the independent concurrence of another physician to a reasonable degree of medical certainty and in accord with accepted medical standards.[1]

LST decisions are further restricted if the patient lacks a surrogate:

> If the attending physician, with independent concurrence of a second physician designated by the hospital, determines to a reasonable degree of medical certainty that (i) life-sustaining treatment offers the patient no medical benefit because the patient will die imminently, even if the treatment is provided; and (ii) the provision of life-sustaining treatment would violate accepted medical standards, then such treatment may be withdrawn or withheld from an adult patient.[2]

Therefore, whether a treatment can be withheld or withdrawn under FHCDA may depend on whether the treatment is deemed to be life-sustaining for the patient being treated. The responsibility for making that determination is delegated to the patient's physician, not to a lawyer or court:

> "Life-sustaining treatment" means any medical treatment or procedure without which the patient will die within a relatively short time, as determined by an attending physician to a reasonable degree of medical certainty.[3]

For Some Patients, Tube Feeding Is Life-Sustaining

Tube feeding is defined as the provision of artificially administered nutrition and hydration through a percutaneous endoscopic gastrostomy (PEG) or naso-gastric (NG) tube. It is a treatment that may or may not be life-sustaining, depending on the patient being treated.

Tube feeding sometimes qualifies as LST. For example, when there is impairment of swallowing due to head and neck cancer, tube feeding can sustain life while radiation and other treatments are given to eradicate the tumor.[4] Tube feeding can sustain life in Lou Gehrig's disease, although the need for tube feeding will likely be permanent.[5] Tube feeding is also life-sustaining for patients in vegetative states, e.g., the patients involved in the Cruzan[6] and Schiavo[7,8] decisions, who died shortly after the tubes were withdrawn.

For Patients With Advanced Dementia, Tube Feeding Is Not Life-Sustaining

Although tube feeding is life-sustaining for some patients, we must not make the mistake of assuming it is life-sustaining for all. Patients with progressive advanced dementia,[9] if they survive long enough, ultimately decrease their oral intake, develop malnutrition and/or dehydration, and become potential candidates for tube feeding. However, when these patients develop inadequate oral intake, best available evidence is that feeding by PEG or NG tube does not prolong life. Furthermore, it causes demonstrable harm.

Finucane et al. exhaustively reviewed all published studies over a 34-year period (1966 through 1999) that

compared advanced dementia patients who received tube feeding with those who did not. There was no reported evidence of benefit for any clinically important outcomes including survival, aspiration pneumonia, infections, pressure sores, improved functioning, or palliation.[10] A 2009 Cochrane review came to the same conclusion.[11] A study of admissions to a single acute care hospital of severely demented patients found a 50% 6-month mortality rate; there was no difference in survival between the patients who received (or already had) a feeding tube vs the patients who did not have a tube placed.[12] A Veterans Affairs Hospital study showed no difference in survival of demented patients who received PEG vs patients for whom PEG was recommended but the surrogates declined.[13] Mitchell et al. compared outcomes in 1,386 institutionalized demented patients for those receiving vs. not receiving tube feedings. Even after adjusting for multiple risk factors that could decrease survival in the tube-fed group, there was no survival benefit demonstrable. Nor did tube feeding improve complication rates. Aspiration pneumonia was more common in tube-fed patients, and pressure sore formation was not decreased.[14] In a data set of 5,266 nursing home residents (not all demented) studied by the same group, tube-fed residents had a higher mortality rate than those who were not tube fed, even after adjusting for confounding covariates.[15] Tube feeding in nursing home patients with advanced dementia was associated with a 1-year survival of 64%, median survival of 56 days, and a 19% rate of tube failure necessitating tube replacement or repositioning.[16] And in a recent study, patients with advanced dementia who were tube fed were more than twice as likely to develop pressure sores, and less likely to have pressure sores heal, compared to matched controls who are hand fed.[17]

On March 7, 2013, based on the strong evidence provided by these and other reports, the American Geriatrics Society released the following practice guideline: "Don't recommend percutaneous feeding tubes in patients with advanced dementia; instead, offer oral assisted feeding." The AGS cited the lack of life prolongation with feeding tubes as well as increased pressure ulcers, pneumonia, agitation, and need for chemical and physical restraints.[18]

Long-Term Tube Feeding Is Considered Major Medical Treatment by the FHCDA in Patients Without a Surrogate

If tube feeding is not deemed LST, based upon the evidence-based medical literature, in a patient or nursing facility resident with advanced dementia for whom no surrogate is reasonably available, willing, or competent to act, then on what basis can a decision to proceed with tube feeding be made? The FHCDA excludes the long-term provision of NG tubes from the scope of services normally provided under routine medical care.[19] Therefore, it falls under the scope of major medical treatment. For major medical treatment decisions, the FHCDA requires an attending physician to make such a recommendation in consultation with hospital staff directly responsible for the patient's care. In a general hospital, it requires that at least one other physician, designated by the hospital, must independently determine that he or she concurs that the recommendation is appropriate. In a residential health care facility, it states that the medical director of the facility, or a physician designated by the medical director, must independently determine that he or she concurs that the recommendation is appropriate. As is readily apparent, the burden of proof would be documenting that such major medical treatment is appropriate, which would conflict with the evidence-based medical literature that tube feeding does not prolong survival, prevent aspiration, prevent pressure sores, or improve quality of life.

Conclusion

Tube feeding for patients with advanced dementia and inadequate oral intake causes major complications, does not prolong life, and should not be classified as life-sustaining treatment (LST). The standard of medical care for these patients is to not perform tube feeding and to offer oral assisted feeding instead.[18,20] Individualized patient assessment is still required, and in exceptional circumstances the attending physician may perceive potential life-prolonging effect of tube feeding. But the evidence shows that will rarely be the case.

If a hospital or nursing facility incorrectly classifies tube feeding as LST for patients with advanced dementia, there is a risk that those patients could be forced to have non-beneficial feeding tubes inserted. That is because New York's Family Health Care Decisions Act (FHCDA) limits the authority of health care institutions to withhold or withdraw LST, especially for patients who lack surrogate decision-makers.

To prevent this harm, it is the responsibility of physicians who work at health care facilities to correctly determine if tube feeding is LST for patients under their care. It is the responsibility of facility legal counsel to acknowledge the physician's role under FHCDA in making that determination.

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The views and advice expressed in this article are purely those of the authors and members of the HHC Bioethics Council and do not necessarily reflect the opinions or policies of HHC.

Statements in Support of the Surrogate Decision-Making Improvement Act

New York State Bar Association Health Law Section, and
Greater New York Hospital Association

Editor's Note: In May 2013 Senate Health Committee Chair Kemp Hannon and Assembly Health Committee Chair, Richard Gottfried introduced identical bills: S.5321 and A.7571. The bills, informally referred to as "the Surrogate Decision-Making Improvement Act" (SDMIA), can be found by searching by bill number at http://public.leginfo.state.ny.us/menuf.cgi.

The following are statements in support recently issued by the NYSBA Health Law Section, and by the Greater New York Hospital Association.

NYSBA Health Law Section Legislative Report

Bill: S.5321(Hannon) / A.7571(Gottfried) AN ACT to amend the public health law and the surrogate's court procedure act, in relation to making technical, clarifying and coordinating amendments regarding health care agents and proxies, decisions under the family health care decisions act and non-hospital orders not to resuscitate, and amending provisions relating to health care decisions for people with developmental disabilities; and to repeal article 29-B of the public health law relating to orders not to resuscitate for residents of mental hygiene facilities

Also known as "The Surrogate Decision-Making Improvement Act (SDMIA)"

Position: **Support**

The NYSBA Health Law Section has long supported changes in New York law that would promote the rights and interests of patients. The Health Law Section was a strong supporter of the Family Health Care Decisions Act (Ch. 8, L. 2010) and is committed to help ensure the successful implementation of the FHCDA, and to identify, advance and support proposals to improve the FHCDA and other statutes that govern decisions on behalf of patients who lack the capacity to decide for themselves.

To facilitate successful implementation of the FHCDA, the Section has undertaken several activities. The Section, its leaders, and members, have:

- created a website, accessible to the public, with extensive information about the FHCDA, including a detailed set of frequently asked questions and answers.[1]
- organized several professional educational programs.[2]
- published a special edition of the NYS Bar Association Health Law Journal on "Implementing the Family Health Care Decisions Act," with sixteen articles on the FHCDA by attorneys, physicians, bioethicists and others.[3]
- published other important articles on the FHCDA.[4]

The FHCDA effected sweeping changes in New York law to improve decision-making for incapacitated patients by expanding, and clarifying the authority of family members, domestic partners, and others close to the patient to make health care decisions for patients who lack capacity and did not previously appoint a health care agent, in accord with appropriate standards and safeguards.

At this time, it is clear that the statute should be extended to govern decisions about CPR in facilities licensed or operated by the Office of Mental Health. In addition, provisions of the Health Care Proxy Law, the Non-Hospital DNR Law, the Surrogate's Court Procedure Act, and the FHCDA require revision to reconcile language in the four laws and to clarify the intent of certain provisions. For this reason, the Health Law Section supports the Surrogate Decision-Making Improvement Act ("SDMIA").

Summary and Analysis

The SDMIA, in its more significant provision, will:

1. Replace PHL Article 29-B, Orders Not to Resuscitate for Mental Hygiene Facilities. (SDMIA §1)

PHL Article 29-B ("Orders Not to Resuscitate in Mental Hygiene Facilities") governs DNR orders in OPWDD operated "schools" (an outdated term) and in OMH operated and licensed psychiatric hospitals and units. There is no longer a need for this article. DNR decisions in OPWDD operated developmental centers facilities (the successor to OMRDD "schools") are already governed by SCPA 1750-b. DNR decisions in psychiatric hospitals and units could easily be made subject to the FHCDA, which has principles similar to those in PHL Art. 29-B. This would be particularly helpful for general hospitals, which now have to follow slightly different DNR rules in their medical units from those in their psychiatric units, with no policy rationale for the differences.

2. Reconcile the authority of agents and surrogates with respect to decisions about medically-provided nutrition and hydration. (§§5, 6)

When strict clinical criteria are satisfied, the FHCDA allows a surrogate to make a decision to withhold or withdraw life-sustaining treatment, including medically-provided nutrition and hydration based on the patient's wishes, if reasonably known, or else the patient's best interests. But the Health Care Proxy Law authorizes an agent to decide to withhold or withdraw medically-provided nutrition and hydration based solely on the patient's wishes, if reasonably known—and not the patient's best interests if the patient's wishes are not reasonably known. The SDMIA would amend the Health Care Proxy Law to allow an agent to make a decision about artificial nutrition and hydration based on the patient's best interests. This is an appropriate amendment—a health care agent, specifically appointed by the patient, should be able to act in furtherance of a principal's best interests when the patient's wishes are not reasonably known. (§4)

3. Conform various provisions in the Health Care Proxy Law and the FHCDA. (§§6, 14)

The SDMIA eliminates many discrepancies in language between the Health Care Proxy Law and the FHCDA, mostly in the provisions about determining incapacity. Those discrepancies, though mostly non-substantive, are a source of confusion and other implementation complications.

4. Require a concurring determination of incapacity, and a determination of incapacity by specially qualified professionals, only for life-sustaining treatment decisions. (§§6, 14)

Currently, both the Health Care Proxy Law and the FHCDA require: (i) that the attending physician determine whether a patient lacks capacity; (ii) that if the decision relates to the withdrawal or witholding of life-sustaining treatment there must be a concurring determination of incapacity; and (iii) that if the basis for that determination is a developmental disability or mental illness, either the attending physician must have special qualifications or must secure a concurring opinion by another person with special qualifications. Also, the FHCDA requires a concurring opinion of incapacity for all determinations involving nursing home residents. The SDMIA amendment would make the Health Care Proxy Law and FHCDA requirement of a determination by a person with special qualifications and the FHCDA requirement of a concurring opinion in nursing homes, applicable only to cases involving withdrawal or witholding life-sustaining treatment decisions, and not to cases involving consent to treatment. This change ensures that additional safeguards, and the additional time, effort and resources that those safeguards require, are mandated in the cases where they are most important—for decisions to withhold or withdraw life-sustaining treatment—and not where they could impede the delivery of treatment to a patient.

5. Clarify that the duties that arise when a surrogate insists upon treatment do not apply when the hospital or physician is carrying out an adult patient's prior decision. (§17)

Currently, both the Health Care Proxy Law and FHCDA state that if a health care agent or surrogate directs the provision of life-sustaining treatment, but the hospital or individual health care provider "does not wish to provide such treatment," the hospital or individual provider nevertheless must either comply with the agent's decision, transfer the patient or seek court review. §§2984.5 and 2994-f.3. The SDMIA would amend this requirement to clarify that it does not apply:

- in the case of a health care agent, when the hospital or individual health care provider is carrying out a prior decision by the patient. (§7), and
- in the case of a surrogate, when the hospital or individual health care provider is carrying out a prior decision by the patient made in accord with the FHCDA provisions.

The obligation to honor the clear prior instructions of an adult patient is firmly supported by the United States and New York State Constitutions, as well as numerous federal and New York State statutes, regulations and case-law. Sections 2984.5 and 2994-f.3 should not be read to override that obligation. Moreover, under the FHCDA, if a provider has adequate prior instructions from a patient, there is no need to seek an agent's or surrogate's consent. See §2994-d.3(ii).

6. Clarify medical futility as a basis for a DNR order. (§§15, 18, 32)

The FHCDA establishes that two physicians can consent to a DNR order if the treatment "offers the patient no medical benefit and the patient will die imminently even if treatment is provided, and the provision of treatment would violate accepted medical standards…." The proposed amendment in Section 19 clarifies the meaning of medical futility in the context of a DNR order. The amendments also clarify that physicians can enter a DNR order on the basis of medical futility even if the patient is eligible for decision-making by an Article 80 surrogate decision-making committee, since the decision about futility, as defined in the statute, is strictly a medical determination.

Under the former DNR law (PHL Art 29-B), a surrogate could consent to a DNR order if the patient met any one of four clinical criteria, including a finding by two physicians that resuscitation would be "medically futile," defined to mean that resuscitation "will be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period

before death occurs." The former DNR law also allowed two physicians to write a DNR order on medical futility grounds for a patient who did not have a surrogate.

For decisions by family members and other surrogates, the FHCDA established standards for the withdrawal or withholding of a broader range of life-sustaining treatment, including resuscitation. The FHCDA does not specify medical futility as a basis for a DNR order or for other treatments. However, medical futility would clearly be encompassed by the existing standards for decision-making under the FHCDA.

The Section members have different views on the value of including the medical futility standard as a basis for a surrogate consent for a DNR order. However, we support explicitly clarifying the manner in which the medical futility standard applies as a basis for approval of a DNR order for a patient who does not have a surrogate (or for whom a MHL Art. 80 surrogate decision-making panel would be the surrogate).

7. Clarify the right of developmentally disabled persons who have capacity to make decisions. (§30)

Currently, SCPA §1750-b authorizes life-sustaining treatment decisions only when made by SCPA 1750-b guardians. This amendment clarifies that if the developmentally disabled person is found to have capacity, he or she can make his or her own decisions relating to life-sustaining treatment. (§31). It also provides that if the developmentally disabled person created a health care proxy, then such decisions can be made pursuant to the Health Care Proxy Law.

8. Modify the roles of Surrogate Decision Making Committees and Mental Hygiene Legal Services with respect to DNR orders. (§§33, 34)

Surrogate Decision Making Committees—Under the former DNR law, the MHL Article 80 Surrogate Decision Making Committee (SDMC) had no role in reviewing DNR orders. The FHCDA, by making SCPA 1750-b applicable to DNR orders for developmentally disabled persons, indirectly required SDMC review of DNR orders for such persons. This bill removes the SDMC's role in the review of DNR orders entered on the basis of medical futility. (§35)

Mental Hygiene Legal Services—Under the former DNR law, for patients in or transferred from a mental hygiene facility, notice of a DNR order had to be given to the facility director, but not to mental hygiene legal services (the MHLS) prior to entry of order. By making SCPA §1750-b applicable to most such patients, the FHCDA requires notice to MHLS of all decisions to withhold or withdraw life-sustaining treatment, including DNR orders. Moreover, if MHLS objects to the order, it must be stayed. Notice to MHLS of all DNR orders for developmentally disabled persons in hospitals or nursing homes is not supported by identified problems or poor decisions and delays what may be urgent treatment decisions for these patients. Restoring the previous procedure, and eliminating both the notice to MHLS and its authority to object would reduce a burden on hospitals and nursing homes, and prevent unnecessary and sometimes harmful delays in the issuance of appropriate DNR orders while MHLS investigates each case.

The proposed amendments preserve the safeguard of notice to MHLS, but provide that an objection by MHLS will not stay the DNR order unless MHLS provides a basis for its objection, including clinical support. This approach strikes a reasonable balance. (§36).

Conclusion

The Surrogate Decision-Making Improvement Act makes a series of valuable clarifications and adjustments to the FHCDA and related laws. The Health Law Section urges passage of the bill to further realize the intention of New York's laws on treatment decisions.

* * *

Greater New York Hospital Association Statement of Support

May 20, 2013

TO: Members of the New York State Legislature

FROM: Greater New York Hospital Association

RE: S.5321 (Hannon) / A.7571 (Gottfried)—The Surrogate Decision-Making Improvement Act

S.5321 / A.7571 would amend New York State laws governing surrogate decision-making, specifically the Family Health Care Decisions Act (FHCDA) and the health care proxy law, as well as the surrogate court procedure act in relation to decision-making for persons with developmental disabilities. Additionally, S.5321 / A.7571 repeals the public health law relating to orders not to resuscitate residents of mental hygiene facilities, which are subsumed by FHCDA.

Greater New York Hospital Association (GNYHA) has a longstanding interest in respecting patients' rights to have their wishes followed regarding medical care, or to decline unwanted treatment. GNYHA strongly supported FHCDA's enactment and advocated for its passage for almost two decades. Since FHCDA became law, GNYHA has worked with its members to ensure its requirements are understood and effectively implemented.

The FHCDA, which became effective in 2010, creates a process for allowing surrogates to make decisions on behalf of patients who become incapacitated, but have neither appointed a health care proxy nor provided "clear

and convincing" evidence of his or her wishes. As noted above, FHCDA's passage was historic. The law addresses many gaps in current New York State law that concern surrogate decision-making, while providing sufficient procedural safeguards to adequately protect patients' rights. It provides a sensitive approach to making treatment decisions on behalf of individuals who have surrogates available, and creates a thoughtful process for respecting the rights and dignity of individuals who may have no one to speak on their behalf. However, there are several areas where existing laws need to be better coordinated with FHCDA to ensure that all patients are afforded the same rights and opportunities with regard to a surrogate's ability to act on their behalf.

GNYHA believes that S.5321 / A.7571, Health Care Decisions for People who Lack Capacity, clarifies and coordinates FHCDA with existing laws in a meaningful way and will help ensure more effective implementation across the State. GNYHA fully supports the passage of S.5321 / A.7571, and supports the adoption of the technical corrections it contains, as well as the following provisions:

- ***Orders Not to Resuscitate for Mental Hygiene Facilities***

  S.5321 / A.7571 repeals the DNR law and provides that do not resuscitate (DNR) decisions for patients in psychiatric hospitals and psychiatric units of general hospitals are now governed by FHCDA, and confirms that DNR decisions for persons with developmental disabilities are governed by the Surrogate Court Procedures Act (SCPA). There is no need for a separate DNR law for these settings, and S.5321 / A.7571 will help eliminate the confusion and complexity that the variance in DNR standards has created.

- ***Health Care Proxy Law and FHCDA Requirements***

  S.5321 / A.7571 aligns the health care proxy law and FHCDA standards with respect to the definitions of "health care" and "health or social services practitioner," decisions about artificial nutrition and hydration, and the requirements for determining that a patient lacks capacity.

- ***Concurring Determination of Incapacity for Life-Sustaining Treatment Decisions***

  The requirement to obtain a concurring opinion for determining incapacity before a health care agent or surrogate can decide to withdraw or withhold life-sustaining treatment is a very appropriate safeguard. However, the requirement for a concurring opinion to be provided for determining incapacity for a health care agent's or surrogate's decisions concerning beneficial treatment is also required. This can be a barrier to treatment and can create a delay in such treatment. S.5321 / A.7571 proposes to limit the concurring opinion requirement to decisions involving life-sustaining treatment decisions in hospitals, nursing homes, and cases in which the determination of incapacity is based on a patient's mental illness or developmental disability.

- ***The Primacy of a Patient's Prior Decision***

  The Health Care Proxy Law and FHCDA state that if a health care agent or surrogate directs the provision of life-sustaining treatment, but the hospital or individual health care provider "does not wish to provide such treatment," the hospital or individual provider nevertheless must either comply with the agent's decision, transfer the patient, or seek court review. While the provision is appropriate as applied to a dispute between the agent or surrogate and the provider, it is constitutionally and ethically problematic if applied to override a patient's clear prior decision. The proposed amendment in S.5321 / A.7571 clarifies that the provision relating to a dispute between the agent and the provider does not apply when the hospital or individual health care provider is carrying out a patients' prior decision made with respect to decisions to withdraw or withhold life-sustaining treatment.

- ***Medical Futility as a Basis for a DNR Order***

  Under the former DNR law, a surrogate could consent to a DNR order if the patient met any one of four clinical criteria, one of which was a finding by two physicians that resuscitation "will be unsuccessful in restoring cardiac and respiratory function or that the patient will experience repeated arrest in a short time period before death occurs." The former DNR law also would allow a DNR order to be entered for a patient who did not have a surrogate. The FHCDA, in contrast, established standards for withdrawing or withholding a broader range of life-sustaining treatment, and did not include a standard specifically relating to the medical futility of resuscitation. Experience is showing that the broader FHCDA standards, especially the standard for patients without surrogates, can be difficult to apply to decisions about resuscitation. This bill would restore the former DNR law's medical futility standard as an alternative basis for surrogate consent to a DNR order, or for issuance of a DNR order for a patient who does not have a surrogate, under both FHCDA and SCPA.

- ***Rights of Developmentally Disabled Persons***

  S.5321 / A.7571 clarifies that a developmentally disabled person who is determined to have capacity can make his or her own decisions relating to life-sustaining treatment, and provides that a developmentally disabled person who has a valid health

care proxy shall have all such decisions made in accordance with the health care proxy law.

- ***Roles of Surrogate Decision-Making Committees (SDMC), OPWDD-Licensed Facility Directors, and Mental Hygiene Legal Services (MHLS)***

  S.5321 / A.7571 modifies the roles of the Surrogate Decision-Making Committee (SDMC) and Mental Hygiene Legal Services (MHLS) with respect to DNR orders. It would require Facility Directors and MHLS to provide a legal basis for objecting to a surrogate's decision against life-sustaining treatment before such objection will stay the decision. The bill restores a provision, "Notification to the facility director shall not delay issuance of an order not to resuscitate," unless the objection is accompanied by clinical support for the objection to the DNR order, and makes it applicable to notices to MHLS, as well.

- ***Determinations of Incapacity for Patients with Developmental Disabilities***

  One provision of S.5321 / A.7571 amends provisions of the Health Care Proxy law, the FHCDA, and the health care decisions act for mentally retarded persons (SCPA §1750-b) relating to the qualifications the attending physician or concurring professional must have to make a determination of incapacity on the basis of developmental disability. Under the amendment, with respect to patients in hospitals, residential health care facilities, and hospice programs, either the attending physician or the health or social services practitioner providing the concurring determination, where one is required, must be qualified by training or experience to make such determination, in accordance with policies adopted by the facility. A record of such consultation shall be included in the patient's medical record.

For the reasons outlined above, GNYHA strongly supports enacting S.5321 / A.7571 into law.

Endnotes

1. See www.nysba.org / fhcda.
2. E.g., "Health Care Decision Making: Implementation of the Family Health Care Decisions Act, Recent Developments and Ethical Considerations," Albany (May 6, 2011) and NYC (May 13, 2011).
3. NYSBA Health L. J., Spring 2011.
4. See. e.g., Tracy Miller, "New York Adopts Broad Law on Changes to Treatment Decisions," 243 *N.Y.L.J.* 1 (March 21, 2010) and Robert N. Swidler, "New York's Family Health Care Decisions Act: The Legal and Political Background, Key Provisions and Emerging Issues," 82 *N.Y. Bar J.* 18 (June 2010).

The HIV Law: Still a Risk for Physicians and Staff

By Donnaline Richman

New York State law has provided special protections for the confidentiality of HIV-related treatment information since 1989.[1] Amendments to the basic provisions of this law have been infrequent, but have significantly expanded the scope of protected HIV information. Some amendments govern the release of HIV-related treatment information to entities such as insurance companies and require HIV testing for pregnant women and newborns. Recent changes to the HIV law now require physicians, dentists, hospitals, and other facilities to offer HIV testing to all patients aged 13–64 who present to a hospital or primary care service.[2]

If a patient agrees to undergo an HIV test in accordance with this new law and those test results are positive, that patient's medical records are subject to the HIV confidentiality provisions. However, the New York State Department of Health has advised that, in accordance with the new statute, the mere offer of an HIV test, or a patient's refusal to undergo an HIV test, are not considered confidential information.[3]

Although the New York State HIV confidentiality law is decades old and is one of the most stringent in the United States, many providers still fail to comply with the law when releasing patient records or discussing patients who are HIV positive or have HIV-related illnesses. It is important to understand that the definition of HIV-related information includes far more than just the diagnosis of HIV, AIDS or an HIV-related illness. The fact that a patient has undergone an HIV test, regardless of the test results, is also protected. Any individual who provides health or social services for the patient, or who obtains HIV-related information with the patient's authorization, or has information which does or could reasonably identify a protected individual or his / her contact, is deemed to possess confidential HIV-related information and must protect this information in full compliance with the law.[4]

When medical records containing HIV-related information are requested by a third party, providers must obtain a written, signed authorization from the patient which specifically directs the release of HIV information to that third party. If the patient lacks capacity, a healthcare proxy agent or other individual legally authorized to make healthcare decisions for the patient may sign the authorization. A general authorization to release "my entire medical record" is not sufficient to release HIV-related information, except under very limited exemptions.[5] In order to release HIV-related information, the patient, or their legally authorized representative, must complete a form specifically authorizing the release of HIV information.[6,7] If the form requires initials next to the phrase "HIV information," the patient must initial this section so that the records can be released. Finally, whenever HIV-related information is disclosed to a third party pursuant to a valid written authorization, the information must be accompanied by a Notice of Prohibition against Redisclosure.

Exemptions to the Specific Disclosure Requirements

Although the HIV laws are quite strict, HIV-related treatment information may be released upon receipt of a general authorization in certain well defined circumstances.[8] Some exemptions are based upon the healthcare provider's need to know such information in order to provide effective treatment to a protected adult or child, or to identify and treat a contact. Only the minimum information necessary for the stated purpose of the release may be provided. Other exemptions include the right of insurance companies and certain government agencies to obtain HIV-related information when necessary for reimbursement for care and treatment rendered to the patient, or to protect a child who is either in foster care or being adopted.

Although a healthcare provider may disclose possible exposure to HIV to a contact of a patient, the identity of the patient cannot be disclosed.[9] A healthcare provider may also choose to disclose the information about the contact (but not the patient) to a public health officer who in turn may notify the contact of possible exposure to HIV. Contact notification is not mandatory. If a healthcare provider fails to notify a contact that may be at risk for HIV infection, or fails to make a good faith disclosure about a contact to a public health officer, the provider is still protected from criminal and / or civil liability.[10]

When the protected individual is deceased, the law permits disclosure of confidential HIV-related information under limited circumstances. These exemptions include disclosure to:

1. An executor or administrator of the estate of the deceased, as needed to fulfill his / her responsibilities as an executor or administrator;[11]
2. Contacts of the deceased if contacts are known to the physician (e.g. spouse) and the physician believes the protected person had not informed such contacts;[12]
3. A funeral director upon taking charge of the remains of a deceased when such funeral director has access in the ordinary course of business to HIV-

related information on the death certificate of the deceased, as authorized by Public Health Law § 4142;[13] and,

4. A beneficiary or claimant for benefits under an insurance policy, a health services plan, or an employee welfare benefit plan as defined in 29 U.S.C. 1002(1) covering such protected individual.[14]

For all other third parties who request the record of a deceased protected individual, a court order must be sought by the third party. The court must weigh the need for disclosure to the third-party against the privacy interests of the deceased protected party.[15] However, court action can be avoided if all HIV-related information can be redacted and the third party who is authorized to request the deceased patient's records will accept a redacted copy of the record.

If you are uncertain about whether to release a specific patient's HIV-related information and / or whether there is an applicable exemption to the rules for disclosure, healthcare law counsel should be consulted.

Testing

Every individual who agrees to be tested for HIV or AIDS must receive both pre- and post-test counseling. The law requires that providers cover seven specific points in their discussions, including:

- How an individual can become infected with HIV;
- Available treatments for HIV;
- Availability of safe practices to protect others from exposure;
- The HIV test is voluntary and can be performed anonymously;
- State law specifically protects HIV-related information; and
- Discrimination based upon an individual's HIV status is prohibited.
- Informed consent for HIV testing is valid until the patient revokes his / her consent.[16]

The provider must obtain the patient's written consent to be tested before an HIV test is ordered. As with all treatment, patients can refuse HIV testing. However, if a pregnant patient refuses to be tested during pregnancy, the newborn must then be tested to facilitate prompt treatment.[17] The post-test counseling and test results can be delivered by regular mail.

Infection Control and Disclosure

HIV-related information may not be disclosed to a provider or other individual caring for the patient solely to "protect" that individual from infection or exposure. It is not always possible to know which patients are HIV positive. In the offices of physicians and dentists and hospitals, Federal Occupational Safety and Health Administration (OSH A) regulations require implementation of universal precautions for all patients to minimize exposure to potentially infectious blood and other bodily fluids.[18] However, Federal law does permit disclosure of a patient's HIV status to an Emergency Medical Services (EMS) provider who has been exposed to a patient's blood and / or bodily fluids and would potentially require HIV prophylaxis in a timely manner.[19]

Penalties for Disclosure

Improper disclosure of HIV-related information can be costly. Allegations of professional misconduct may arise, which can involve sanctions ranging from censure and reprimand to license revocation as well as a fine.[20] Civil penalties of up to $5,000 can be assessed for each occurrence.[21] Such penalties are not covered by a provider's professional liability insurance carrier. Further, if the violation is determined to be willful, the individual who made the disclosure can be charged with a crime. Criminal penalties include up to one year in jail and / or a fine.[22],[23] Additionally, physicians who improperly disclose HIV-related information can also be sued for medical malpractice and breach of confidentiality.

Finally, a provider who discriminates against a patient based on his / her HIV status may face allegations of discrimination which often result in legal proceedings brought against the individual by either the New York Division of Human Rights or the Federal Equal Employment Opportunity Commission. Be aware that professional liability insurance policies exclude coverage of claims of discrimination brought by a government agency.

Subpoenas

State law requires that subpoenas for patient medical records must be accompanied by the patient's written authorization for records. However, HIV-related information must not be released unless the patient's written authorization also includes specific consent for such release. If there is no specific authorization for release of HIV information, subpoenas alone are not sufficient to compel disclosure of HIV information contained in a medical record. If an individual wishes to obtain HIV-related information without a patient's authorization, he / she must obtain a court order.[24] However, a subpoena bearing the simple statement "so ordered," even if signed by a judge, is not sufficient. Rather, to issue an appropriate court order, the presiding judge must conduct a hearing, giving notice to all parties (including the patient) before granting a court order. The person seeking disclosure must show:

1. A compelling need for disclosure; or

2. There is a clear and imminent danger to an individual, such that disclosure is required; or

3. The party making the application is a state, county or local public health officer alleging clear and imminent danger to public health; or

4. The applicant is otherwise lawfully entitled to this information.

All papers from the hearing must be sealed, and all judicial proceedings must take place "in camera," i.e., in the judge's chambers. The patient's name must not be disclosed on any of the legal papers.

Finally, if and when a court does issue an order for release of protected HIV-related information, the court must limit the disclosure only to that information necessary for the purpose of the order and only to those individuals with a legitimate "need to know" the information.

In sum, if you receive a subpoena for a record that includes HIV information and you do not have a specific written authorization from the patient, you must not release any information unless the subpoena is accompanied by a formal court order, signed by a judge, reciting the reasons why the information should be disclosed.

Risk Management Principles to Prevent Improper Release of HIV-related Information

1. Carefully review all records before releasing them to determine whether they contain HIV-related information.

2. Carefully review the authorization provided to be certain that it contains wording that specifically authorizes release of HIV-related information or information regarding release of such information, and that the patient has initialed the appropriate HIV line.

3. When releasing records containing HIV-related information to third parties, always include the Notice of Prohibition against Redisclosure.

4. If the authorization does not specifically allow the release of HIV-related information, you must either:

    a. Contact the patient directly to request completion of a new written authorization which specifically allows release of HIV-related information; or

    b. If you are unable to contact the patient, and there are only one or two references to HIV-related information, you may redact only the HIV-related information from a copy of the record.

        i. To redact HIV-related information, make a copy of the portion(s) of the record which contains the HIV-related information. On the copy only, white out or blacken only the HIV-related information. Recopy the page(s), so that the redacted portion(s) cannot be read through the black marker or white-out.

        ii. When sending redacted records to the requesting party, you must advise them that the records have been redacted in accordance with New York State law. You cannot say the redaction was done because the patient's record contains HIV-related information or even cite the relevant law, for to do so would alert the requestor to the fact that HIV information is contained in the record. Although your response may anger the requestor, you must comply with State law.

        iii. If an attorney demands an unredacted (complete) copy of the record, request that the patient contact your office directly to obtain and sign a proper authorization. Again, do not mention that HIV-related information is contained in the record or that the patient will be requested to sign an authorization for release of HIV-related information.

5. Never release HIV-related information pursuant to a subpoena unless it is accompanied by an authorization specifically releasing the records or by a court order after a hearing with notice to all parties which meets the requirements previously described.

6. In summary, the HIV law is complex, and it is easy to make a mistake when releasing patient records. However, the foregoing recommendations can help protect physicians and their employees from violating both the law and the patient's confidentiality. Physicians and staff who act with due care, and comply fully with HIV laws and regulations, can minimize the risk of facing allegations of professional misconduct, civil or criminal penalties, administrative proceedings, and litigation alleging a breach of confidentiality stemming from negligent or inappropriate disclosure of HIV-related information.

Endnotes

1. Public Health Law §§ 2780 et seq.
2. Public Health Law § 2781-a.

3. Frequently asked questions regarding the HIV Testing Law. Accessed on September 4, 2012 at http://www.health.ny.gov/diseases/aids/testing/law/faqs.htm.
4. 10 N.Y.C.R.R. § 63.1(h).
5. 10 N.Y.C.R.R. § 63.6
6. Department of Health Form DOH-2557.
7. OCA Official Form No. 960.
8. 10 N.Y.C.R.R. § 63.6(b)(3).
9. 10 N.Y.C.R.R.§ 63.8.
10. 10 N.Y.C.R.R. § 63.8(i).
11. Public Health Law § 2782(1)(q).
12. 10 N.Y.C.R.R. § 63.8(h).
13. 10 N.Y.C.R.R. § 63.6(a)(11).
14. 10 N.Y.C.R.R. § 63.6(a)(10)(iii).
15. Public Health Law § 2785.
16. Public Health Law § 2781(3).
17. 10 N.Y.C.R.R. § 405.21(c)(8)(i)(h).
18. 42 C.F.R. §1910.1030 (d) (1).
19. Ryan White Comprehensive AIDS Resources Emergency Act, 42 U.S.C.A. §§ 300ff-131 et seq.
20. Education Law § 6530 (23).
21. Public Health Law § 2783 (1)(b).
22. Public Health Law § 2783 (2).
23. Public Health Law § 12-b (2). Until 4/1/2014, the fine is $10,000. After 4/1/14, the fine is $2,000.
24. Public Health Law § 2785. 3.

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COMMENTS BY THE HEALTH LAW SECTION

Health #1 April 8, 2013

On behalf of the Health Law Section of the New York State Bar Association, we thank you for the opportunity to submit comments in response to the February 25, 2013 letter of Karen Lipson and Joan Cleary Miron.

1. ***Question:*** Should New York State expand or modify the criteria that define a DTC under 10 NYCRR § 600.8?

   Answer: Yes, New York State should modify the criteria in § 600.8 for the reasons that follow.

   We note, as a preliminary matter, that the licensure and regulation of physicians engaged in the private practice of medicine, whether in small groups or in complex multi-specialty mega-practices, is the purview of the Department of Education, not the Department of Health.[1] Thus, any attempt by the Department of Health ("DOH") or the Public Health and Health Planning Council ("PHHPC") to amend Title 10 of the NYCRR in order to bring any type of physician practice under the regulation of the Department of Health as a diagnostic and treatment center, and to subject it to Certificate of Need approval, would likely not survive the expected legal challenges to such an administrative action. We believe legislation would be necessary. See, e.g., *Boreali v. Axelrod,* 71 NY2d 1 (1987).[2]

[1] The PHHPC appears to be aware of this issue, since it states the following in an appendix to its recently adopted report on redesigning the CON process: "Notably, private physician practices are generally not covered by CON," citing to *Clifton Springs Sanitarium Co, Inc v. Axelrod*, 115 A.D.2d 949 (1985). *See* PHHPC Report on Redesigning Certificate of Need and Health Planning adopted on 12/6/2012 at Appendix F, fn 2. Leave to appeal was denied, 67 N.Y.2d 609, 494 N.E.2d 114, 1986 N.Y. LEXIS 18174, 502 N.Y.S.2d 1028 (1986).

[2] In this connection, legislation was advanced by Governor Mario Cuomo in the early 1980s seeking to subject the acquisition of certain imaging equipment (such as CAT and MRI equipment) to CON review. That legislation was never enacted. The failure to enact that legislation could be used to support an argument that DOH lacks authority now to require a CON. Indeed, the court in *Clifton Springs* notes that "efforts in recent years to bring privately owned equipment used on hospital inpatients within the State's CON requirements have consistently failed to obtain legislative approval."

The purpose of § 600.8 is to define what constitutes a "facility or institution engaged principally in providing services by or under the supervision of a physician…" pursuant to Public Health Law § 2801(1) and to distinguish such a facility from the operation of a physician office. The former is subject to licensure and CON review by DOH, and the latter is not.

- The criteria currently listed in § 600.8 fail adequately to distinguish between the operation of a facility and the private practice of medicine. The current criteria are both over- and under- exclusive, and are outmoded. Examples follow:
    - § 600.8(a) only mentions one legal way to organize a group practice, as a professional service corporation ("PC"), and fails to mention other ways now legal under New York law, including as a professional limited liability company ("PLLC") or a university faculty practice corporation ("UFPC") organized under section 1412 of the Not-For-Profit Corporation Law.
    - § 600.8(c)(1) and (c)(4)(ii) and (v): In a large, muli-specialty group, a primary care physician may refer a patient for laboratory or radiology services to "another location" not in his office.
    - § 600.8(c)(3): In a large physician practice, the practice may allow "after hours" services, where a patient may end up seeing a physician that the group practice has assigned to see all patients of the group practice after regular office hours.
    - § 600.8(c)(4)(iii): In this day and age, a physician group practice often "insures adherence to standards" such as quality standards and other standards required by third party payors such as Medicare and MCOs.
    - § 600.8(c)(5):
        - Physician group practices enter into managed care contracts that require the group to determine the amounts to be billed. Payments generally are made to the group, not to the individual physician.
        - Given HIPAA requirements and laws and regulations governing electronic medical records, the group is responsible for maintaining medical records and patient charts.
        - Income distribution is a function of the partnership agreement, PLLC operating agreement or employment contract between the group and the physician.
    - The criteria fail to consider *control* by non-physicians through financing, administration, and management.

- The Department of Health ("DOH") does not actively enforce the provisions of the current regulation. Having regulations that the state does not enforce undermines respect for the law. It also makes it difficult for attorneys to advise clients on properly structuring arrangements.

- Moreover, we are aware of instances in which DOH staff have advised entities that meet the criteria in section 600.8 not to seek licensure as a DTC, apparently because of the potential impact on Medicaid reimbursement. As we understand it, Medicaid reimbursement to a DTC for the facility fee under APGs, together with reimbursement for the professional services under the Medicaid fee schedule, is usually higher than fee-for-service reimbursement on a global basis to a site organized as a physician office . If it is not in the state's economic interest for a site to become a DTC due to the impact on Medicaid reimbursement, then DOH should consider deleting section 600.8 or modifying it (together with modifying the criteria for establishment and licensure of DTCs) to identify only those entities that DOH believes should be licensed as a DTC and should be reimbursed under APGs for ambulatory services to Medicaid patients. Alternatively, the state should consider modifying its Medicaid reimbursement regulations to provide the appropriate amount of reimbursement for ambulatory patients in each ambulatory setting. We recognize that the state has already made significant revisions in Medicaid reimbursement to ambulatory sites licensed under Article 28 in Part 86-8 of its regulations, and has also approved some increases to physician reimbursement to lessen the Medicaid differential between sites of service. We also understand that, as Medicaid fee-for-service patients transition to mandatory managed care, this difference in reimbursement may disappear, since many managed care companies pay the same amount to DTCs and to physician offices. Nonetheless, as long as Medicaid fee-for-service reimbursement continues to exist, this differential in payment will continue to exist, as well, creating an incentive for DOH staff (i) not to enforce § 600.8 and (ii) to discourage applicants who wish to become licensed as a DTC.

- In the event that physician acquisition or operation of major medical equipment were to be subject to CON review, it would be essential that the need methodologies for this equipment be thoroughly reviewed and substantially updated. To some extent, the need criteria take into account the existing physician resources. However, if physician practices were suddenly to be subject to CON review and if existing physician owned or leased equipment were counted in determining need under the existing need methodologies, the result could well be a determination that there is no need for any additional imaging equipment or linear accelerators —even though an aging population, at greater risk of cancer, may well require substantially more of such equipment. As a result, unless the need methodology is thoroughly revisited, the effect of expanding CON review for the operation of this equipment would be to enact a virtual moratorium on any new capacity, which would stymie both hospitals and physicians from meeting real unmet need.

For the reasons set forth above, we submit that DOH should significantly modify the criteria set forth in section 600.8 or delete this section of the regulations. In conjunction with deciding what criteria to use in a revised regulation, DOH should consider which

entities should be licensed or otherwise regulated under Article 28 of the Public Health Law. DOH should also consider the impact, if any, of Medicaid reimbursement methodologies on the position it takes as to which entities need to be licensed under Article 28 of the Public Health Law. Finally, if DOH expands CON review for any type of facility or equipment to physician practices, it should do so only after reviewing and revising the need methodology.

2. ***Question:*** Should New York State modify its approach to the corporate practice of medicine?

Answer: Yes, for the reasons that follow.

- While there are strong justifications for maintaining a corporate practice prohibition to assure that physicians and other licensed entities control medical service delivery,[3] the existing prohibition on the "corporate practice of medicine" does not take into account the desirability of promoting certain healthcare delivery models. Indeed, this prohibition – if enforced – would hinder use of care delivery models that promote the Triple Aim. This prohibition also creates anomalies in the employment relationships that are allowed and disallowed under NY law, without promoting any legitimate public policy purposes for doing so. Examples follow.

    - Taken to its logical extension, the "corporate practice of medicine" prohibition would bar a hospital from requiring its employed physicians to turn over all fees for professional services rendered at physician office sites that are not on the hospital's operating certificate. This is because the hospital is not "licensed" to operate from these sites, and the prohibition is really a prohibition on the unlicensed practice of medicine by a corporation.[4] The fact pattern noted above implicates not only the prohibition against the "corporate

[3] Thus, we acknowledge that New York State has a legitimate interest in preventing corporations that have no license from any state agency to provide any type of healthcare from employing physicians and holding themselves out to the public as providing medical services.

[4] The prohibition on the "corporate practice of medicine" is – in reality – a prohibition on the unlicensed practice of medicine. That is, it is a prohibition on the employment of physicians by a corporation that has no license issued by the state authorizing it, as part of its licensed duties, to employ physicians to provide healthcare services to the public. Thus, a series of cases interpret this prohibition as providing exceptions allowing corporations to employ physicians as long as the corporation has a license issued by the state that authorizes it to provide healthcare services to the public, such as a hospital or a medical school. See, e.g., *Albany Medical College v. McShane*, 104 AD2d 119, 481 NYS2d 591 (3d Dep't. 1984); aff'd 66 NY2d 982,199 NYS2d 376 (1985).

practice of medicine," but also fee splitting and § 401.2(b) of the DOH regulations relating to operating certificates, which limits where the established operator may operate.[5] See, e.g., *Glassman v. ProHealth Ambulatory Surgery Center,* 23 A.D.3d 522, 806 NYS2d 648 (App. Div. 2d Dept. 2005); rev'd on other grounds in 14 N.Y. 3d 898, 930 N.E.2d 263, 904 N.Y.S.2d 342 (2010). *See* fn. 7, *infra*. As we note below, in practice these restrictions are frequently disregarded and not enforced.

- In contrast, employed physicians of a medical school can be required to turn over all fees earned at all sites, even sites not on an operating certificate, since a medical school may employ physicians to work at any site pursuant to its faculty practice plan and its charter that allows training of residents. See, e.g., *Albany Medical College v. McShane*, 66 NY 2d 982, 489 NE2d 1278, 499 NYS2d 376 (1985).
- From a public policy perspective, it makes no sense to allow physicians who are employees of a medical school to have an unrestricted practice, but to place restrictions on the physician employees of a hospital.
- The irrationality of this outcome is underscored by the difference in treatment accorded to hospitals whose affiliated medical schools are in the same corporation, compared to those that are in separate corporations.
    - Where a hospital and a medical school are in the same corporate entity, the corporate practice of medicine doctrine, as applied, has allowed the entity to require employed physicians to turn over their income from all sites, even sites not on the hospital's operating certificate.
    - However, where a hospital and a medical school are not in the same corporate entity, the corporate practice of medicine doctrine – together with section 401.2(b) of the Department's regulations - bars the hospital from employing physicians to work at sites not on its operating certificate. It makes no sense for the law to have this anomalous outcome.

- Moreover, under the federal Antikickback and Stark laws, as well as their New York counterparts, the exceptions that apply to physicians who are employees of a hospital give greater flexibility in structuring compensation relationships than the exceptions that apply to physicians who are independent contractors. The state should not, through the "corporate practice of medicine" prohibition, discourage the employment of physicians by hospitals.

[5] Section 401.2(b) provides: "An operating certificate shall be used only by the established operator for the designated site of operation, except that the commissioner may permit the established operator to operate at an alternate or additional site approved by the commissioner on a temporary basis in an emergency."

- For example, many hospitals in New York have established so-called "Captive PCs" in order to structure relationships with physicians who practice at the hospital as well as at non-hospital sites.[6] A Captive PC is a professional service corporation controlled indirectly by a hospital, with the shares in the PC held by a licensed physician who is employed by the hospital with a particular job title, and a shareholder's agreement requiring that physician to relinquish the shares to the next holder of that title if he/she ever ceases to hold such title.
- Under the Captive PC model, the PC employs the physicians. When the physicians are employees of the PC and not of the hospital, the hospital and the physicians do not have the benefit of the more flexible employment exception that exists under the federal Antikickback and Stark laws, as well as their state counterparts. Moreover, complex legal and business issues arise with respect to contractual relationships and the flow of funds between the hospital and the PC.

- In addition, the "corporate practice of medicine" prohibition creates legal issues when trying to structure a network of providers for purposes of contracting with self-insured employers. These networks *arrange* for the provision of medical services, which New York State defines as the practice of medicine. Moreover, an IPA cannot be used to contract with a self-insured employer, since that is not a purpose allowed under Part 98 of the DOH regulations.
- New York State has rarely enforced the "corporate practice of medicine" prohibition, at least in recent years.
  - Instead, this prohibition appears most often to be raised by private litigants in the context of breach of contract lawsuits, where one party seeks to get out of its contractual obligations by claiming that the entire contract should be void as against public policy or that a particular provision should be severed as illegal. See, e.g., *Glassman v. ProHealth Ambulatory Surgery Center, 23 A.D.3d 522, 806 NYS2d 648 (App. Div. 2d Dept. 2005); rev'd* on other grounds 14 N.Y. 3d 898, 930 N.E.2d 263, 904 N.Y.S.2d 342 (2010).[7]

[6] A physician group practice, whether formed as a PC, a professional limited liability company, or a partnership is permitted, by its license to practice anywhere in the state.

[7] In reversing the appellate court's holding, which had severed as illegal a provision in an employment contract between an ASC and a physician requiring the physician to turn over to the ASC all fees earned at non-ASC sites, the Court of Appeals did not hold that the contested contract provision was legal. Instead, the Court held that the provision was at most "merely malum prohibitum and, therefore, enforceable in a breach of contract action." The court explained that DOH has authority to enforce the provisions of its regulations in section 401.2(b) that authorize an Article 28 facility to operate only from sites on its operating certificate, and that OPMC has authority to enforce fee splitting violations. It also noted that the plaintiff had not "identified an overarching public policy that mandates voiding the contract." 14 N.Y. 3d 898, 930 N.E.2d 263, 904 N.Y.S.2d 342 (2010).

- Applying this prohibition to hospitals and to networks of providers contracting with self-insured employers, while not enforcing it, creates impediments for law abiding citizens and facilities who are trying to structure legally binding arrangements. This is particularly the case here, since the penalties include criminal penalties. The unlicensed practice of medicine, as well as abetting the unlicensed practice of medicine, are Class E felonies. Ed. L. § 6512.[8]

- As we noted above, in discussing section 600.8, the failure to enforce a law promotes disrespect for the law. If the state is not going to enforce the "corporate practice of medicine" prohibition, it should eliminate it. Of course, this will likely require legislation.[9]

- ***Other Licensed Professionals:*** If the state eliminates or modifies the prohibition on the "corporate practice of medicine," it should also consider eliminating or modifying this prohibition as it applies to other licensed health professions.

- ***Fee Splitting:*** The state should also consider modifying the prohibition against fee splitting to take account of the current and proposed models of health care delivery that are designed to achieve the Triple Aim. The facts that support a charge of violating the "corporate practice of medicine" usually also implicate the prohibition against "fee splitting." Therefore, if you address one prohibition, we suggest that you also consider addressing the other, as well.[10]

Other Observations:

Finally, we share the Department's concern about the lack of access to capital by New York hospitals. We note that this problem would potentially be exacerbated if the Department were to relax the prohibition on the corporate practice of medicine by entities not licensed under Article 28 of the Public Health Law (thereby, in effect, allowing physicians access to capital), while at the same time retaining (rather than relaxing) the

[8] Moreover, willfully violating § 401.2(b) of the DOH regulations is a misdemeanor, with a potential sanction of one (1) year in jail effective 4/1/2014. *See* Public Health Law § 12-b.

[9] However, if DOH were to revise its regulations in section 401.2(b) to authorize a hospital to employ physicians to work at a site not on the hospital's operating certificate so long as the services are not billed as hospital outpatient services (and instead are billed as physician office services), this might obviate the need for legislation.

[10] In this connection, we are pleased that the PHHPC has recommended "relax[ing] the prohibition on revenue sharing among providers that are not established as co-operators" presently prohibited by section 600.9, which is sometimes referred to as "corporate fee-splitting." *See* Recommendation #22 of the PHHPC Report on Redesigning Certificate of Need and Health Planning, adopted 12/6/2012 at p. 46.

CON restrictions applicable to entities licensed under Article 28. We respectfully request that you keep this in mind as you consider potential regulatory and legislative changes.

Section Chair: Ellen V. Weissman, Esq.

NEWS flash

What's Happening in the Section

New Section Officers

The Section's new officers began their terms on 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
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The new Chair 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.

Kathleen M. Burke

Ms. Burke is a longstanding and member of the Health Law Section. She chaired the Committee on Ethical Issues in the Provision of Health Care for several years, and organized several of the Section's programs.

Upcoming Events

- *2013 Section Fall Meeting:* The Section's 2013 Fall Meeting will be held on Friday October 25, 2013 at the Bar Center, One Elk Street, Albany NY. For more information about this and other upcoming events, go to nysba.org/health and click on Events.
- *2014 Annual Meeting*: The Section's Annual Meeting will be held on January 29, 2014 at the Hilton in New York City. Further information will be available on the NYSBA website as the event approaches.

Recent Events

- *Antitrust CLE Program*. The Section co-sponsored a program with the Antitrust Law Section of the NYSBA in Pittsford, NY on May 9, 2013. The program was entitled: "An Apple a Day: What You Need to Know about Antitrust and Healthcare."
- *Membership Reception*. On June 11, 2013, our Section held a membership reception, together with the Food, Drug and Cosmetic Law Section of the NYSBA, at the offices of Hodgson Russ in New York City, at 1540 Broadway, 24th floor.

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

Section Committees and Chairs

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

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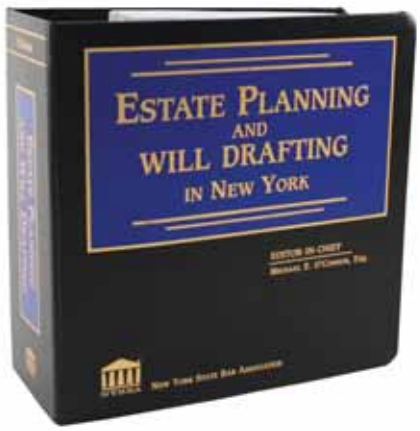

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