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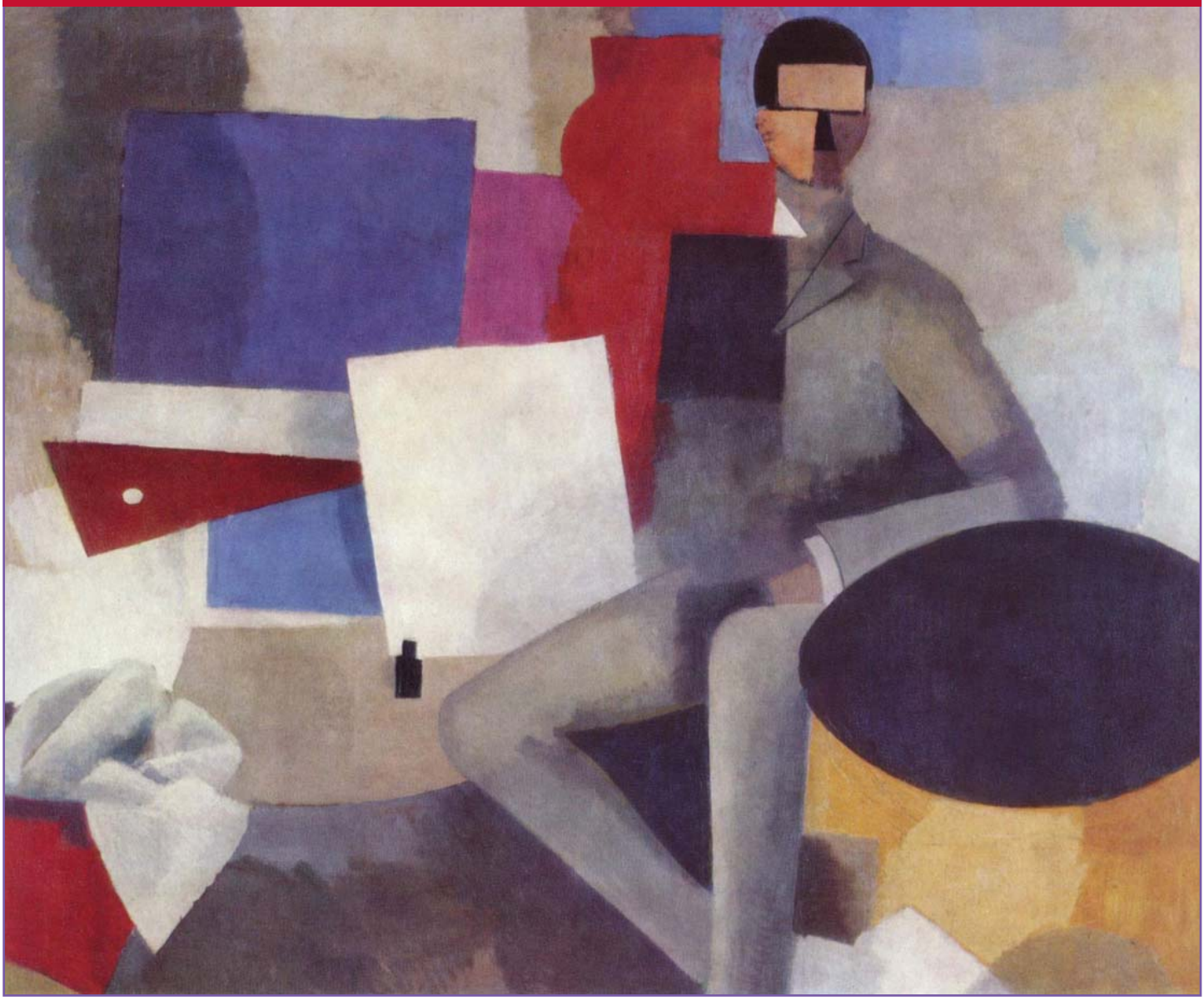
Health Law Journal

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

Special Edition: Telehealth in New York



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Fourth Edition

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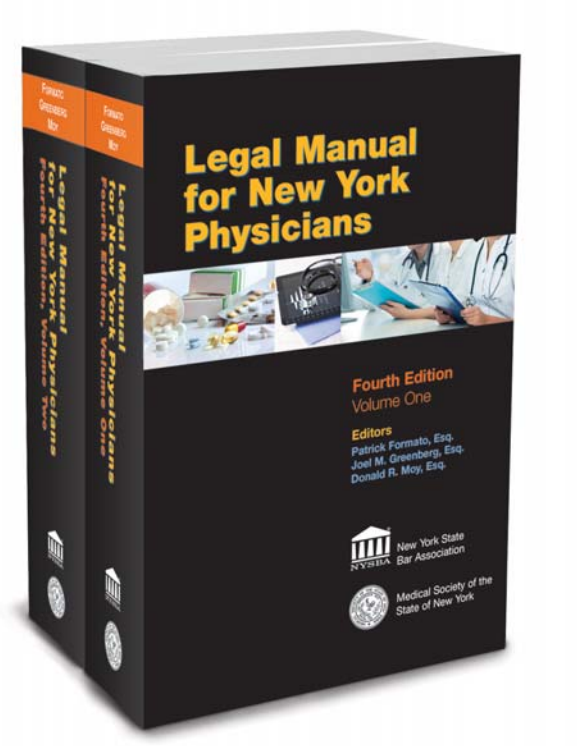

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HEALTH LAW JOURNAL

Winter 2015

Vol. 20, No. 1

THE HEALTH LAW SECTION
NEW YORK STATE BAR ASSOCIATION

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***Homme assis* by Roger-Noël-François de La Fresnaye,1914**

A Message from the Section Chair

The Health Law Section has been active both through its committees and various educational programming. The Section recently sponsored the following programs:

- HIPAA/HITECH for Lawyers Update 2014, held on December 3, 2014
- The Ebola Crisis and Global Health Law (a teleconference with Lawrence Gostin, University Professor of Global Health at Georgetown Law School)
  —(This was one of a series of public health law webinars held by the Public Health Committee)

The Section also held a networking reception on December 16, 2014 in New York City at the offices of Duane Morris.

All members are encouraged to join a committee. Much of the activity of the Section occurs through committees, and membership in a committee is a great way to increase knowledge and get to know other health lawyers. For example, the Medical Research and Biotechnology Committee is involved in an extremely interesting project on technology that enhances human capacity and the legal and ethical issues relating to such.

The Section committees include:

- Continuing Legal Education
- E-Health and Information
- Ethical Issues in Provision of Health Care
- Health Care Providers and Networks
- Legislative Issues
- Managed Care and Insurance
- Medical Research and Biotechnology
- Membership (with a Diversity Subcommittee)
- Mental Hygiene and Developmental Disabilities
- Professional Discipline
- Public Health
- Reimbursement, Enforcement, and Compliance
- Young Lawyers

The Young Lawyers Committee is a new committee that is designed for health lawyers in practice less than ten years. It is just getting off the ground, and would welcome participation by health lawyers in New York who want additional knowledge and contacts in health law.

All of the committees can be found on the Health Law Section website at http://www.nysba.org/Sections/Health/Committee_Information/Committee_Information.html.

Please contact me with any questions at mdavino@kbrlaw.com or (212) 980-9600.

Margaret J. Davino

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http://www.nysba.org/Health

In the New York State Courts

By Leonard M. Rosenberg

Family Court Finds Confidential Health Records Disclosed and Used in an Article 10 Abuse and Neglect Proceeding Cannot Be Redisclosed or Used in Other Proceedings, Absent Invocation of the Correct Procedure

In re Kayla S., No. NA-XXXX/14, 2014 WL 6710854 (N.Y. Fam. Ct. Nov. 3, 2014). In the Family Court, Bronx County, the Administration for Children's Services commenced an Article 10 abuse and neglect proceeding by filing a petition, alleging Respondent sexually abused his child. In addition, Respondent faced criminal charges in the Criminal Court, Bronx County based on the same allegations.

During trial for the Article 10 proceeding, the Court entered into evidence the child's medical and mental health records. No party objected to the Court's use of these records, but Respondent opposed any limitation on the redisclosure or use of the records in any other proceeding. The Court believed he opposed the protective order in the hopes of using the records in the criminal case.

The Court, however, found it could not grant the disclosure or use of the child's records beyond the limited purposes of the Article 10 proceeding. The Court began its analysis by noting that a patient's health and mental records are generally confidential. Then, in review of the Health and Insurance Portability and Accountability Act ("HIPAA"), the Court concluded that the statutes prohibit disclosure of such confidential health information, absent the patient's consent, an appropriate court order, or the application of a specific HIPAA exception. The Court found one such HIPAA exception was built into the Family Court Act ("FCA") for Article 10 abuse and neglect proceedings. The Court noted that FCA § 1038(a) authorized the use of material records relating to alleged abuse or neglect in order to safeguard

against erroneous determinations and to protect children from harm.

The Court further determined that, even if confidential health records are disclosed under FCA § 1038(a), such disclosure does not constitute a waiver of confidentiality, as the privacy interest in the records belongs to the child, who did not consent to production or use of the records. Thus, people other than the patient do not have the right to use the patient's records for purposes other than in connection with the Article 10 proceeding.

With respect to the Penal Law and Criminal Procedure Law, the Court was unable to find any similar built-in exception. Instead, the Court held that a party seeking to use confidential information in a criminal case must provide the criminal court with a specific showing of need to overcome the statutory privileges. Therefore, the Court ruled that the Respondent would have to seek and obtain an order from the Criminal Court in order to use the patient's records in the criminal proceeding, even though he or his attorney may already be in possession of the records through the Article 10 proceeding.

Labor Law § 741 Does Not Apply to Registered Nurse Employed to Review Documentation of Human Subject Research for Compliance with Regulations

Moynihan v. New York City Health and Hospitals Corporation, 120 A.D.3d 1029 (1st Dep't 2014). Appellant, New York City Health and Hospitals Corporation ("HHC"), appealed New York County Supreme Court's granting of Petitioner's motion for leave to file a late notice of claim against HHC. Petitioner, an employee of HHC's Office of Clinical and Health Services Research ("OCHSR"), reviewed documentation of human-subject research projects for regulatory compliance. Petitioner notified affiliates and officials at HHC hospitals and administration about concerns regarding failure to comply with HIPAA, IRB, and protocol requirements and failure to submit required informed consents and information. Petitioner alleged that she was fired in retaliation for voicing her objections and concerns, and that her termination was in violation of Labor Law §§ 740 and 741.

Because Petitioner failed to file her petition for leave to file a late notice of claim prior to the expiration of the one-year limitations period under Section 740, the Court held that her cause of action was time-barred. While the Court would have been able to entertain a motion for leave to serve a late notice of claim, Petitioner needed to have made such motion within the limitations period. The Court held that the one-year limitations period of Section 740 takes precedence over the one-year and 90-day limitations period under § 20(2) of the HHC Act. Although the petition for leave to file a late notice of claim would have fallen within the one-year and 90-day limitations period, it came over two months after the one-year limitations period under Section 740 had expired.

Turning to Petitioner's claim under Section 741, the Court applied precedent analyzing which employees fall under the definition of "employee" provided by the statute. The statute affords an employee a cause of action against the employer for retaliatory action taken because the employee discloses in good faith to a supervisor a policy or practice of the employer believed to constitute improper quality of patient care. Because the statute defines "employee" as, in part, "any person who

performs health care services" the Court held that Petitioner was not the type of worker contemplated by the provision. Noting that Petitioner's job responsibilities were to review documentation generated by medical researchers for compliance with regulations, the Court held that her work neither required her to perform health care services, nor to make judgments as to the quality of patient care. Citing the standard articulated by the New York Court of Appeals in *Reddington v. Staten Island University Hospital*, the Court stressed the fact that the statute was enacted for the sole protection of those who provide treatment to patients, making knowledgeable judgments that they are qualified by training or experience to make as to the quality of patient care. The Court further emphasized that individuals covered by Section 741 must hold positions that require them to make such judgments and that merely coordinating with parties who supply health care services is insufficient. Given that Petitioner did not allege having interaction with patients or decision-making authority with respect to the administration of patient care, the Court held that she lacked standing to sue under Section 741.

The Court also held that Petitioner's claims for violation of Administrative Code of the City of New York § 12-113 and violation of her constitutional right of free speech were barred, as her commencement of an action under §§ 740 and 741 constituted a waiver of those claims.

Second Circuit Holds That Terminated Employee Is Not Entitled to Jury Trial on Labor Law § 741 Claim, as Statutory Remedies Under Whistleblower Law Are Equitable

Pal v. New York University, 583 Fed. Appx. 7 (2d Cir. 2014). Plaintiff, a former employee of Defendant New York University ("NYU"), filed suit under New York Labor Law § 741 alleging that she was terminated in retaliation for expressing concerns about the quality of care in Defendant's Program for Surgical Weight Loss (the "Program"). The U.S. District Court for the Southern District of New York struck Plaintiff's request for a jury trial and awarded judgment to Defendant on partial findings pursuant to Federal Rule of Civil Procedure 52(c) regarding Plaintiff's claim of retaliatory termination.

On appeal, Plaintiff argued that the District Court erred in attributing her termination to only the Chairman of the Department of Surgery (the "Chairman"), rather than two attending physicians in the Program. Plaintiff also contended that the District Court erred in striking her request for a jury trial under New York Labor Law and in granting judgment on an affirmative defense prior to the Defendant's case-in-chief. The Second Circuit affirmed the decision of the District Court, holding that: (i) where the District Court's factual findings are based on credibility determinations, particularly strong deference is appropriate, (ii) a claimant is not entitled to a jury trial when her claim falls under a statute offering only equitable remedies, and (iii) pursuant to Rule 52(c), a court may enter judgment against a party who has presented fully on a disputed issue without waiting for the other party's case if the claim can be defeated or maintained only with a favorable finding on that issue.

With respect to Plaintiff's claim of retaliatory termination, the Second Circuit reviewed the District Court's findings of fact for clear error. The Court held that it may not "second-guess either the trial court's credibility assessments or its choice between permissible competing inferences." Satisfied that the District Court did not commit clear error in its assessment of pertinent testimony and NYU's disciplinary policy, the Court affirmed the District Court's determination that the Chairman was solely responsible for Plaintiff's termination.

The Second Circuit reviewed Plaintiff's entitlement to a jury trial *de novo* because whether a party is entitled to trial by jury is a question of law. Explaining that "it is the court itself which awards relief" under Labor Law §§ 740 and 741, the Court held that because Plaintiff's action was for equitable remedies (including back pay) under both federal and state law, she was not entitled to trial by jury. Here, the Court applied precedent established by New York state courts, which have concluded that the list of various types of equitable relief in § 740(5) contemplates court-issued relief rather than trial by jury.

Labor Law § 741(5) offers an affirmative defense for an employer who is able to demonstrate that the challenged personnel action was based on grounds other than the employee's exercise of rights protected by Section 741. The Court also rejected Plaintiff's argument that the District Court needed to hear Defendant's case-in-chief prior to making a determination, and held that NYU's cross-examination of Plaintiff's witnesses established the necessary factual basis for granting judgment based on the affirmative defense under Section 741(5).

Third Department Holds That Chimpanzee Is Not a "Person" Entitled to Habeas Corpus Relief Under CPLR Article 70

People ex rel. Nonhuman Rights Project, Inc. v. Lavery, 2014 N.Y. Slip Op. 08531 (App. Div., 3d Dep't Dec. 4, 2014). Petitioner-Appellant, a nonprofit organization in support of animal rights, brought a habeas corpus petition, pursuant to CPLR Article 70, seeking the release of a chimpanzee that it alleged was being unlawfully held on Respondents' property. In support of its order to show cause to commence the proceeding, Petitioner submitted several affidavits from experts in order to establish that "chimpanzees have attributes sufficient to consider them 'persons' for the purposes of their interest in personal autonomy and freedom from unlawful detention," including "highly complex cognitive functions…such as autonomy, self-awareness, and self-determination." On December 18, 2013, following an ex-parte hearing,

the Supreme Court, Fulton County, declined to sign Petitioner's order to show case. Petitioner appealed.

As Petitioner did not allege any violation of state or federal law concerning the possession of wild animals, the Appellate Division, Third Department limited its inquiry to "the novel question of whether a chimpanzee is a 'person' entitled to the rights and protections afforded by the writ of habeas corpus." The Court began its analysis by observing that Article 70 "does not purport to define the term 'person,'" as the Legislature intended that the availability of habeas corpus relief be determined by the evolution of common law. While noting that it is not dispositive, the Court stated that "animals have never been considered persons for the purposes of habeas corpus relief, nor have they been explicitly considered as persons or entities capable of asserting rights for the purpose of state or federal law." Moreover, the Court remarked that habeas corpus relief has never been granted to a nonhuman entity.

Holding that they cannot be considered legal persons, the Court declined to extend the availability of habeas corpus relief to chimpanzees. The Court reasoned that "legal personhood has consistently been defined in terms of both rights and duties." The Court stated that corporations and other associations "may be considered legal persons" because, like humans, they are able to "bear legal duties in exchange for their legal rights." However, the Court concluded that "unlike humans, chimpanzees cannot bear any legal duties, submit to societal responsibilities or be held legally accountable for their actions." Accordingly, the Court found it "inappropriate to confer upon chimpanzees the legal rights—such as the fundamental right to liberty protected by the writ of habeas corpus—that have been afforded to human beings."

Finally, the Court clarified that its holding does not render animals defenseless under the law. The Court observed that the "Legislature has extended significant protections to animals, subject to criminal penalties," and that "subject to certain express exceptions, New Yorkers may not possess primates as pets." Although it rejected Petitioner's attempt "to establish that common-law relief in the nature of habeas corpus" is available for the protection of chimpanzees, the Court contended that Petitioner "is fully able to importune the Legislature to extend [them] further legal protections."

Appellate Division Holds That Consulting Psychiatrist Does Not Owe Patient a Duty of Care to Perform Neurological Examination on Patient Presenting with Symptoms of Depression

Chin v. Long Island College Hosp., 119 A.D.3d 833 (2d Dep't 2014). Plaintiff, a hospital patient admitted for depression, brought a medical malpractice action against a hospital, the hospital's consulting psychiatrist and others, alleging that the consulting psychiatrist departed from accepted medical practice by failing to perform a neurological examination upon Plaintiff's admission, which contributed to the failure to timely diagnose and treat Plaintiff's stroke. Reversing the trial court, the Appellate Division, Second Department, held that the consulting psychiatrist had no duty beyond performing an evaluation to determine whether Plaintiff was a danger to himself or others, as would require involuntary admission to the hospital.

Plaintiff was admitted to the Defendant hospital with complaints of feeling overwhelmed by stress. Appellant, a consulting psychiatrist, evaluated Plaintiff, concluded Plaintiff was not a danger to himself or others, and referred Plaintiff for outpatient treatment for depression. Before Plaintiff was formally discharged from the hospital and before Plaintiff's medical test results were returned, Plaintiff left the hospital to return home. In the cab ride home from the hospital, Plaintiff suffered a stroke and returned to the hospital in less than an hour. Plaintiff thereafter sued the hospital, the consulting psychiatrist and others, alleging that the consulting psychiatrist departed from accepted medical practice by failing to perform a neurological examination and rule out a neurological etiology for his symptoms, develop a list of differential diagnoses, and refer Plaintiff for further diagnostic studies. The consulting psychiatrist moved for summary judgment to dismiss Plaintiff's complaint against him.

Reversing the decision of the trial court, the Second Department granted the psychiatrist's motion for summary judgment. In arriving at its decision, the Court held that where the Plaintiff was being actively treated by emergency room physicians for any medical causes of his symptoms and did not exhibit any clear signs of neurological problems, the consulting psychiatrist had no duty beyond properly performing an evaluation to determine whether the Plaintiff was a danger to himself or others and would require involuntary admission to the hospital for depression.

Appellate Division Finds Hospital Defendant Is Entitled to Summary Judgment as to Claim of Vicarious Liability for Actions of a Private Attending Physician

Muslim v. Horizon Med. Grp., P.C., 118 A.D.3d 681, 988 N.Y.S.2d 628 (2d Dep't. 2014). Plaintiff received treatment at Defendant St. Anthony's Community Hospital (the "Hospital") for the birth of her infant daughter. On August 29, 2008, Plaintiff went to the Hospital at the instructions of her private obstetrician, Defendant Alex Joanow. Upon her arrival, her personal representative signed a consent form authorizing treatment from the Hospital's medical staff. Thereafter, Joanow assembled for her treatment a team of nurses and physicians, one of whom was Defendant Dominic Berlingieri.

Prior to August 29, 2008, Plaintiff recalled receiving from the Hospital forms which, inter alia, requested she select a private pediatric practice to treat her child immediately after

the birth. She did not recall selecting Berlingieri. The Hospital considered Berlingieri to be a private attending physician with privileges at the Hospital rather than its employee.

Plaintiffs brought this action in the Supreme Court, Orange County, seeking damages for Berlingieri's alleged medical malpractice and claiming vicarious liability on the part of the Hospital. The Hospital moved to dismiss, asserting that it could not be held liable for treatment rendered by a non-employee and Plaintiff failed to raise a triable issue of fact as to whether, in seeking the Hospital's services, she relied on a perceived employment relationship between Berlingieri and the Hospital. The Supreme Court granted the motion and dismissed the complaint against the Hospital. Plaintiffs appealed.

The Appellate Division, Second Department affirmed the Supreme Court's holding. The Court began its inquiry with the general rule enunciated in *Toth v. Bloshinsky* and *Coletta v. Fischer* that a hospital is not vicariously liable for the malpractice of a private attending physician who is not an employee. The Court noted that an exception to this rule exists where the patient came to the emergency room seeking treatment from the hospital rather than from a particular physician of the patient's choosing.

Therefore, the Court concluded that, to show entitlement to judgment as a matter of law, a hospital must show (1) the attending physician was not an employee and (2) the exception to the general rule is inapplicable. In this instance, the Court held that the Hospital had met its burden because it demonstrated that Berlingieri was not its employee and the patient had sought treatment from her private obstetrician when she went to the Hospital at his instructions.

The Court further asserted that a Plaintiff may rebut this prima facie showing by raising a triable issue of fact as to whether the Hospital could be held liable on the theory of "apparent or ostensible" agency. The Court explained that this showing requires evidence sufficient to support the conclusion that a hospital engaged in misleading conduct upon which a Plaintiff reasonably relied when accepting the hospital's medical services. The Court, however, determined that Plaintiff had failed to set forth any such evidence. Therefore, the Court found the Supreme Court properly granted the motion for summary judgment dismissing the complaint against the Hospital.

Appellate Division Holds That Alleged Withdrawal of Blood from a Psychiatric Patient Over His Religious Objection Was Not Extreme and Outrageous Conduct

Gilewicz v. Buffalo Gen. Psychiatric Unit et al., 118 A.D.3d 1298, 988 N.Y.S.2d 334 (4th Dep't 2014). Plaintiff, a former psychiatric patient, brought claims of medical malpractice, assault, emotional distress and constitutional violations against the psychiatric unit of a hospital, alleging that the hospital withdrew his blood over his religious objection. Reversing the trial court in part, the Appellate Division, Fourth Department held that the hospital's alleged withdrawal of Plaintiff's blood and continued treatment over his religious objection was not extreme and outrageous conduct.

As a threshold matter, the Court held that the trial court properly denied Defendants' motion to dismiss Plaintiff's causes of action alleging constitutional violations for failure to comply with CPLR § 305(b), finding that Plaintiff gave sufficient notice required under the statute.

The Court did, however, agree with Defendants that the trial court erred in denying that part of Defendants' motion to dismiss Plaintiff's claim of intentional infliction of emotional distress. Construing the allegations in Plaintiff's complaint liberally, the Court found Plaintiff's conclusory allegations that the Defendants withdrew blood from Plaintiff over his religious objection and that they continued with treatment of him despite his objections did not rise to "the type of extreme and outrageous conduct that is actionable." Accordingly, the Court dismissed Plaintiff's claim for intentional infliction of emotional distress for failure to state a cause of action under CPLR § 3211(a)(7).

Serial Qui Tam Relator Sanctioned for Bringing Frivolous Lawsuit Against Long-Term Care Pharmacy Network

United States ex rel. Fox Rx, Inc. v. Omnicare, Inc., 2014 WL 6750277 (S.D.N.Y. Dec. 1, 2014). Relator is a former Medicare Part D plan sponsor that brought at least six qui tam lawsuits around the country under the False Claims Act. In this action, which it brought on behalf of the United States, the District of Columbia, and twenty-one states, Relator broadly alleged that Defendants (1) violated state laws requiring the automatic substitution of generic for brand-name drugs, and (2) violated state laws prohibiting pharmacies from dispensing drugs past their expiration date. Relator claimed that "by engaging in such practices, Defendants falsely indicated in 'submissions' to a federal agency that the drugs they dispensed were 'covered' by Medicare, and overcharged Medicare and Medicaid."

Moving Defendant MHA Long-Term Care Network ("MHA") is not a pharmacy, but rather an intermediary that contracts with independent long-term care pharmacies and enters into agreements with pharmacy benefit managers ("PBMs") on their behalf "that allow the PBMs to provide claims adjudication services when claims are submitted to Medicare and Medicaid for payment." MHA "does not itself dispense drugs, and exercises no control or supervision of the Network Pharmacies' dispensing."

On January 10, 2014, counsel for MHA held a meeting with Relator's principal and counsel in an effort to correct numerous factual inaccuracies in the complaint and to demonstrate that the claims against it were meritless. In the presentation, MHA stressed that it (1) is not a pharmacy and does not provide pharmacy services, (2) has no involvement in any

pharmacy's decisions concerning the dispensing of drugs, (3) receives the same fee regardless of whether a branded or generic drug is dispensed, (4) has no involvement in the submission of claims to a PBM, (5) has no role in the payment of claims by a Medicare Part D sponsor, and (6) has no role in the submission of claims data for Medicare Part D reimbursement. To further reinforce its position, MHA provided Relator with several agreements that it signed with PBMs on behalf of its network pharmacies. MHA threatened to move for sanctions if Relator refused to withdraw the action as against it.

On February 10, 2014, Relator amended its complaint "to reflect the fact that MHA…did not dispense drugs," but inserted a new allegation that MHA had a duty to oversee the dispensing of medication at its network pharmacies. In support, Relator attached one of the provider agreements that MHA had signed with a PBM on behalf of its network pharmacies, which requires "Pharmacy Providers" to ensure that any pharmacist acting on their behalf comply with all legal, professional, and ethical obligations in each jurisdiction where pharmacy services are provided. Relator argued that by signing the provider agreement, MHA "had undertaken to supervise and ensure compliance" with this provision. MHA moved to dismiss, arguing that it signed the provider agreement merely as an agent of the network pharmacies and producing a companion agreement that it signed on its own behalf, which "imposes no compliance or oversight obligations on MHA…with respect to the Network Pharmacies."

In an August 12, 2014 opinion, the Court categorically rejected Relator's theory of liability. The Court found that the "agreement has a definition of 'Pharmacy Provider' that excludes MHA," and declined to read any further obligation of oversight into the provider agreement based upon MHA's signature on the document. Accordingly, the Court held that Relator failed to "allege with particularity any act by MHA that resulted in a branded drug being dispensed instead of a generic, in a pharmacist dispensing a medication beyond its expiration date…or in the submission of any inaccurate information."

MHA then moved for an award of attorneys' fees and costs pursuant to 31 U.S.C. § 3730, "which authorizes such an award in certain [False Claims Act] actions where 'the court finds that the claim…was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.'" The Court found that following the January 10, 2014 meeting with MHA's counsel, Relator should have dismissed the action against MHA, but instead "concocted a theory of liability…based on an obvious misreading" of the PBM provider agreement. Thus, the Court asserted that "[v]iewed objectively," Relator's claims against MHA "had no reasonable chance of success, and…presented no valid argument to modify the governing law." Accordingly, the Court held that MHA is entitled to fees and costs incurred in defending the action after January 10, 2014.

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

Turning the Page

Introduction: The poignant pairing of the death of Mario M. Cuomo and the Second Inaugural of his son, Governor Andrew Cuomo, marked the first day of 2015—and prompted many of us to reflect upon the legacy of both Governors in the healthcare policy arena. While this update will restrict itself to providing you with a brief review of what occurred during the 2014 legislative session and what may happen in 2015, a future column may be devoted to considering the roles both Cuomos have played in shaping the New York State healthcare environment.

2014 Legislative Session: During the course of the 2014 legislative session, 658 bills passed both houses, seven more than last year, but continuing a trend of relatively fewer bills passing the Legislature and reaching the Governor during recent years than had been the case even a decade ago. Of those bills, Governor Andrew Cuomo signed 550 into law, vetoed 103 (or nearly nineteen percent), while five bills remain pending as of the start of 2015.

All of the Governor's vetoes occurred after this fall's election: the Governor vetoed 45 percent of the bills submitted to him post-November 4th. The 103 bills vetoed thus far by the Governor substantially exceeded the veto totals of each of his prior three years in office—but reflected a trend among recent Governors of vetoing more bills in the final year of their term. (Governor Paterson vetoed 147 bills in his last year in office, when he also issued a whopping 6,692 budget-related line item vetoes; Governor Pataki vetoed 211 bills in his final year.)

As is apparent from what follows, health-related legislation continued to comprise a very significant component of the New York State legislative output. The past year saw the enactment of major healthcare-related legislation, including:

- Medical Marijuana Authorization;
- New rules regarding "out-of-network" coverage and "surprise bills";
- A package of heroin-related legislation affecting the treatment modalities, new criminal penalties and insurance coverage mandates;
- Nurse Practitioner Modernization Act, relieving experienced nurse practitioners of the obligation to have written collaboration agreements in place;
- New insurance coverage for telehealth and for ostomy-related services;
- New programs to address eating disorders, concussion treatment, and maternal depression and new discharge planning obligations related to visually impaired patients;
- A new $1.2 billion capital restructuring program, tied to the DSRIP initiative;
- New regulatory requirements for compounding pharmacies and an extension of the collaborative drug therapy management demonstration;
- Further refinements and relaxation of HIV testing requirements;
- Authorization for the Department of Health to contract with a not-for-profit organization for the management of the State's underperforming organ donor registry; and
- New Safe Patient Handling requirements—to name just a few of the highlights.

The list underscores the importance of States in the overall legal and regulatory schemes that govern the nation's healthcare system—and the necessity for healthcare practitioners to follow New York State regulatory and legal developments with some care.

2015 Legislative Session Prospects: The pace of healthcare reform during the first Cuomo term has been extraordinary—and, while many healthcare stakeholders might prefer that 2015 could mark the start of a period for consolidating and implementing those changes, there is little evidence yet to suggest that would be the case. A number of the key healthcare issues likely to be debated during 2015 would be the following:

Nurse Staffing Ratios. Legislation to establish nurse-to-patient ratios within hospitals in New York State will remain in play during the 2015 session. Proponents of the bill point to better quality care, better patient outcomes and reduced hospital stays, while opponents caution that an inflexible statewide mandate would codify a one-size-fits-all approach to hospital staffing and patient care, would fail to consider patient acuity or the professional expertise of hospital staff and could have substantial fiscal implications. At the close of the 2014 legislative session, the New York State Nurses Association made it clear that the legislation would be its top priority for 2015 and launched a campaign to draw more attention to the issue during the summer of 2014—prompting a coalition of opponents of the legislation to redouble its efforts.

*Women's Equality Act***.** The Women's Equality Act will again be debated in the Legislature, certain components of which have significant healthcare ramifications. First introduced in 2013, the governor presented the package as a series of reforms promoting gender fairness and equality and included provisions to strengthen laws against human trafficking, domestic violence, and sexual harassment in the workplace. The most controversial of those reforms remains a proposal that sought to codify the Constitutional protections relating to reproductive choice. While the package was supported and passed by the Assembly, the reforms were ultimately divided by the Senate into ten separate proposals, nine of which (excluding the reproductive choice element) were passed in the Senate in 2013 and 2014. The Women's Equality Agenda became a high-priority item during the governor's re-election campaign, leading to the creation of the Women's Equality Party. Passage of the ten-point legislative package will likely remain a priority issue for the Governor and advocates going into 2015, but will continue to face opposition of the Republican State Senate.

Inequality. In his inaugural address, Governor Cuomo identified the need to address chronic high poverty in this state, "from the South Bronx to Rochester," through policies such as a higher minimum wage and education reform that will confront failing schools in poorer neighborhoods. The Administration has been working with local officials and legislators in affected areas of the State to develop an anti-poverty agenda that may be incorporated in his budget and policy proposals that he will be advancing this year. Focus on poverty and income inequality may also result in attention paid to healthcare disparities and may revive interest in legislation aimed at addressing what some advocates have seen as a two-tier healthcare system.

*State Health Innovation Plan***.** The Cuomo Administration's multi-year effort to redesign the Medicaid program continues, now with the implementation of the Delivery System Reform Incentive Payment (DSRIP). In the next phase, it is expected that the Administration will refocus on the entire healthcare system, including the elements funded by private insurance, for similar reform through the State Health Innovation Plan (SHIP). The Governor described this next component in his October platform as an effort that would build on the Administration's success in reforming the Medicaid program, but which would now be extended "to align the entire health care system, including private insurance, to further improve quality, keep costs low, and improve the health of all New Yorkers." The plan envisions collaborating with stakeholders to develop a five-year strategic blueprint for the overall healthcare system reform—with the expectation that savings in the billions of dollars will be identified.

Public Health Initiatives. The Administration has launched an important effort to end the AIDS epidemic. In June, Governor Cuomo announced a three-point plan to decrease new HIV infections to the point where the number of people living with HIV in New York State is reduced for the first time by:

- Identifying people with HIV who remain undiagnosed and linking them to health care;
- Linking and retaining people diagnosed with HIV to health care and getting them on anti-HIV therapy to maximize HIV virus suppression so they remain healthy and prevent further transmission; and
- Providing access to Pre-Exposure Prophylaxis (PrEP) for high-risk people to keep them HIV negative.

The Administration may be called upon to update and revise its approach to the Ebola epidemic in light of the latest information on the treatment protocols that appear to have successfully curbed its spread and to provide more resources to prepare the healthcare system for Ebola and other modern public health threats.

Single payor system. Assemblyman Richard Gottfried has been traveling the state seeking input and support for his proposal for a single payor system in New York—a proposal that may be considered by the State Assembly in the coming year. While the proposal is not going to be seriously considered by the Republican-led State Senate and may have been damaged by the Governor of Vermont's recent decision to abandon the initiative in the Green Mountain State, it is worth remembering that other initiatives sponsored by Mr. Gottfried—such as same sex marriage, medical marijuana and the Family Health Care Decisions Act—took some time to gain traction but eventually were enacted.

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

In the New York State Agencies

By Francis J. Serbaroli

Statewide Planning and Research Cooperative System (SPARCS)

Notice of Adoption. The Department of Health amended section 400.18 of Title 10 NYCRR to delete obsolete language, realign to current practice, and add new provisions, including mandated outpatient clinic data collection. Filing date: August 18, 2014. Effective date: September 3, 2014. *See* N.Y. Register September 3, 2014.

Statewide Health Information Network for New York (SHIN-NY)

Notice of Proposed Rulemaking. The Department of Health proposed adding Part 300 to Title 10 NYCRR to promulgate regulations, consistent with federal law and policies that govern the Statewide Health Information Network for NY. *See* N.Y. Register September 3, 2014.

HCBS Community Transition Services

Notice of Proposed Rulemaking. The Office for People With Developmental Disabilities proposed amending sections 635-10.4 and 635-10.5 of Title 14 NYCRR to implement a new HCBS waiver service. *See* N.Y. Register September 3, 2014.

Adult Day Health Care Programs and Managed Long-Term Care

Notice of Adoption. The Department of Health amended Part 425 of Title 10 NYCRR to create a hybrid model of adult day health care. Filing date: August 22, 2014. Effective date: September 10, 2014. *See* N.Y. Register September 10, 2014.

Organ Transplant Provisions

Notice of Adoption. The Department of Health amended section 405.13, repealed of section 405.22(c) and (k), and added sections 405.30 and 405.31 to Title 10 NYCRR to

update and add new provisions regarding organ transplant. Filing date: August 26, 2014. Effective date: September 10, 2014. *See* N.Y. Register September 10, 2014.

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

Notice of Proposed Rulemaking. The Department of Health proposed amending 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. *See* N.Y. Register September 10, 2014.

Applications for Certification of Need

Notice of Adoption. The Office for People With Developmental Disabilities amended section 620.7(a) of Title 14 NYCRR to change requirements concerning the method of submission of CON applications. Filing date: August 26, 2014. Effective date: September 10, 2014. *See* N.Y. Register September 10, 2014.

Emergency Medical Services

Notice of Proposed Rulemaking. The Department of Health proposed amending Part 800 of Title 10 NYCRR to clarify terminology, eliminate vagueness, address legal statutes/crimes and incorporate modern professional, ethical and moral standards. *See* N.Y. Register September 17, 2014.

Telepsychiatry Services in OMH-Licensed Clinics

Notice of Proposed Rulemaking. The Office of Mental Health proposed adding section 599.17 to Title 14 NYCRR to establish basic standards and parameters to approve telepsychiatry in OMH-licensed clinic programs choosing to offer this service. *See* N.Y. Register September 24, 2014.

Pathway to Employment Fee Adjustment

Notice of Adoption. The Office for People With Developmental Disabilities amended Subparts 635-10, 635-99 and section 686.99 of Title 14 NYCRR to increase fees for Region 3 and make other changes to requirements for the pathway to employment service. Filing date: September 9, 2014. Effective date: September 24, 2014. *See* N.Y. Register September 24, 2014.

Amendments to Rate Setting for Non-State Providers: IRA/CR Residential Habilitation and Day Habilitation

Notice of Adoption. The Office for People With Developmental Disabilities amended Subpart 641-1 of Title 14 NYCRR to amend the new rate methodology effective July 2014. Filing date: September 9, 2014. Effective date: September 24, 2014. *See* N.Y. Register September 24, 2014.

Amendments to Rate Setting for Non-State Providers: Rates for ICF/DD Services

Notice of Adoption. The Office for People With Developmental Disabilities amended Subpart 641-2 of Title 14 NYCRR to amend the new rate methodology effective July 2014. Filing date: September 9, 2014. Effective date: September 24, 2014. *See* N.Y. Register September 24, 2014.

Supervised IRA/CR Residential Habilitation Unit of Service

Notice of Adoption. The Office for People With Developmental Disabilities amended sections 635-10.5(b) and 671.1 of Title 14 NYCRR to conform existing OPWDD regulations to the change in the unit of service from monthly to daily. Filing date: September 9, 2014. Effective date: September 24, 2014. *See* N.Y. Register September 24, 2014.

Repeal of 14 NYCRR Part 1034: Requirements for the Operation of Inpatient Substance Abuse Treatment and Rehabilitation Programs

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services repealed Part 1034 of Title 14 NYCRR to remove an outdated regulation. Filing date: September 11, 2014. Effective date: October 1, 2014. *See* N.Y. Register October 1, 2014.

Implementation of a Program for the Designation of Vital Access Providers

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services added Part 802 to Title 14 NYCRR to ensure preservation of access to essential services in economically challenged regions of the state. Filing date: September 10, 2014. Effective date: September 10, 2014. *See* N.Y. Register October 1, 2014.

Medical Records Access Review Committees (MRARCs)

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 50-3 of Title 10 NYCRR to designate rather than appoint MRARCs to hear appeals from the denial of access to patient information. *See* N.Y. Register October 1, 2014.

HCBS Waiver Community Habilitation

Notice of Adoption. The Office for People With Developmental Disabilities amended Subpart 635-10 of Title 14 NYCRR to make revisions to HCBS Community Habilitation Services. Filing date: September 16, 2014. Effective date: October 1, 2014. *See* N.Y. Register October 1, 2014.

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

Notice of Emergency Rulemaking. The Department of Health amended Parts 487 and 488 of Title 18 NYCRR to revise Parts 487 and 488 in regards to the establishment of the Justice Center for Protection of People with Special Needs. Filing date: September 18, 2014. Effective date: September 18, 2014. *See* N.Y. Register October 8, 2014.

Inpatient Rate for Language Assistance Services

Notice of Proposed Rulemaking. The Department of Health proposed adding section 86-1.45 to Title 10 NYCRR to establish hospital inpatient payment rate to reimburse hospitals for the costs of providing language interpretation services. *See* N.Y. Register October 8, 2014.

Nursing Home (NH) Transfer and Discharge Rights

Notice of Proposed Rulemaking. The Department of Health proposed amending section 415.3 of Title 10 NYCRR to clarify requirements governing NH transfers and discharges so that facilities will uniformly comply with Federal regulations. *See* N.Y. Register October 8, 2014.

Managed Care Organizations

Notice of Proposed Rulemaking. The Department of Health proposed amending section 98-1.11 of Title 10 NYCRR to lower the contingent reserve requirement applied to the Medicaid Managed Care, Family Health Plus and HIV SNP Programs. *See* N.Y. Register October 8, 2014.

Medical Assistance Payment for Outpatient Programs and COPS

Notice of Adoption. The Office of Mental Health amended Part 588; and repealed Part 592 of Title 14 NYCRR to amend Part 588 by increasing Medicaid fees paid to OMH-licensed day treatment programs for children and repeal outdated rules. Filing date: September 22, 2014. Effective date: October 8, 2014. *See* N.Y. Register October 8, 2014.

Certificate of Need (CON) Requirements

Notice of Proposed Rulemaking. The Department of Health proposed amending section 710.1 of Title 10 NYCRR to simplify CON review requirements for projects involving nonclinical infrastructure, equipment replacement and repair and maintenance. *See* N.Y. Register October 15, 2014.

HCBS Waiver Community Habilitation Services

Notice of Emergency Rulemaking. The Office for People With Developmental Disabilities amended Subpart 635-10 of Title 14 NYCRR to modify proposed Community Habilitation regulations that were adopted on October 1, 2014. Filing date: September 30, 2014. Effective date: October 1, 2014. *See* N.Y. Register October 15, 2014.

Audited Financial Statements for Managed Care Organizations

Notice of Proposed Rulemaking. The Department of Health proposed amending section 98-1.16(c) and adding Subpart 98-3 to Title 10 NYCRR to extend audit and reporting standards to all managed care organizations (MCOs), including PHSPs, HIV SNPs and MLTCPs. *See* N.Y. Register October 22, 2014.

Hospital Observation Services

Notice of Proposed Rulemaking. The Department of Health proposed amending section 405.19 and adding section 405.32 to Title 10 NYCRR to amend current observation services provisions to be in compliance with changes in Public Health Law, Section 2805-v. *See* N.Y. Register October 29, 2014.

Physician Assistants and Specialist Assistants

Notice of Revised Rulemaking. The Department of Health amended Part 94 of Title 10 NYCRR to allow LPAs to prescribe controlled substances (including Schedule II) to patients under the care of the supervising physician. *See* N.Y. Register October 29, 2014.

Personalized Recovery Oriented Services (PROS)

Notice of Adoption. The Office of Mental Health amended Part 512 of Title 14 NYCRR to provide enhancements to individuals transitioning to more independent community living and reimburse providers for enhanced services. Filing date: October 23, 2014. Effective date: November 12, 2014. *See* N.Y. Register November 12, 2014.

HCBS Community Transition Services

Notice of Adoption. The Office for People With Developmental Disabilities amended sections 635-10.4 and 635-10.5 of Title 14 NYCRR to implement a new HCBS waiver service. Filing date: October 28, 2014. Effective date: November 15, 2014. *See* N.Y. Register November 12, 2014.

Rate Rationalization—Intermediate Care Facilities for Persons with Developmental Disabilities

Notice of Emergency Adoption and Revised Rulemaking. The Department of Health amended Subpart 86-11 of Title 10 NYCRR to amend the new rate methodology effective October 31, 2014. Filing date: October 31, 2014. Effective date: November 1, 2014. *See* N.Y. Register November 19, 2014.

Rate Rationalization for Community Residences/ Individualized Residential Alternatives Habilitation and Day Habilitation

Notice of Emergency Adoption and Revised Rulemaking. The Department of Health amended Subpart 86-10 of Title 10 NYCRR to amend the new rate methodology effective November 1, 2014. Filing date: October 31, 2014. Effective date: November 1, 2014. *See* N.Y. Register November 19, 2014.

Prevention of Influenza Transmission by Healthcare and Residential Facility and Agency Personnel

Notice of Adoption. The Department of Health amended section 2.59 of Title 10 NYCRR to clarify regulatory amendments and implement more flexible reporting provisions. Filing date: November 4, 2014. Effective date: November 19, 2014. *See* N.Y. Register November 19, 2014.

Vital Access Program and Providers

Notice of Emergency Rulemaking. The Office of Mental Health added Part 530 to Title 14 NYCRR to establish a process by which providers may be designated as Vital Access Providers to receive supplemental funding. Filing date: November 4, 2014. Effective date: November 4, 2014. *See* N.Y. Register November 19, 2014.

Amendments to Rate Setting Methodology: Rates for Residential Habilitation Delivered in IRAs and CRs and for Day Habilitation

Notice of Emergency/Proposed Rulemaking. The Office for People With Developmental Disabilities amended Subpart 641-1 of Title 14 NYCRR to amend the new rate setting methodology effective July 2014. Filing date: October 31, 2014. Effective date: November 1, 2014. *See* N.Y. Register November 19, 2014.

Amendment to Rate Setting for Non-State Providers: Intermediate Care Facilities for Persons with Developmental Disabilities

Notice of Emergency/Proposed Rulemaking. The Office for People With Developmental Disabilities amended Subpart 641-2 of Title 14 NYCRR to amend the new rate setting methodology effective July 2014. Filing date: October 31, 2014. Effective date: November 1, 2014. *See* N.Y. Register November 19, 2014.

Opioid Overdose Programs

Notice of Emergency Rulemaking. The Department of Health amended section 80.138 of Title 10 NYCRR to modify the rule to be consistent with new statutory language and with the emergency nature of opioid overdose response. Filing date: November 10, 2014. Effective date: November 10, 2014. *See* N.Y. Register November 26, 2014.

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

Notice of Proposed Rulemaking. The Office of Mental Health amended Part 578 of Title 14 NYCRR to eliminate trend factor effective July 1, 2014. *See* N.Y. Register November 26, 2014.

Certificate of Public Advantage

Notice of Adoption. The Department of Health added Subpart 83-1 to Title 10 NYCRR in order for the health care industry to obtain reasonable protections from antitrust liability through an active state oversight program. Filing date: December 2, 2014. Effective date: December 17, 2014. *See* N.Y. Register December 17, 2014.

Transgender Related Care and Services

Notice of Proposed Rulemaking. The Department of Health proposed amending section 505.2(l) of Title 18 NYCRR to authorize Medicaid coverage for transgender related care and services. *See* N.Y. Register December 17, 2014.

Clinic Treatment Programs

Notice of Adoption. The Office of Mental Health amended Part 599 of Title 14 NYCRR to adjust billing units associated with reimbursement of clinic services and to allow flexibility in delivery of complex care management. Filing date: December 2, 2014. Effective date: December 17, 2014. *See* N.Y. Register December 17, 2014.

HCBS Waiver Community Habilitation Services

Notice of Adoption. The Office for People With Developmental Disabilities amended Subpart 635-10 of Title 14 NYCRR to modify proposed Community Habilitation regulations that were adopted on October 1, 2014. Filing date: December 2, 2014. Effective date: December 17, 2014. *See* N.Y. Register December 17, 2014.

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

Notice of Emergency Rulemaking. The Department of Health amended sections 505.14 and 505.28 of Title 18 NYCRR to establish definitions, criteria and requirements associated with the provision of continuous PC and continuous CDPA services. Filing date: December 8, 2014. Effective date: December 8, 2014. *See* N.Y. Register December 24, 2014.

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

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 810 and added new Part 810 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: December 15, 2014. Effective date: December 15, 2014. *See* N.Y. Register December 31, 2014.

Criminal History Information Reviews

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services added Part 805 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: December 15, 2014. Effective date: December 15, 2014. *See* N.Y. Register December 31, 2014.

Patient Rights

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 815 and added new Part 815 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: December 15, 2014. Effective date: December 15, 2014. *See* N.Y. Register December 31, 2014.

Credentialing of Addictions Professionals

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 853 and added new Part 853 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: December 15, 2014. Effective date: December 15, 2014. *See* N.Y. Register December 31, 2014.

Incident Reporting in OASAS Certified, Licensed, Funded or Operated Programs

Notice of Emergency Rulemaking. The Office of Alcoholism and Substance Abuse Services repealed Part 836 and added new Part 836 to Title 14 NYCRR to enhance protections for service recipients in the OASAS system. Filing date: December 15, 2014. Effective date: December 15, 2014. *See* N.Y. Register December 31, 2014.

Integrated Outpatient Services

Notice of Adoption. The Office of Alcoholism and Substance Abuse Services added Part 825 to Title 14 NYCRR to promote access to physical and behavioral health services at a single site and to foster the delivery of integrated services. Filing date: December 16, 2014. Effective date: December 31, 2014. *See* N.Y. Register December 31, 2014.

Children's Camps

Notice of Emergency Rulemaking. The Department of Health amended Subpart 7-2 of Title 10 NYCRR to include camps for children with developmental disabilities as a type of facility within the oversight of the Justice Center. Filing date: December 15, 2014. Effective date: December 15, 2014. *See* N.Y. Register December 31, 2014.

State Aid for Public Health Services: Counties and Cities

Notice of Adoption. The Department of Health repealed Parts 30 and 40 and added new Part 40 to Title 10 NYCRR to modernize certain regulations, including standards of performance for eligible public health services. Filing date: December 16, 2014. Effective date: December 31, 2014. *See* N.Y. Register December 31, 2014.

Integrated Outpatient Services

Notice of Adoption. The Department of Health added Part 404 to Title 10 NYCRR to establish standards applicable to programs licensed or certified by the DOH, OMH or OASAS to add existing program services. Filing date: December 16, 2014. Effective date: January 1, 2015. *See* N.Y. Register December 31, 2014.

Accountable Care Organizations (ACOs)

Notice of Adoption. The Department of Health added Part 1003 and amended Subpart 98-1 of Title 10 NYCRR to promote ACOs and establish a certification process to regulate the use of ACOs to deliver an array of health care services. Filing date: December 16, 2014. Effective date: December 31, 2014. *See* N.Y. Register December 31, 2014.

Medical Use of Marijuana

Notice of Proposed Rulemaking. The Department of Health proposed amending Subpart 55-2; and adding Subpart 80-1 to Title 10 NYCRR to comprehensively regulate the manufacture, sale and use of medical marijuana. *See* N.Y. Register December 31, 2014.

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

Notice of Emergency Rulemaking. The Office of Mental Health amended Parts 501 and 550, repealed Part 524, and added new Part 524 to Title 14 NYCRR to enhance protections for people with mental illness served in the OMH system. Filing date: December 15, 2014. Effective date: December 1r, 2014. *See* N.Y. Register December 31, 2014.

Integrated Outpatient Services

Notice of Adoption. The Office of Mental Health added Subpart 599-1 to Title 14 NYCRR to promote increased access to physical and behavioral health services at a single site and foster delivery of integrated services. Filing date: December 16, 2014. Effective date: January 1, 2015. *See* N.Y. Register December 31, 2014.

Medical Assistance Payments for Community Rehabilitation Services Within Residential Programs for Adults, Children, Adolescents

Notice of Adoption. The Office of Mental Health amended Part 593 of Title 14 NYCRR to provide enhancements to individuals transitioning to more independent community living through use of BIP funding. Filing date: December 12, 2014. Effective date: December 31, 2014. *See* N.Y. Register December 31, 2014.

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

Notice of Emergency Rulemaking. The Office for People With Developmental Disabilities amended Parts 624, 633 and 687 and added Part 625 to Title 14 NYCRR to enhance protections for people with developmental disabilities served in the OPWDD System. Filing date: December 15, 2014. Effective date: December 15, 2014. *See* N.Y. Register December 31, 2014.

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

New York State Fraud, Abuse and Compliance Developments

Edited by Melissa M. Zambri

New York State Department of Health OMIG Audit Decisions

Compiled by Eugene M. Laks

Rite Aid of New York, Inc., Pharmacy Store #10824 (DOH administrative hearing decision dated October 3, 2014, Denise Lepicier, Administrative Law Judge). This was an audit of pharmacy paid claims by the previous operator Eckerd Corporation during the period January 2004 through December 2005. The ALJ sustained the audit findings, under the 2009 OMIG audit protocol in effect at the time of completion of the audit, of partial disallowances limited to the pharmacy dispensing fee for discrepancies between the prescriber identified on the Medicaid claim and the actual prescriber on the prescription order. The value of the disallowance was extrapolated over the universe of claims for the audit period. The ALJ held that a subsequent 2012 OMIG audit protocol that did not extrapolate this type of error did not apply to the audit completed in 2009.

New York State Attorney General Press Releases

Compiled by Karen S. Southwick

Attorney General Issues Statement Regarding Decision Involving Pharmaceutical Manufacturer and Alzheimer's Patients—December 12, 2014—Attorney General Eric T. Schneiderman released a statement regarding a decision by the United States District Court for the Southern District of New York, which granted New York's motion for a preliminary injunction against Defendants Actavis PLC and Forest Laboratories LLC. The Attorney General stated that the decision "prevents Actavis from pursuing its scheme to block competition and maintain its high drug prices. Our lawsuit against Actavis sends a clear message: drug companies cannot illegally prioritize profits over patients." http://www.ag.ny.gov/press-release/statement-ag-schneiderman-decision-blocking-pharmaceutical-manufacturer-manipulating.

Settlement Reached With Manhattan Doctor's Office for Allegedly Deceptive Business Practices—December 11, 2014—New York reached an agreement with PATH Medical, P.C. ("PATH-Medical") that requires the Manhattan-based business to ensure patients receive accurate information about their financial responsibility before undergoing medical testing and other services. PATH-Medical conducted extensive and expensive diagnostic tests during patients' initial visits and sold packages of tests and services to patients that ranged in cost from $10,000 to $100,000. PATH-Medical led some consumers to believe that a significant percentage of the charges would be covered by their health plan's out-of-network benefit. However, a significant percentage of the total charges typically were not covered. Under the agreement, PATH-Medical is required to reform its practices to ensure patients are provided with accurate information about their financial responsibility before they agree to undergo any testing or other services, and is required to discontinue and modify other business practices that the Attorney General's Office identified during the course of its investigation. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-manhattan-doctor%E2%80%99s-office-alleged-deceptive.

Nurse Arrested for Allegedly Striking Elderly Resident in Dutchess County Nursing Home—December 10, 2014—A licensed practical nurse

was arrested for allegedly slapping an elderly resident of a nursing center following a verbal altercation with the resident. The interaction was caught on a surveillance camera. The nurse faces a felony endangerment charge and up to four years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nurse-accused-striking-elderly-resident-dutchess.

Unlicensed Syracuse Adult Care Facility Enters Settlement—December 10, 2014—New York reached a settlement with a residence that was operating as an unlicensed adult care facility. Under the settlement, the facility must retain a monitor to assist in evaluating and assessing compliance, restructure its Board of Directors, pay a $20,000 fine, and create a new fund to assist individuals who otherwise would not financially qualify for admission to the facility. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-unlicensed-syracuse-adult-care-facility.

Brooklyn Pharmacies and Individuals Indicted on Charges of Defrauding Medicaid Over $5 Million—November 24, 2014—Three pharmacies and seven individuals were indicted for allegedly defrauding Medicaid of over $5 million by paying customers for prescriptions obtained from a local doctor and then billing Medicaid for the medications even though the medications were not dispensed. Two of the pharmacies were owned and operated by an individual who was banned from billing Medicaid and deported following a federal

conviction for adulteration of prescription drugs and the filing of false tax returns. The individual's daughter was listed as the owner of the pharmacies allegedly in order to hide the individual's involvement. In addition, two of the pharmacies received payments from Medicaid for rendering services while allegedly using a supervising pharmacist who had been barred or excluded from the Medicaid program. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-indictment-three-brooklyn-pharmacies-pharmacy-owners-and.

Finger Lakes Health Network to Strengthen Communications Policies With the Deaf or Hard of Hearing—November 13, 2014—New York reached an agreement with the Finger Lakes Health Network to strengthen its policies concerning communication with patients and their family members or companions who are deaf or hard of hearing. As a result of the agreement, the network will expand access to sign-language interpreters and improve policies and training to ensure that medical staff members are able to effectively communicate with the deaf and hard of hearing. http://www.ag.ny.gov/press-release/ag-schneiderman-secures-agreement-finger-lakes-health-network-expanding-accommodations.

Doctor and Nurse Charged in Allegedly Fraudulent Scheme in Dutchess County—November 13, 2014—A medical doctor and a registered nurse were arrested after the filing of felony complaints in Dutchess County's Town of Wappinger Justice Court. The complaints contain charges that the doctor and nurse conspired for the nurse to provide physician services to hundreds of the doctor's elderly and infirm homebound patients. The doctor allegedly gave the nurse blank and pre-signed prescription slips issued in the doctor's name and the nurse, in her sole discretion, filled out the prescriptions for medications, including narcotics, for the doctor's patients. The doctor also is charged with defrauding Medicare of more than $50,000 and Medicaid of more than $1,000 by submitting claims for more expensive physician services when those services were provided by a nurse. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-doctor-and-nurse-alleged-fraud-scheme-dutchess.

Help for Consumers Comparing Health Care Plans in Advance of State Marketplace Open Enrollment—November 10, 2014—The Attorney General issued a brochure offering tips to New Yorkers buying health insurance coverage for 2015. The pamphlet was offered in advance of the Marketplace's open enrollment period, which began on November 15. http://www.ag.ny.gov/press-release/ag-schneiderman-offers-tips-help-consumers-compare-health-care-plans-advance-nys.

$31 Million Settlement Reached With Drug Manufacturer to Resolve Allegations of False Billings to Medicaid Programs—October 15, 2014—Several states, including New York, and the federal government entered into a $31 million settlement agreement with drug manufacturer Organon to settle allegations that Organon underpaid rebates to New York's Medicaid program, offered improper financial incentives to nursing home pharmacy companies, promoted its antidepressants for unapproved uses, and misrepresented its drug prices to New York's Medicaid program. The settlement resulted from two whistleblower lawsuits filed in federal courts in Massachusetts and Texas. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-31-million-national-medicaid-settlement-pharmaceutical.

Utica Certified Nurse's Aide Arrested For Allegedly Abusing Nursing Home Resident—October 14, 2014—A male Utica certified nurse's aide was charged with three counts each of Sexual Abuse in the First Degree, Endangering the Welfare of a Vulnerable Elderly Person or an Incompetent or Physically Disabled Person in the Second Degree, and Willful Violation of Health Laws. The aide allegedly engaged in forcible sexual contact with a disabled female resident of a rehabilitation and nursing center. http:/www.ag.ny.gov/press-release/nurse%E2%80%99s-aide-arrested-charges-he-abused-female-nursing-home-resident.

Specialty Pharmacy Enters into $846,000 Settlement to Resolve Allegations of Medicaid Fraud—October 9, 2014—New York entered into a settlement agreement with New York-based Sorkin's Ltd Rx. d/b/a CareMed Pharmaceutical Services ("Sorkin's"), a specialty pharmacy, to resolve allegations that Sorkin's made false statements to the State's Medicaid program to secure expeditious prior authorizations for the coverage of specialty drugs and that it submitted false claims to Medicaid for certain prescription medications that were restocked and resold and for refills that recipients never obtained. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-846000-settlement-new-york-specialty-pharmacy-resolve.

Health Care Helpline Assisted 20,000 Consumers and Saved New Yorkers $12.5 Million—October 6, 2014—The Health Care Bureau's Helpline has investigated and resolved approximately 13,000 consumer complaints since 2011, resulting in a savings or return of over $12.5 million in health care expenses to New York consumers. Many consumers, who called the Helpline, sought assistance for urgent problems, including gaining access to medically necessary care. The Helpline serves as an important source of consumer information for the Health Care Bureau, which helps providers implement best practices and enables the Bureau to bring swift enforcement action when misconduct is discovered. http://www.ag.ny.

gov/press-release/ag-schneiderman-issues-report-highlighting-offices-health-care-helpline-has-assisted.

Settlement Reached With Prison Health Care Contractor—September 25, 2014—New York entered into a settlement agreement with Correctional Medical Care, Inc. ("CMC"), a prison health care contractor that provides medical services in jails in 13 upstate counties. The investigation revealed that CMC violated key provisions of its contracts with Monroe and Tioga counties by understaffing facilities and shifting work hours from physicians and dentists to less qualified and lower-wage staff, including, in one case, a nurse with a felony conviction. There were significant lapses in medical care at facilities with which CMC had contracts. In addition, CMC violated New York's prohibition of the corporate practice of medicine. The settlement agreement provides for the restructuring of CMC contracts, oversight of CMC by an independent monitor, restitution, and civil penalties. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-health-care-company-provided-substandared-service.

Long Island Psychiatrist Arrested on Charges of Selling Prescriptions for Controlled Substances to Undercover Investigators—September 23, 2014—A Long Island psychiatrist was arrested and charged with unlawfully selling prescriptions for controlled substances to undercover investigators posing as patients who sought the drugs for illegitimate purposes. The psychiatrist allegedly gave prescriptions to the undercover investigators, who posed as patients, after brief visits—some lasting a minute or less—without conducting a medical history, physical assessment, or psychological evaluation of their symptoms and in disregard for the individual's behavior, which included statements that the drugs would be shared with others. The psychiatrist, who has surrendered her license based upon a finding that she had inappropriately prescribed and overprescribed controlled substances to numerous patients, is charged with 15 counts of Criminal Sale of a Prescription for a Controlled Substance (a class C felony). Each count has the potential for 5 1/2 years of incarceration. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-felony-arrest-long-island-psychiatrist-charges-illegally.

Buffalo Nursing Home Assistants Charged With Neglect—September 23, 2014—Two nursing assistants were arrested for neglecting a nursing home resident at the Erie County Medical Center Skilled Nursing Facility (now known as Terrace View Long Term Care Facility) in Buffalo. The assistants are charged with numerous felony and misdemeanor counts for allegedly neglecting an elderly resident, who suffers from Alzheimer's disease and dementia and is non-ambulatory. The arrests followed an investigation, which relied on a hidden camera in the resident's room, into the treatment of the resident. The assistants allegedly violated the resident's personal care plan and falsified documents in an effort to conceal the neglect. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-two-nursing-home-employees-charges-they-neglected-0.

Settlement Reached with Device-Manufacturer to Resolve Claims of Improper Inducement of Physicians—September 18, 2014—Forty-six states and the District of Columbia reached a settlement with Medtronic, a Minnesota-based company, to resolve claims under the False Claims Act that Medtronic improperly induced physicians to recommend Medtronic devices to treat cardiac rhythmic disease. Each settling state's Medicaid program will receive a portion of this settlement. New York will receive $67,369.31 of the settlement. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-national-settlement-medtronic-medicaid-violations.

Attorney General Files Antitrust Lawsuit to Prevent Pharmaceutical Manufacturer from Manipulating Alzheimer Patients' Medications—September 16, 2014—The Attorney General filed a lawsuit to prevent pharmaceutical manufacturer Actavis PLC and its New-York based subsidiary Forest Laboratories from forcing Alzheimer's patients to switch medications as part of an anti-competitive strategy designed to maintain high drug prices. Actavis had announced a plan to withdraw its Alzheimer drug Namenda from the market. The patent on Namenda will expire shortly; thus Actavis would face competition from generic drug makers. Actavis allegedly planned to force patients to switch unnecessarily to a very similar drug with a longer patent to avoid facing competition. Once patients switch to the new drug, it is likely they may remain on the drug even after the generic medications enter the market due to the practical difficulties of switching back. The lawsuit alleges that forcing patients to switch medications violates antitrust laws designed to encourage competition and maintain lower prices for consumers. http://www.ag.ny.gov/press-release/ag-schneiderman-files-groundbreaking-lawsuit-block-pharmaceutical-manufacturer.

Licensed Practical Nurse Arrested for Allegedly Stealing Narcotics from Nursing Home Resident—September 10, 2014—A licensed practical nurse was arrested for allegedly stealing oxycodone pills from a nursing home resident who was paralyzed and had sustained head and neck trauma. The nurse allegedly replaced the pills with a similar looking non-narcotic allergy medication. The nurse, who was formerly employed by Northeast Center for Special Care in the Town of Ulster, was charged with one count of Endangering the Welfare of an Incompetent or Physically Disabled Person in the First Degree (a class E Felony); one count of

Falsifying Business Records in the First Degree (a class E Felony); one count of Criminal Possession of a Controlled Substance in the Seventh Degree (a class A Misdemeanor); and one count of Petit Larceny (a class A Misdemeanor). Each felony has a maximum penalty of four years of incarceration and each misdemeanor has a maximum penalty of one year of incarceration. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-nurse-allegedly-stealing-narcotics-brain-trauma.

State Reaches Agreement with New York's Largest Health Insurer to Increase Member Communications and Establishes a $3.5 Million Fund to Reimburse Members—September 9, 2014—The State reached an agreement with GHI, a subsidiary of EmblemHealth, Inc., New York's largest health insurer, that requires improved plan disclosures for out-of-network provider benefits to those members who sign up for GHI's Comprehensive Benefits Plan ("CBP"). The settlement also requires that GHI establish a $3.5 million consumer assistance fund to provide financial relief to members, most of them New York City employees, and pay $300,000 in penalties to the State. The investigation focused on the reimbursement rate for out-of-network providers in the CBP. The rates were tied to a 1983 fee schedule that was rarely updated, and thus rarely came close to covering the amount billed. GHI must make the fee reimbursement schedule accessible and transparent to members and prospective members. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-settlement-health-insurer-increases-out-network-disclosure.

Former Department of Health Contract Employee Pleads Guilty to Stealing from State—September 5, 2014—A former Department of Health ("DOH") contract employee pled guilty to one count of offering a false instrument for filing in the first degree, a Class E felony, in Albany County Court. The individual, who was the former executive director of the American Academy of Pediatrics, District II ("AAP-II"), created false invoices and submitted fraudulent vouchers to inflate AAP-II's expenses while under contract with the DOH to provide training and education on childhood immunization issues. The individual was expected to repay $110,000 at his sentencing and receive a sentence including 30 days of incarceration, a five-year term of probation, and community service. http://www.ag.ny.gov/press-release/ag-schneiderman-and-comptroller-dinapoli-announce-guilty-plea-110000-health-contract.

Long Island Nurse Indicted on Charges of Attempting to Cover Up Morphine Overdose of Patient—September 3, 2014—A nurse who attempted to cover up her mistake of administering the wrong medication to a resident of Bayview Nursing and Rehabilitation Center was charged with one count of endangering the welfare of a vulnerable elderly person, or an incompetent or physically disabled person, in the second degree (a class E felony); one count of endangering the welfare of an incompetent or physically disabled person (a class A misdemeanor); one count of willful violation of the public health laws (an unclassified misdemeanor); and two counts of falsifying business records in the first degree (a class E felony). The nurse did not reveal the mistake even after the resident lost consciousness and was admitted to Long Beach Medical Center for five days of treatment to counter the effects of the medication mistake. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-indictment-long-island-nurse-charges-attempting-cover.

Four Individuals Arrested for The Unlawful Practice of Dentistry in Brooklyn—August 28, 2014—Four individuals were arrested for allegedly practicing dentistry without a license at two Brooklyn dental clinics. The individuals were arrested after an undercover investigation by the Attorney General's Medicaid Fraud Control Unit. Investigators allegedly observed the individuals performing dental procedures on patients. The individuals face one felony count of Unlawful Practice of a Profession (Dentistry), a class E Felony. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrests-unlicensed-dentists-charges-they-treated-patients.

Medication Technician Pleads Guilty to Stealing Narcotics From Nursing Home Residents—August 22, 2014—A medication technician who stole prescription narcotics from nursing home residents at the Pittsford-based Heather Heights Assisted Living and Memory Care Facility pled guilty to the misdemeanor crime of Attempted Scheme to Defraud in the 1st Degree. The medication technician stole approximately 650 prescription narcotics for personal consumption and attempted to conceal the theft by substituting pills with a similar appearance. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-guilty-plea-medication-technician-who-stole-approximately.

New Rochelle Nursing Home Enters into $2.2 Million Settlement for Fraudulent Billings—August 20, 2014—A New Rochelle-based nursing home and its owner entered into settlement agreements with State and federal authorities to resolve allegations that the facility and its owner submitted tens of thousands of inflated claims to the New York State Medicaid program. The claims sought reimbursement for services provided at artificially high rates. The settlement follows the 2011 conviction of the nursing home's former administrator, who served a state prison sentence, lost her Nursing Home Administrator license, and was excluded from participating in the state's Medicaid program. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-22-million-settlement-new-rochelle-nursing-home-fraudulent.

Home Health Care Worker Charged With Felony Charges of Medicaid Theft—August 20, 2014—A Rochester home health aide was charged with submitting false time sheets to Innovative Care, LLC, which billed Medicaid for work the aide had not performed. Based on the false time sheets, Innovative Care billed the Medicaid Program $3,958.23, and the aide received approximately $1,800.00 in pay for the alleged services. The aide was arraigned on one count of Grand Larceny in the Third Degree (a class "D" felony), and Grand Larceny in the Fourth Degree (a class "E" felony). The aide faces a maximum penalty of 2 1/3 to 7 years in prison. http://www.ag.ny.gov/press-release/ag-schneiderman-announces-arrest-home-health-care-worker-facing-felony-charges.

New York State Office of the Medicaid Inspector General Update

Compiled by Jamie Dughi Hogenkamp

2014 Compliance Program Certification Information, Forms Posted—December 1, 2014—http://www.omig.ny.gov/latest-news/827-2014-compliance-program-certification-information-forms-posted.

Compliance Certification Questions and Answers Posted—November 25, 2014—http://www.omig.ny.gov/latest-news/826-webinar-23-questions-and-answers-posted.

Compliance Certification Webinar Posted—November 12, 2014—http://www.omig.ny.gov/latest-news/820-compliance-certification-webinar-posted.

NYS Office of the Medicaid Inspector General Issues 2013 Annual Report—October 9, 2014—http://www.omig.ny.gov/latest-news/816-nys-office-of-the-medicaid-inspector-general-issues-2013-annual-report.

Mental Health Providers—Comprehensive Psychiatric Emergency Programs Compliance Guidance Published—October 7, 2014—http://omig.ny.gov/images/stories/compliance_alerts/20141007_compliance_guidance-2014-05.pdf.

Mental Health Providers—Rehabilitation in Community Residences- Adult Services Compliance Guidance Published—October 7, 2014—http://omig.ny.gov/images/stories/compliance_alerts/20141007_compliance_guidance-2014-06_revised.pdf.

Transportation Providers Compliance Guidance Published—October 7, 2014—http://omig.ny.gov/images/stories/compliance_alerts/20141007_compliance_guidance-2014-07.pdf.

Exclusion and Reinstatement Webinar Posted—September 29, 2014—http://www.omig.ny.gov/latest-news/812-exclusion-and-reinstatement-webinar-posted.

Providers Should View the Self-Disclosure Webinar—August 6, 2014—http://omig.ny.gov/resources/webinars/796-omig-webinar-21-self-disclosure.

Inpatient Chemical Dependency Rehabilitation and Outpatient Chemical Dependency Services Compliance Guidance Published—July 29, 2014—http://omig.ny.gov/images/stories/compliance_alerts/20140729_compliance_guidance-2014-04-revision-1.pdf.

Full List of OMIG's Compliance Guidance for Medicaid Providers is available at http://omig.ny.gov/general-guidance.

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Aligning Incentives In Accountable Care Organizations: The Role Of Medical Malpractice Reform, Laura D. Hermer, 17 J. Health Care L. & Pol'y 271 (2014).

Distinction Without a Difference: Reforming the Medicare Three-Day Qualifying Stay Rule for SNF Care, Jonathan W. Padish, 21 Elder L.J. 465 (2014).

Health Care Fraud, Daniel Colbert, Steven Harrison and Irina Kotchach, 51 Am. Crim. L. Rev. 1315 (Fall 2014).

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Something Old, Something New: Recent Developments in the Enforceability of Agreements to Arbitrate Disputes Between Nursing Homes and Their Residents, John R. Schleppenbach, 22 Elder L.J. 141 (2014).

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For Your Information

By Claudia O. Torrey

In the Winter 2014 issue of the *Health Law Journal*, this author reported that: 'On February 12, 2014, The Department of Health and Human Services released its coverage report regarding enrollees under the Patient Protection and Affordable Care Act.[1] The report revealed 3.3 *million people selecting "health care exchange" plans for the time* period of October 1, 2013 to February 1, 2014. Ironically, just when the country is increasing its numbers of people with health insurance, the United States is experiencing a dearth of primary care physicians amongst a growing aging population![2] A suggested approach to this problem involves the use of the terms telemedicine,[3] telehealth,[4] and mHealth;[5] collectively, these terms are sometimes categorized as "connected health."[6] The marriage of connected health and health care will create a digital learning curve that arguably can be eased by following guidance laid out in the 2001 Institute of Medicine ("IOM")report—*Crossing the quality chasm: a new health system for the 21st century.*[7] The IOM report called for health care that is safe, effective, patient-centered, timely, efficient, and equitable.

According to Dr. Lee H. Schwamm, the Telehealth Medical Director at Massachusetts General Hospital in Boston, health care has largely been a local and synchronous service. Dr. Schwamm asserts that the future of health care delivery can be distilled down to seven critical strategies:

- understanding patients' and providers' expectations;
- untethering telehealth from traditional revenue expectations;
- deconstructing the traditional health care encounter;
- being open to discovery;
- being mindful of the importance of space in which virtual encounters occur;
- redesigning care to improve value in health care; and
- being bold and visionary.[8]

Relentless innovation is a crucial driver in creating value across all industries, and health care is no exception;[9] the next frontier or "brave new world" of health care will have to tackle the issue of how best to train the next generation of health care providers to utilize technology as part of "good" medicine.

When this author put the above paragraphs from "pen to paper," there was no prior knowledge that on December 15, 2014 the ATA would launch an accreditation program for online, direct-to-consumer healthcare consultations.[10] The goal of the program is to ensure transparency and patient safety as online services for healthcare proliferates.[11] The program also seeks to reassure payers that the virtual services being reimbursed: follow federal and state laws/regulations; create patient privacy; are transparent in pricing and operations; use qualified licensed providers; and follow appropriate clinical practices and guidelines. Available to both for-profit and not-for-profit entities, the program plans to expand to Canada in 2015![12]

Endnotes

1. http://aspe.hhs.gov/health/reports/2014/MarketplaceEnrollment/Feb2014/1b_2014feb_enrollment.pdf.
2. Inglehart, J.K.,"Expanding the role of advanced nurse practitioners—risks and rewards," N. Engl. J. Med. 2013; 368 (20): 1935-41.
3. According to the American Telemedicine Association ("ATA"), Telemedicine is "[t]he use of medical information exchange from one site to another via electronic communications to improve a patient's clinical health status." American Telemedicine Association, *What is telemedicine?*, available at http://www.americantelemed.org.
4. Telehealth services allow consumers to access health education and self- management support through the Internet via computers and/or wireless devices. *See* Kvedar, J., Coye, M.J., Everett, W. "Connected Health: A Review Of Technologies And Strategies To Improve Patient Care With TelemedicineAnd Telehealth," *Health Affairs*, 33, no. 2 (2014): 194-99.
5. *Id.* (services accessed mobile wireless technologies).
6. *Id.*
7. National Academies Press, Washington, DC.
8. Schwamm, L.H., "Telehealth: Seven Strategies To Successfully Implement Disruptive Technology And Transform Health Care," *Health Affairs*, 33, no. 2 (2014): 200-06.
9. *Id.*
10. http://www.americantelemed.org/news-landing/2014/12/15.
11. *Id.*
12. *Id.*

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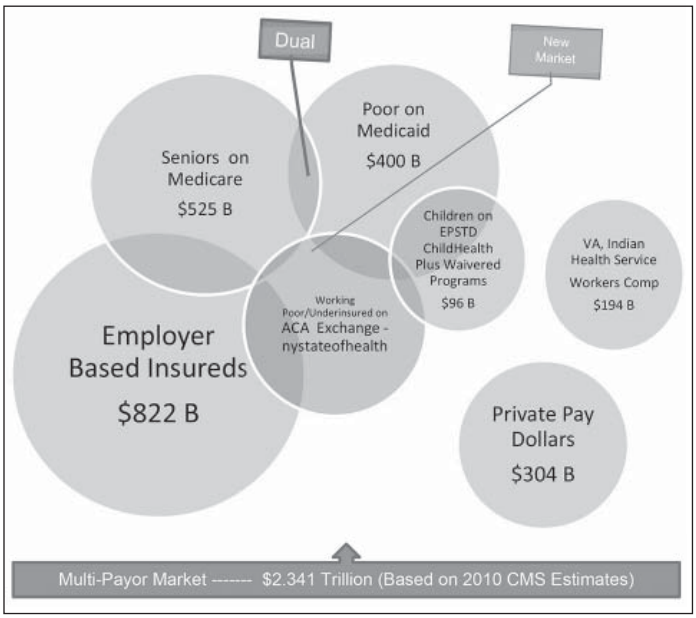
Telehealth and Telemedicine Reimbursement Issues

By Raul A. Tabora, Jr

Payors of care control the purse strings and can set standards based on policy, budgets and political pressures. As with many health care services, Telehealth reimbursement will depend on how each payor weighs these factors. As we look at any issue of reimbursement, it is helpful to see how these payors have been segregated by distinct markets over the decades. The following chart provides a vantage point in this regard:



Telehealth has been a hot topic over the past decade and has increasingly been seen to further patient care while addressing budgetary limitations. However, there are significant hurdles in the political space. Total spending for Telehealth has gone from virtually non-existent in the 1990s to a gradual increase projected to be over $4 billion by industry sources for all markets. This presentation will provide a basic understanding and legal background as it relates to reimbursement for the Medicare, Medicaid and Managed Care segments of this market. Additionally, a significant expansion of telehealth and telemedicine in New York will take place under provisions signed into law on December 29, 2014. (See Chapter 550[1] discussed below in Part C of this article.) The new law requires that both insurers and Medicaid provide coverage for the provision of telehealth and telemedicine services as plans are issued or modified on or after January 1, 2015.

A. Medicare Reimbursement Issues

Out of all the payors, Medicare has established the most elaborate standards for reimbursement of telehealth services. Efforts at the legislative level started with the Health Insurance Portability and Accountability Act of 1996. Section 192 provided for a study on telemedicine based on encouraging reports from various demonstration projects existing at the time:

> REPORT ON MEDICARE REIMBURSEMENT OF TELEMEDICINE.
>
> The Health Care Financing Administration shall complete its ongoing study of Medicare reimbursement of all telemedicine services and submit a report to Congress on Medicare reimbursement of telemedicine services by not later than March 1, 1997. The report shall—
>
> (1) utilize data compiled from the current demonstration projects already under review and gather data from other ongoing telemedicine networks;
>
> (2) include an analysis of the cost of services provided via telemedicine; and
>
> (3) include a proposal for Medicare reimbursement of such services.

Efforts then proceeded slowly and incrementally over the following decade. Under the Balanced Budget Act (BBA) of 1997, the first telehealth codes were authorized:

> SEC. 4206. MEDICARE REIMBURSEMENT FOR TELEHEALTH SERVICES.
>
> Not later than January 1, 1999, the Secretary of Health and Human Services shall make payments from the Federal Supplementary Medical Insurance Trust Fund under part B of title XVIII of the Social Security Act (42 U.S.C. § 1395j et seq.) in accordance with the methodology described in subsection 42 U.S.C. § 1395l.
>
> (b) ***for professional consultation via telecommunications systems with a physician*** (as defined in section 1861(r) of such Act (42 U.S.C. § 1395x(r)) or a practitioner (described in section 1842(b)(18)(C) of such Act (42 U.S.C. § 1395u(b)(18)(C)) ***furnishing a service for which payment may be made under such part to a beneficiary***

> ***under the Medicare program residing in a county in a rural area*** (as defined in section 1886(d)(2)(D) of such Act (42 U.S.C. § 1395ww(d)(2)(D))) that is ***designated as a health professional shortage area*** under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. § 254e(a)(1)(A)), ***notwithstanding that the individual physician or practitioner providing the professional consultation is not at the same location as the physician or practitioner furnishing the service to that beneficiary***.

Of course, such telephonic consultations were common by 1997 amongst medical professionals. What was uncommon, however, was getting paid for the consult. In this regard, the BBA established a methodology for payment as follows:

> (b) METHODOLOGY FOR DETERMINING AMOUNT OF PAYMENTS—*** the Secretary shall establish a methodology for determining the amount of payments made under subsection (a) within the following parameters:
>
> > (1) The ***payment shall be shared between the referring physician or practitioner and the consulting physician or practitioner***. The amount of such payment shall ***not be greater than the current fee schedule of the consulting physician or practitioner for the health care services provided.***
> >
> > (2) ***The payment shall not include any reimbursement for any telephone line charges or any facility fees, and a beneficiary may not be billed for any such charges or fees***.

As such, the policy on payment included the following basic concepts:

1. Sharing of fees by the professionals involved.
2. Coverage only where the patient resides in a rural area designated as having a shortage of health professionals.
3. Coverage and payment based on already covered and payable Medicare services involved in the consult.
4. No payment for hard costs such as telecommunications equipment and capital.
5. No charges to the patient.

The Benefits Improvement and Protection Act of 2000 (BIPA) expanded coverage and removed some constraints, yet maintained substantial limitations related to geographic location, originating sites, and eligible telehealth services. Effective October 1, 2001, BIPA amended section 1834 of the BBA to provide for a new subsection (m): "Payment for Telehealth Services" which expanded the payment for telemedicine services. However, BIPA also limited reimbursement to those eligible individuals who received services at originating sites. These sites include: office of a physician or practitioner, critical access hospital, rural health clinic, federally qualified health center, or a hospital. The changes included additional services over a broader geographic area. Among the provisions passed were the following:

- elimination of a "fee sharing" requirement, instead using the concept of paying Originating Sites a fee of $20 per visit to recover facility costs, with increases in the future;
- expanded telemedicine services to include direct patient care, physician consultations, and office psychiatry services;
- included payment for the physician or practitioner at the Distant Site at the rate applicable to services generally;
- expanded the definition of Originating Sites to include physician and practitioner offices, critical access hospitals, rural health clinics, federally qualified health centers, and hospitals (but did not include nursing homes);
- expanded the geographic regions in which Originating Sites are located to include rural health professional shortage areas, any county not located in a Metropolitan Statistical Area, and from any entity approved for a federal telemedicine demonstration project; and
- permitted use of store and forward applications in Alaska and Hawaii for federal demonstration projects.

These changes were intended to improve access of medical care to rural and other medically underserved areas and pave the way for increased reimbursement by other payors. Regulatory provisions were then enacted as supplemented to date providing a more structured method of reimbursement for telehealth under 42 CFR § 414.65. These regulations split the reimbursement between those billable by the "originating site" where the

patient is located and the billings of the "distance site" where the professional rendering a telehealth service is situated. Limitations and compliance obligations apply to both coverage and the financial relationship in this process:

> § 414.65 Payment for telehealth services.
>
> (a) Professional service. Medicare payment for the professional service via an interactive telecommunications system is made according to the following limitations:
>
> (1) *The Medicare payment amount for *** services furnished via an interactive telecommunications system is equal to the current fee schedule amount applicable for the service of the physician or practitioner.*
>
> ***
>
> (2) *Only the physician or practitioner at the distant site may bill and receive payment for the professional service via an interactive telecommunications system.*
>
> (3) *Payments made to the physician or practitioner at the distant site, including deductible and coinsurance, for the professional service may not be shared with the referring practitioner or telepresenter.*
>
> (b) Originating site facility fee. For telehealth services furnished on or after October 1, 2001:
>
> (1) For services furnished on or after October 1, 2001 through December 31, 2002, *the payment amount to the originating site is the lesser of the actual charge or the originating site facility fee of $20.* For services furnished on or after January 1 of each subsequent year, the facility fee for the originating site will be updated by the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act.
>
> (2) Only the originating site may bill for the originating site facility fee and only on an assignment-related basis. *The distant site physician or practitioner may not bill for or receive payment for facility fees associated with the professional service furnished via an interactive telecommunications system.*
>
> (c) Deductible and coinsurance apply. The payment for the professional service and originating site facility fee is subject to the coinsurance and deductible requirements of sections 1833(a)(1) and (b) of the Act.
>
> (d) Assignment required for physicians, practitioners, and originating sites. Payment to physicians, practitioners, and originating sites is made only on an assignment-related basis.

Accordingly, Medicare uses the existing fee code values as proxies for the amounts to be paid when such services are rendered via telehealth. A "Q" code is appended to the CPT to designate the fact that telehealth is at work. Moreover, the "originating site" is allowed a graduated per-patient fee which is currently set at approximately $24.00.

Significantly, reimbursement is also restricted in terms of the technology needed to ensure coverage. Under 42 CFR § 410.78(b), a telehealth service must generally be furnished via an interactive telecommunications system. Under § 410.78(a)(3), an interactive telecommunications system is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, *real-time interactive communication* between the patient and distant site physician or practitioner. Telephones, facsimile machines, and electronic mail systems do not meet the definition of an interactive telecommunications system regardless of whether such methods are within a standard of health care in any particular State.

Most of the expansion in Telehealth reimbursement for Medicare's fee-for-service program is now accomplished through regulatory rulemaking. A process of yearly review is undertaken by CMS along with various associations and institutions involved in telehealth implementation to determine the extent of any changes in reimbursement. The most recent regulatory issuance was published in the Federal Register on July 14, 2014. (79 FR 40916.)[2] In this regard, CMS outlines the process for adding services to or deleting services from the list of Medicare telehealth services. Requests for expansion of Telehealth reimbursement is assigned to one of two categories:

- Category 1: Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for

similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the proposed service; for example, the use of interactive audio and video equipment.

- Category 2: Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient.

As with the policy first established under the Balanced Budget Act of 1997, a priority is given under Category I requests to those services which are similar to already existing uses of telehealth and similarity in utilization procedures. Under Category II requests, the standard of review is much higher. CMS has required extensive supporting evidence for such requests and looks for evidence indicating that the use of a telecommunications system in furnishing telehealth service produces tangible "clinical benefits" to the patient. The rules require both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves diagnosis, treatment or functioning for patients along with support from published peer reviewed articles. "Clinical benefits" under the rule include the following examples:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

Under the recently filed proposed rule for 2015 services, CMS has now added the following reimbursement codes to the existing list under the Category I process to be effective January 1, 2015:

- Psychotherapy services CPT codes 90845, 90846 and 90847.
- Prolonged service office CPT codes 99354 and 99355.
- Annual wellness visit HCPCS codes G0438 and G0439.

The proposed rule was recently finalized and published in the Federal Register on November 13, 2014 as a final rule with a 30-day comment period. No significant changes were made from the proposed allowances and rejections. For the two relevant categories, the following chart exemplifies what was added versus what was rejected:

• Category 1: Services that are similar to current list of telehealth services (e.g., similarities in the telecommunications system used to deliver the proposed service; for example, the use of interactive audio and video equipment).	**Added:** **CPT codes 90845 (Psychoanalysis);** **HCPCS codes G0438, G0439 (annual wellness visit; includes a personalized prevention plan of service (pps), initial visit and subsequent.**
• Category 2: Other Services which can be accurately described by the corresponding code when furnished via telehealth and which use a telecommunications system to deliver the service producing ***demonstrated clinical benefit to the patient.***	Rejected: CPT codes 92250 (fundus photography with interpretation and report); 93010 (electrocardiogram, routine ECG with at least 12 leads; interpretation and report only).

The process actually provides a conservative standard which cautions against duplicative procedure codes and those which relate to a service which cannot be practically or effectively accomplished at a distance. To have an idea of the analysis for proposed but rejected reimbursement codes, the following justification is provided within the proposed rule for dermatology codes as proposed by an association.

For example, CPT codes 92250 (fundus photography with interpretation and report) along with 93010 (electrocardiogram, routine ECG with at least 12 leads; interpretation and report only) and several similar CPT codes were rejected. CMS noted that the services include a technical component (TC) and a professional component (PC) which cannot fit within the process used for inclusion of procedures as covered telehealth services. Once again, an analysis of why these codes have been rejected reveals the conservative bent of the review process. CMS provided the following points in this regard:

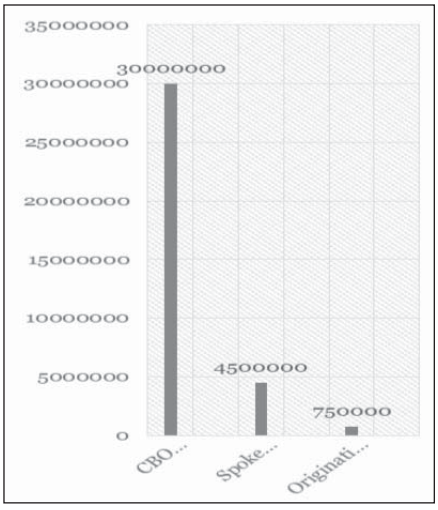
- By definition, the TC portion of these services needs to be furnished in the same location as the patient and thus cannot be furnished via telehealth.
- The PC portion of these services could be (and typically would be) furnished without the patient being present in the same location. (Note: For services that have a TC and a PC, there is sometimes an entirely different code that is used when only the PC portion of the service is being furnished, and other times the same CPT code is used with a -26 modifier to indicate that only the PC is being billed.) For example, the interpretation by a physician of an actual electrocardiogram, or electroencephalogram tracing that has been transmitted electronically, can be furnished without the patient being present in the same location as the physician.
- Given the nature of these services, it is not necessary to consider including the PC of these services for addition to the telehealth list. When these PC services are furnished remotely, they do not meet the definition of Medicare telehealth services under section 1834(m) of the Act. Rather, these remote services are considered physicians' services in the same way as services that are furnished in-person without the use of telecommunications technology; they are paid under the same conditions as in-person physicians' services (with no requirements regarding permissible originating sites), and should be reported in the same way as other physicians' services (that is, without the -GT or -GQ modifiers).

Some of the codes rejected involved psychological counseling. (CPT codes 96101, 96102, 96118 and 96119.) CPT 96101 is described as "Psychological testing (includes psychodiagnostic assessment of emotionality, intellectual abilities, personality and psychopathology), per hour of the psychologist's or physician's time, both face-to-face time with the patient and time interpreting test results and preparing the report."

CMS rejected the request to add such codes to the allowable telehealth category noting that they are not similar to other services on the telehealth list, "as they require close observation of how a patient responds." Additionally, CMS noted that the requestor did not submit evidence supporting the clinical benefit of furnishing these services on a category 2 basis.

The process is frugal; however, it provides a fairly comprehensive method of assessing new telehealth codes. CMS is currently soliciting public requests to add services to the list of Medicare telehealth services for rulemaking for to be effective 2016 which must be received by December 31, 2014. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request.[3]

The CMS approach has been slow and deliberative despite original projections of the Congressional Budget Office (CBO), which had pegged estimated telehealth fee-for-service payments at $30 million per year starting in 2001. The reality has been average yearly payments of under $3 million per year. Comparing the CBO estimates to reality shows the largest degree of error made by the CBO ever in assessing the impact of new legislation (see chart at right).



These results, as well as the slow progression of CMS in allowing further telehealth coverage, have led to a focused re-examination of reimbursement policy. MEDPAC studied the reasons for CBO's dramatic variation and set out reasons for low claim volume in a 2012 report to Congress. They noted that the following factors have led to decreased utilization:

- lack of private payer coverage, thereby discouraging capital investment in telehealth;
- interstate licensure issues;
- non-uniform engineering standards;
- confidentiality and liability concerns;
- would-be distant practitioners may consider providing telehealth services to be a poor investment of their time;
- practitioners with a full workload may decide that telehealth requires more time and effort than they are willing to commit;
- in addition, telehealth disrupts usual practice patterns, and practitioners may not be interested in adjusting their routines to accommodate it;
- the cost of managing the daily operation of video networks;
- the cost of peripheral devices, such as dermatology cameras and digital stethoscopes;
- prior adverse experiences in telehealth, such as scheduling issues, cancelations, and technical difficulties with videoconferencing, also may discourage the adoption of telehealth;
- providers may not want to deal with these administrative difficulties if they already have a sufficient population of local patients.

(See "Report to the Congress: Medicare and the Health Care Delivery System June 2012, Chapter 5, Serving Rural Medicare Beneficiaries (Medicare Payment Advisory Commission).")

Given the focus on cost savings in a world of unsustainable growth for health care expenditures nationwide, many have lobbied for significant expansion of Medicare telehealth coverage. For example, on July 28, 2014 U.S. Senators Thad Cochran (R-Miss.) and Roger Wicker (R-Miss.) issued a press release noting that they had introduced legislation to expand the use of telehealth technology to improve health care for seniors and other patients in underserved areas.

According to the press release, Senate bill #2662 would waive statutory Medicare restrictions on telehealth services in order to encourage greater use of telehealth technologies. The measure would extend telehealth coverage to all critical access and sole-community hospitals regardless of metropolitan status. In some circumstances, the legislation would cover more home-based video services for hospice care, home dialysis and homebound seniors if their residence is conducive to such technology. The bill would also give states the opportunity to modify Medicaid coverage to include telehealth services for women with high-risk pregnancies by creating birthing networks that would allow medical providers to treat conditions such as gestational diabetes and hypertension.[4]

B. Medicaid Reimbursement

Unlike Medicare, which is fully federally funded, the Medicaid program is a Federal-State-Local partnership which may be administered by each state in distinct ways so long as the state complies with the minimum standards set forth within 42 U.S.C. § 1396a. There is no Federal state plan mandate for states to adopt telehealth reimbursement models. However, the Federal government has the authority to grant waivers which provide broad flexibility for state redesign of their programs. (See sections 1915(b) and 1115 of the SSA.) Otherwise, a state must assure that they are following CMS policy with regard to structuring reimbursement under their existing Medicaid plans and modify their plans when significant changes occur (known as SPAs—"State Plan Amendments"). With regard to telemedicine, CMS has provided some guidance which again reflects a cautioned approach to expansion of telemedicine:

- States are not required to submit a (separate) SPA for coverage or reimbursement of telemedicine services, if they decide to reimburse for telemedicine services the same way/amount that they pay for face-to-face services/visits/consultations.
- States must submit a (separate) reimbursement (attachment 4.19-B) SPA if they want to provide reimbursement for telemedicine services or components of telemedicine differently than is currently being reimbursed for face-to-face services.
- States may submit a coverage SPA to better describe the telemedicine services they choose to cover, such as which providers/practitioners are; where it is provided; how it is provided, etc. In this case, and in order to avoid unnecessary SPA submissions, it is recommended that a brief description of the framework of telemedicine be placed in an introductory section of the State Plan and then a reference made to telemedicine coverage in the applicable benefit sections of the State Plan. For example, in the physician section it might say that dermatology services can be delivered via telemedicine provided all state requirements related to telemedicine as described in the state plan are otherwise met.

http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Delivery-Systems/Telemedicine.html.

In New York, the state has historically funded telehealth with respect to home care. In this regard, one of the

first telecommunication systems reimbursed by the state originated from the need to monitor and assure emergency intervention for patients in their homes, known as Personal Emergency Response systems.[5]

Under Social Services Law § 367-u, "Payment for home telehealth services" and Public Health Law § 3614.3-c. "Home telehealth," New York has been funding telehealth using demonstration rates of payment. The law provides reimbursement to home health care agencies and home care providers, among others, "in order to ensure the availability of technology-based patient monitoring, communication and health management." Under the statute, reimbursement for telehealth services may be provided only in connection with Federal Food and Drug Administration-approved and interoperable devices, and must be incorporated as part of the patient's plan of care. Under section 3614.3-c(b). Some of the elements include:

1. The purposes of such services shall be to assist in the effective monitoring and management of patients whose medical, functional and/or environmental needs can be appropriately and cost-effectively met at home through the application of telehealth intervention.
2. Reimbursement…shall be for services to patients with conditions or clinical circumstances associated with the need for frequent monitoring, and/or the need for frequent physician, skilled nursing or acute care services, and where the provision of telehealth services can appropriately reduce the need for on-site or in-office visits or acute or long term care facility admissions. Such conditions and clinical circumstances shall include:
   a. congestive heart failure,
   b. diabetes,
   c. chronic pulmonary obstructive disease,
   d. wound care,
   e. polypharmacy,
   f. mental or behavioral problems limiting self-management, and
   g. technology-dependent care such as continuous oxygen, ventilator care, total parenteral nutrition or enteral feeding.
3. Reimbursement shall reflect telehealth services costs on a monthly basis in order to account for daily variation in the intensity and complexity of patients' telehealth service needs; provided that such demonstration rates shall further reflect the cost of the daily operation and provision of such services, which costs shall include the following functions:
   a. Monitoring of patient vital signs;
   b. Patient education;
   c. Medication management;
   d. Equipment maintenance;
   e. Review of patient trends and/or other changes in patient condition necessitating professional intervention; and
   f. Such other activities as the commissioner may deem necessary and appropriate to this section.

Similar to Federal Medicare policy, the statute requires that DOH "seek the input of representatives from participating providers and other interested parties in the development of such rates or fees and any applicable requirements" for telehealth in home care.

For physician services, the State has developed fee codes which authorize payment in tightly controlled circumstances. This expansion has been implemented through modifications to the State's MMIS payment system for fee-for-service payments to providers.

In September of 2006, DOH announced authorization for physician payments relating to telehealth for the following services:

Physician Billing for Telemedicine

- Payment for telemedicine specialist consultations will be limited to codes **99241-99245 and 99251-99255.** Reimbursement will be the same amount as in-person specialist consultations;
- The **specialist** at the hub site bills the **consult code** with the **-GT modifier;**
- The emergency room or attending inpatient physician at the spoke site bills the applicable evaluation and management code without the -GT modifier, (Note: *if evaluation and management services are already included in the emergency room or inpatient rate then the respective physician cannot bill an evaluation and management code);*
- Payment will be made to **only one physician for the professional component (reading and interpretation)** of diagnostic tests such as radiological procedures and diagnostic assessments;
- If specialist services are **included in the facility rate** where the patient is admitted, **no separate consultant physician payment** is reimbursable;
- The place of service entered on the claim is the location of the patient: "21" for inpatient hospital and "23" for emergency room-hospital;

- If the telemedicine consultation service is owned by a hub hospital and relevant specialist services are already included in the hub facility's rate, then no separate reimbursement is permissible for telemedicine consultations performed by employed specialists.

https://www.health.ny.gov/health_care/medicaid/program/update/2006/sep2006.htm#tele.

The State has issued updates and expanded upon this initial allowance from 2006 through the last issuance on telehealth with the September, 2011 Medicaid Update. By 2011, the State had further restructured its payment standards in this area and additional procedures were authorized in specialized areas:

> **Telepsychiatry**
> Medicaid will reimburse for consultations provided by a psychiatrist through an audio/visual link as well as ongoing therapy provided by a psychiatrist. As with all other telemedicine services, if the originating "spoke" site is an Article 28 facility (hospital outpatient department or diagnostic and treatment center), the "spoke" site is directly responsible for all patient care, and is also required to credential and privilege the psychiatrist who is located at the distant "hub" site (see the information below on credentialing/privileging requirements). In addition to psychiatric consultations, ongoing therapy provided by the psychiatrist at the distant "hub" site may be billed to Medicaid.
>
> **Diabetes Self-Management Training (DSMT) / Asthma Self-Management Training (ASMT)**
> Medicaid will reimburse for CDE/CAE diabetes and asthma self-management training services provided through telemedicine. As with all other telemedicine services, if the distant "spoke" site is an Article 28 facility (hospital outpatient department or diagnostic and treatment center), the "spoke" site is directly responsible for all patient care. The decision whether a medical practitioner needs to be present to assist the patient receiving CDE/CAE services through telemedicine rests with both the practitioner at the "spoke" site as well as the CDE/CAE providing the education, e.g., it may be advantageous for a practitioner (physician, physician assistant, nurse practitioner, or RN) to be physically present with the patient when certain procedures are taught or presented such as insulin injection, use of an insulin pump, appropriate and effective use of a nebulizer, etc.

http://www.health.ny.gov/health_care/medicaid/program/update/2011/2011-09.htm#ln2.

In general, changes to the fee codes used to pay for provider services will adhere to CMS guidelines and standards in the area of telehealth as noted at the beginning of this outline. For more innovative and expansive applications, a waiver or alternative SPAs would be required to ensure that Federal financial participation in payment is made for the underlying services.

Other New York statutes have authorized telehealth reimbursement as part of an overall grant where telehealth may be a component of the demonstration. For example section 2111 of the Public Health Law regarding "Disease management demonstration programs" used the RFP process focusing on "persons with chronic health problems whose care and treatment, because of one or more hospitalizations, multiple disabling conditions requiring residential treatment or other health care requirements, results in high Medicaid expenditures." The services provided by the demonstration program "personal emergency response systems and other monitoring technologies, telehealth services and similar services designed to improve the quality and cost-effectiveness of health care services." This enactment resulted in grants of over $6 million to awardees with telehealth as a component of their project review.

Along these same lines, New York has now embarked on a much larger plan which will use incentive payments along with grants to attempt a fundamental redesign of the delivery system to Medicaid recipients and the uninsured. Public Health Law § 2825, "Capital restructuring financing program," was enacted recently as part of the 2012-15 State Budget and authorized bond financing geared to transforming the health care system in New York to a more "rational patient-centered care system that promotes population health and improved well-being for all New Yorkers." These grants will support a larger effort known as the delivery system reform incentive payment program (DSRIP) which has been approved by the Federal government under a Medicaid waiver. A key component of DSRIP will fund the "development of telehealth infrastructure."

As set forth in the supplementary presentations for this segment, efforts to implement DSRIP will pay special attention to telehealth and telemedicine along with related innovations to efficiently and properly care for hard to serve populations. With the recent enactment of telehealth/telemedicine parity in New York (discussed

below), we may expect further coverage in areas beyond traditional physicians services and home care.

C. Managed Care—Insurance Coverage

As both Medicare and Medicaid move towards a transition of reimbursement of their populations to managed care organizations, decisions relating to telehealth will also shifts to these payors. Unless the agencies administering Medicare and Medicaid provide for specific standards in this area, much of the legislation, regulation and issuances described above may become irrelevant under a managed care environment. The enactment of parity provisions in this area will likely prevent such a result; however, there is still a great degree of ambiguity on how telehealth and telemedicine will be paid across the industry.

As an example, New York has implemented Managed Long Term Care for populations receiving home care within the City of New York and surrounding counties. This implementation essentially transferred responsibility for the payment and coverage of care to managed care plans. Although such plans must abide by a standard addenda and guidance as issued by DOH, the policy is to allow MLTC Plans the flexibility of managing care and setting payment rates through negotiated provider agreements. Telehealth is not mandated as a separate payment stream by the State with regard to its managed care contractors. This issue is highlighted by the transition of the long term care population in NYC to managed care where gaps were identified for patients receiving telehealth as part of their care plans under the prior fee-for-service program. During this transition, DOH issued the following guidance on coverage of telehealth:

> MLTC Policy 13.23: Coverage of Telehealth Services in Managed Long Term Care Plans
> Date of Issuance: September 4, 2013
>
> Consistent with the Medicaid Redesign Initiative #90 to transition recipient's in receipt of community based long term care services (CBLTC) into Managed Long Term Care (MLTC) Plans, the Department implemented the transition of consumers receiving fee–for-service Certified Home Health Agency (CHHA) services for greater than 120 days into partially capitated MLTC plans, Medicaid Advantage Plus (MAP) plans, and PACE plans. Participants of the Long Term Home Health Care Program (LTHHCP) are also being transitioned into MLTC plans.
>
> *It has come to our attention that some of the consumers transitioning are in receipt of telehealth services through their CHHA or LTHHCP. Please be advised that MLTC Plans must honor the 90 day continuity of care requirements as they apply to a recipient who has received a mandatory notice to select a MLTC Plan, and this must include payment for any telehealth services the recipient had been receiving. This 90 day requirement also includes a continuity of the state rate for the affected provider.*
>
> At this time, all plans should directly reimburse the provider for any telehealth services a transitioning recipient is receiving. **The Department will be taking steps to ensure the recipients will continue to have access to telehealth benefits within the managed care environment if appropriate, and is exploring systems issues for inclusion in the benefit package.**
>
> *** This initiative applies to MLTC partial cap plans, Medicaid Advantage Plus, and PACE.

As a purely transitional measure, telehealth was authorized for the long term care populations being transitioned to managed care. As noted by DOH, however, further review would take place as to whether telehealth should be part of a benefit package mandated for such plans. The recent enactment of parity in New York will further support continued coverage within the home care setting in this regard. (See Chapter 550 of the Laws of 2014, signed into law on December 29, 2014—discussed below.)

With regard to managed care and health maintenance organizations in general, there is no single widely-accepted standard for private payers. Some insurance companies value the benefits of telehealth and will reimburse a wide variety of services. Others have yet to develop comprehensive reimbursement policies, and so payment for telehealth may require prior approval.

The area of telehealth coverage in the private sector is still under development. In this regard, a major stakeholder group is the American Telemedicine Association. In a letter dated July 1, 2014 to the National Association of Insurance Commissioners, the ATA provided some suggestions to ensure proper consideration of telehealth and telemedicine in the context of managed care and HMO oversight. The ATA noted that regulators of state insurance policies should "take advantage of health care delivery innovations, including telemedicine, to improve quality, reduce costs, improve timely access to needed care, and improve citizen satisfaction." The ATA is essentially seeking to change the Network Adequacy Model Act to ensure that health plans continue innovations in

delivery of care and incorporate telemedicine services in their provider networks. The specific recommendations of the ATA toward this end are as follows:

> Telemedicine providers can expand access to high quality intensive care or counseling to consumers in rural or underserved areas, enhancing network adequacy. The sentence would be amended to be the following:
>
> The health carrier shall establish and maintain adequate arrangements to ensure reasonable access proximity of participating providers to the business or personal residence of covered persons, such arrangements may also include services provided by telemedicine.
>
> In Subsection B, the access plan description should be revised as follows to include telemedicine-provided services (such as a new (10) and renumbering the current (10) to be (11)):
>
> (10) The health carrier's procedures for accessing telemedicine and making referrals to telemedicine-provided services within and outside its network.
>
> Section 6. Requirements for Health Carriers and Participating Providers. We recommend a specific standard be added for a health carrier regarding a directory of participating providers, as a new Subsection T. We recommend that a standard include health identification of telemedicine providers in the network, the states in which they are licensed, and a basic description of the telemedicine services they offer.

http://www.ncsl.org/research/health/state-coverage-for-telehealth-services.aspx.

The level of interest in attempting to assure continuity of telehealth coverage within the New York State Legislature has been intense over the course of the past year. Just prior to final revisions to this article, one of over 10 bills pending within the legislature was enacted and signed into law.

On December 29, 2014, the Governor signed into law 9129-A, enacted as Chapter 550 requiring limited parity in payor plans for telehealth and telemedicine as well as standards for Medicaid managed care. The new law broadly applies to comprehensive, group, long term care and Article 43 medical plans under sections 3216, 3221, 3229 and 4303 of the Insurance Law which are all expanded to mandate coverage of Telemedicine (limited to Medicare coverage criteria other than originating site requirements) and Telehealth (consistent with home care standards in section 3614.3-c—quoted above). Essentially, these provisions will assure that telemedicine and telehealth are offered privately as otherwise available under Medicare or Medicaid. In addition, section 367-u of the Social Services Law was expanded to assure that telemedicine and telehealth are not excluded from medical assistance payments under New York Medicaid.

All of the new parity provisions refer to new definitions added to section 2 of the Public Health Law. These include new definitions for "Distant Site," "Health Care Provider," "Originating Site," along with Telehealth and Telemedicine. Some flexibility has been included as it pertains to Federal restrictions involving the originating site (where the patient is located). In addition, a new and restrictive but fairly broad definition for health care providers was added under paragraph (p) of section 2, which provides that the term "health care provider" means:

- Physicians under Article 131 of the Education Law
- Physician Assistants under Article 131-B
- Dentists
- Nurses (LPNs, RNs and CPNs)
- Midwives
- Podiatrists
- Optometrists
- Ophthalmologists
- Psychologists
- Social workers
- Speech therapists and audiologists

All "acting within his or her scope of practice, including any lawful practice entity of such health care practitioners."

Flexibility is provided within the definition of "originating site." First, the new definition includes the Federal standard that it is the "a site at which a patient is located at the time health care services are provided." However, the definition provides that "insurers and providers may agree to alternative siting arrangements deemed appropriated by the parties." As noted earlier in this article, Federal Medicare criteria is very restrictive in both requiring that originating sites be institutional settings within rural settings, for the most part.

The new definitions of Telehealth and Telemedicine are also included in a way which is intended to set a standard on par with Federal law:

> (r) Telehealth. The term "telehealth" means delivering health care services by means of information

and communications technologies consisting of telephones, remote patient monitoring devices or other electronic means which facilitate the assessment, diagnosis, consultation, treatment, education, care management and self management of a patient's health care while such patient is at the originating site and the health care provider is at a distant site; ***consistent with applicable federal law and regulations***; unless the term is otherwise defined by law with respect to the provision in which it is used.

(s) Telemedicine. The term "telemedicine" means the delivery of clinical health care services by means of real time two-way electronic audio visual communications, including the application of secure video conferencing or store and forward technology to provide or support healthcare delivery, which facilitate the assessment, diagnosis, consultation, treatment, education, care management and self management of a patient's health care while such patient is at the originating site and the health care provider is at a distant site; ***consistent with applicable federal law and regulations;*** unless the term is otherwise defined by law with respect to the provision in which it is used. (Emphasis supplied.)

The original bill was sponsored by Assemblywoman Addie J. Russell of Jefferson County, an area of the State which has suffered profoundly from a lack medical care. On passage of the bill in the Legislature this past summer, Senator Russell noted:

> The legislation was informed by recommendations of the North Country Health Systems Redesign Commission, of which Assemblywoman Russell has been a member since its formation in late 2013. The Commission was tasked with creating an effective, integrated health care delivery system for preventative, medical, behavioral, and long term care services to all communities throughout the North Country.[6]

The new mandate will be effective for plans and policies which are "issued, renewed, modified, altered or amended" on or after January 1, 2015.

D. Conclusion

As the overall markets seek to move away from the regulatory environment in which reimbursement is driven by an open process of stakeholder involvement and taxpayer concern, it is far too early to tell how telehealth will fare. The experiments in DSRIP, along with creation of large accountable care organizations and integrated delivery systems, will likely encourage telehealth where it may save costs and improve access along with assuring higher quality of care. Meanwhile, in the managed care and insurance environment, one key driver will be the degree to which plans may ultimately adopt preventive measures via telehealth and telemedicine which ultimately reduce risk and overall premiums. With both business models, the markets will likely gravitate to payment methodologies that reduce costs, work amongst health care providers and provide tangible benefits to patients.[7]

Endnotes

1. http://assembly.state.ny.us/leg/?default_fld=&bn=A09129&term=2013&Summary=Y&Actions=Y&Text=Y&Votes=Y.
2. http://www.gpo.gov/fdsys/pkg/FR-2014-07-11/pdf/2014-15948.pdf.
3. 79 FR 67548 (November 13, 2014), "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015." https://www.federalregister.gov/articles/2014/11/13/2014-26183/medicare-program-revisions-to-payment-policies-under-the-physician-fee-schedule-clinical-laboratory.
4. http://www.cochran.senate.gov/public/index.cfm/news-releases?ID=f27d3b6e-c1e7-4ab3-9813-82d5ca73ff65.
5. Section 367-G of the Social Services law has also long funded personal emergency response systems (also known as PERS) which is a form of telehealth monitoring to address urgent and emergency situations in a patient's health when there may be no health care professionals in the home. Under the statute, "personal emergency response services" is defined to mean: (a) the provision and maintenance of electronic communication equipment in the home of an individual which signals a monitoring agency for help when activated by the individual, or after a period of time if a timer mechanism has not been reset, or by any other activating method; and (b) the continuous monitoring of such signals by a trained operator and, in case of receipt of such signal, the immediate notification of such emergency response organizations or persons, if necessary, as the individual has previously specified." The PERS must be part of a plan of care for the recipient "that is based on the comprehensive assessment that such recipient has a medical condition, disability or impairment that warrants use of the service," inter alia.
6. http://assembly.state.ny.us/mem/Addie-J-Russell/story/58902/.
7. On January 16, 2015, the New York State Department of Health introduced proposed legislation to repeal and/or amend the provisions of chapter 550 and add new articles and sections to the public health, insurance, and social service laws. [S. 2405/A. 2552A] [http://open.nysenate.gov/legislation/bill/A2552a-2015]. This suggests the existing statute conflicts and is unsuitable with the manner in which the Department of Health desired to recognize telehealth as a covered service in the State of New York.

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Telemedicine, Telehealth and Cybersecurity

By Robert A. Heverly

Cybersecurity is a significant legal concern in the provision of telehealth and telemedicine,[1] and one that has not yet received substantial direct attention. In contrast, telehealth legal discussions often focus on the privacy implications of breaches of confidentiality that flow from the use of computer and networked technology in health care provision. These are important concerns. The minefield that is medical privacy demands that attorneys involved in telehealth efforts pay close attention to the confidentiality concerns raised by the provision of remote health services. Additional legal concerns revolve around the unauthorized practice of medicine and the implications of reliability of data connections, especially for "live" remote telehealth efforts.

While it is not uncommon for discussions regarding telehealth to include the topic of security or information security, these discussions often veer off of the core cybersecurity issues to the privacy or confidentiality implications of cybersecurity breaches. In this article we will focus more directly on core cybersecurity concerns raised by telehealth practices. Cybersecurity concerns are closely related to the kinds of issues raised more generally—a cybersecurity breach may indeed lead to regulatory and legal liability for the privacy violations that followed the breach, for example—but the focus here will be on the cybersecurity requirements themselves. The goal is not to provide a thorough or complete detailing of cybersecurity requirements relevant to telehealth, but rather to introduce lawyers to cybersecurity's legal requirements in general and to telehealth-related cybersecurity law in particular.

This focus on the technology side of things is a difficult one for many lawyers. As a profession, we tend not to place a premium on understanding technology. From desktop and laptop computers, to tablets and smart phones, to network servers and disk storage, we use these technologies in our practices and in our personal lives, but we don't necessarily have any strong desire to understand what is going on under the hood of the computer-driven technologies we use. When we are giving advice in legal areas that are networking or computer technology enabled, however, we must take the time to understand the basics of how the technology functions, how the various technologies fit together, and, perhaps most importantly, to learn where those technologies may increase the risks of undertaking a particular endeavor.

To get to this point, we need not speak in terms of specific technologies, such as domain name servers, application protocol interfaces, or any other particular device or software, nor do we as lawyers need to learn to "code," or write software ourselves. We will instead speak in terms of actors, their tools, and the implications of their interactions. We will begin by discussing network, computer, and individual threats in the telehealth environment, paying special attention to both the complexity of computerized and networked systems, as well as the true weakest link amidst the technology: people. We will then turn to the overarching regulation of cybersecurity, a discussion that is relatively brief given the lack of any true regulation of cybersecurity as such, followed by a review of telehealth-related cybersecurity regulation. We will end with a discussion of questions that lawyers and their clients can ask with a view to mitigating the cybersecurity risks raised the telehealth field.

I. Telehealth, Technology, People and Cybersecurity

There are a variety of reasons why computer-based network technologies are particularly difficult to secure. Among these are the basic complexities of computer and networked systems, the need for a variety of systems to work together—with additional layers of complexity added by the differing operating systems and types of software that are available to both users and vendors—and users' desires to use their own devices to interact with such systems. These elements conspire together to create complexities that are difficult not only to mitigate but even to fully identify.[2]

Computer and network systems are complex by their very nature. Software code is lengthy, written by individuals or groups of individuals, and while it is often rigorously tested, testing cannot find all possible problems, even within closed systems. Windows 7, for example, has nearly 40 million lines of software code. Finding all of the "bugs" or potential faults in such software is nearly impossible, meaning that there will always be faults in computers and networks, even when they are well designed.

Adding to the complexity of the basic building blocks of computer systems are the additional levels of complexity that flow from the need to have different systems work together (known as interoperability). Not only must one Windows 7 system function alongside and compatibly with another Windows 7 system, but it may need to interact with an Apple iOS system or a Linux system. Add the applications that are needed—in this case to allow the practice of telehealth—and we may have the same program working on different operating systems, different programs working on the same operating systems, or even different programs operating on different operating systems. As software programs are updated, new versions are added, and telehealth systems may have to accommodate varying versions of critical programs running across a host of operating systems.

But we are not yet done with the complexity. Control over the systems involved in practicing telehealth is not necessarily in the hands of one person or entity. Users may want to access telehealth information with their computers, their smart phones, or their tablets. Not having control over end-user devices introduces even more complexity into the system, especially in terms of information security.

And this last point raises another to which we will return: all cybersecurity starts with individuals. People may be uninformed, misunderstand, or lazy; they can be fooled, misdirected, and misled. In addition, where strong security measures are put in place, users may attempt to bypass them if they think it is necessary to achieve whatever goals they are trying to achieve. An end-user may use outdated software, or try methods to avoid technological requirements in order to gain the advantages of being able to be served by telehealth programs. Individuals, whether end-users or employees, vendors or technicians, are often the weakest link in any cybersecurity effort, and one to which cybersecurity measures must be addressed. Cybersecurity is not just about technology, it is also—and importantly—about people.

Telehealth incorporates all of these complexities, some at their most extreme. With the need to interact with patients and other non-employed users, various elements of cybersecurity are outside the direct control of the firm engaged in the telehealth effort. A variety of devices, with varying types and versions of operating systems and programs installed on them, operated by users of varying technological sophistication and subject to social engineering playing on their fears and ignorance of technology and information security, must interact with the telehealth systems. This complexity and variety makes good cybersecurity harder but even more important in the telehealth arena.

II. Cybersecurity and Telehealth: The Legal Landscape

Cybersecurity is:

> [P]revention of damage to, protection of, and restoration of computers, electronic communications systems, electronic communication services, wire communication, and electronic communication, including information contained therein, to ensure its availability, integrity, authentication, confidentiality, and non-repudiation.[3]

One of the biggest difficulties in dealing with cybersecurity law is that it does not truly exist, at least as we understand the concept of a distinct, overarching area of the law. Instead, efforts are under way to formalize expectations regarding cybersecurity in what is otherwise an unsatisfying patchwork quilt of regulatory and statutory provisions. These requirements, from the federal Computer Fraud and Abuse Act[4] to the Electronic Communications Privacy Act,[5] to New York's own statutes relating to computer crimes,[6] provide only sketchy coverages of the kinds of activities that might initially come to mind when considering the term cybersecurity. When we consider the regulation of medical devices by the Food and Drug Administration[7] and the Federal Communications Commission's encouragement of good cybersecurity practices,[8] we simply add more patches to the quilt.

Because existing federal and state statutes are so often directed to the wrongdoer—such as a hacker or rogue employee—or are aimed at preventing or controlling government surveillance and intrusions, many organizations have difficulty finding good guidance in them. Where the statutory structure does not provide clearly applicable rules, the law may step in to fill those gaps using contract law, tort law and common-law privacy law. Each of these areas may have some relevance to telehealth efforts, but the analysis is complicated by the existence of health provider specific statutes and regulations relating to information security. Before looking at those specific requirements, however, we will review the more general cybersecurity law environment at the national the level.

In February 2013, President Obama issued an Executive Order entitled, "Improving Critical Infrastructure Cybersecurity"[9] and a Presidential Policy Directive entitled, "Critical Infrastructure Security and Resilience."[10] These two documents were intended to push the conversation forward in relation to securing critical infrastructure, much of which is in the control of private parties rather than the federal government.

The documents, however, invoked voluntary and industry efforts to develop stronger cybersecurity, choosing to push private actors rather than enact regulatory mandates on the private sector. This choice reflects a continuing theme in this area: the use of voluntary standards, as opposed to mandatory rules, for achieving cybersecurity goals. To some degree this is an admission of the importance of the complexity and uniqueness of today's computer and networking systems—one size does not fit all—but to another degree it is a desire on the part of government to push the important decision-making down to the system's creators and users while concomitantly pushing the responsibility and potential liability down to that level, as well. While voluntary generalist cybersecurity standards may allow significant room for system designers to implement standards that fit well to particular systems, they also increase the potential for liability should those systems not achieve the outcomes desired.[11]

The most concrete and direct result of the President's actions was the development of the National Institute for Standards and Technology's February 2014 "Framework for Improving Critical Infrastructure Cybersecurity."[12] The Framework sets out a methodology intended to allow systems considered part of the nation's critical infrastructure to consider cybersecurity issues. Establishing a common taxonomy, the Framework provides a process for organizations to:

1) Describe their current cybersecurity posture;
2) Describe their target state for cybersecurity;
3) Identify and prioritize opportunities for improvement within the context of a continuous and repeatable process;
4) Assess progress toward the target state; and,
5) Communicate among internal and external stakeholders about cybersecurity risk.[13]

The Framework provides a method of reaching the goal of increased cybersecurity, but does not dictate the path that any particular organization must take. Outside of domains that themselves include stricter cybersecurity requirements—domains such as the health care and financial industries[14]—these general, path-led processes are the primary method of advancing cybersecurity. In December 2014, Congress—somewhat unexpectedly—passed a number of cybersecurity-related measures.[15] Relevant here, the Cybersecurity Enhancement Act of 2014[16] formalized and codified NIST's—and the Framework's—role in cybersecurity,[17] emphasizing as it did so that the framework was voluntary and that NIST was not to develop enforceable requirements as to cybersecurity.[18]

For telehealth, however, the legal requirements are more direct, though they still follow the trend of laying out standards and development processes instead of demanding implementation of particular technologies or specific security methods. Two areas of federal regulation are particularly relevant in the telehealth arena: regulations under HIPAA and the HITECH Act. New York, for its part, has undertaken inquiries regarding cybersecurity focused on the banking/financial[19] and insurance[20] markets.

Specifically relevant here are the HIPAA Privacy Rule[21] and the HIPAA Security Rule.[22] The HITECH Act's requirements are also relevant, but more so to the aftermath of a breach than to the cybersecurity efforts that go into preventing one. For its part, the HITECH Act and its attendant regulations require notifications when there is a breach of unsecured Protected Health Information (PHI) and provide for fines where breaches result in the release of unsecured PHI. While this structure, like the Privacy Rule below, is relevant to the cybersecurity inquiry, cybersecurity under the Security Rule is generally proactive, while the HITECH Act's regulations are reactive: when a breach has occurred, there are steps covered entities must take and fines they may be subject to. While cybersecurity breaches that lead to the disclosure of protected information under HIPAA may lead to significant sanctions under the HITECH Act's requirements, and additional procedures must be in place under the breach rules, the breach notification process itself will not help organizations develop programs to avoid breaches. That process is left, ostensibly, to the HIPAA Security Rule. For that reason, we leave it aside for a fuller discussion of the core cybersecurity elements of the Security Rule itself. This does not mean breach disclosures are not important.

We will also not dwell here on the Privacy Rule, as it is probably the best known of the rules relevant to telehealth practices. It sets national standards for the use and disclosure of protected health information (PHI) by covered entities. The Privacy Rule covers all PHI, whether it is in an electronic format or not. The Privacy Rule is relevant to cybersecurity questions through the Rule's safeguard requirement, which requires that a "covered entity must have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information."[23] Because covered entities were required to comply with the Privacy Rule two years before they were required to comply with the Security Rule, the safeguard requirement initially did some of the heavy lifting in relation to health information cybersecurity. Now that the Security Rule is in place, however, and has been for between nine and ten years (depending on the size of the covered entity), cybersecurity obligations in the health field are generally seen as arising out of the Security Rule.

The Security Rule itself sets standards, processes, and documentation requirements that covered entities must follow to ensure the security of electronic PHI (known as ePHI).[24] These standards are divided into five categories: Administrative Safeguards; Physical Safeguards; Technical Safeguards; Organizational Requirements; and, Policies and Procedures and Documentation Requirements.[25] The regulations provide for implementation specifications in each of these categories, with the implementation specifications being either required or addressable. Required specifications are exactly what you would expect: covered entities are required to meet the standards set out in required implementation specifications. Addressable specifications are slightly less strict, though they are still not optional: covered entities must meet the standards unless it is not reasonable and appropriate for the entity's environment, in which case the entity must document why it is not reasonable and, where reasonable and appropriate, adopt alternative measures designed to achieve the same objectives.[26]

The Department of Health and Human Services' guidance on the Security Rule notes: "In order to comply with the Security Rule, all covered entities should use the same basic approach."[27] According to the guidance, covered entities should: Assess current security, risks, and gaps; develop an implementation plan; implement solutions; document decisions; and, reassess periodically. The Department's guidance further notes that the standards do not express a preference for any particular technology (they are technology neutral), and that they are designed to be flexible enough to be scaled to various sizes and types of covered entities.[28]

From the previous two paragraphs it should be clear why this article cannot provide a complete accounting of cybersecurity's role in telehealth. The requirements are at once both flexible and extensive. They place a premium on process, documentation, and continuous reassessment. Cybersecurity, whether under the Security Rule or not, is not a static, fix it and leave it, endeavor. The rules encourage a process, not a one-time decision, and they cover myriad factual scenarios for actions taken across a host of covered entities. To analyze all possible applications of the rules here is not possible, and such an effort is not intended. Rather, the examples used will hopefully impress upon practitioners the need for thorough understanding and review of the rule and its application in each and every telehealth initiative with which the practitioner is involved.

The Security Rule's Administrative Safeguards cover personnel and related organizational decisions regarding security assignments and priorities.[29] Physical safeguards relate to the machines and media in which PHI is held. Controlling physical access to servers, backups (including those stored off-site) and transmission facilities are all relevant to the development of suitable physical safeguards under the rule.[30] Technical safeguards are focused on the methods of authentication, encryption and protection of data while stored or transmitted.[31] Organizational requirements place a premium on ensuring that business relationships are structured so as to continue to protect PHI.[32]

Any lawyer working on telehealth initiatives must become familiar with the Security Rule, its processes, and its documentation requirements. Telehealth raises concerns in each of the Security Rule's main categories. Administrative safeguards must be in place both for "live" remote telemedicine initiatives and for asynchronous medical practices, such as diagnosis and consultation. Administrative safeguards must be designed to protect PHI from unauthorized disclosure regardless of who is appropriately involved in the process. Safeguards must address physical access to computer systems and appropriate use of technological protection measures such as passwords, encryption and use of particular kinds of networks in both real time and on-demand access transactions to meet physical and technical safeguard requirements. Contractual and related arrangements should be formalized and include appropriate assurances of confidentiality and protection of patient information. All in all, the many and varied moving parts of a telehealth initiative must be identified, analyzed for potential weaknesses related to the systems and individuals involved, and the risks associated with the effort mitigated in compliance with the rules and standards relevant to each of those parts. It is to those risks that we now turn.

III. Planning for and Mitigating the Risks

Developing a regime for protecting patients and their health-related information and for identifying and mitigating risks of liability under regulatory and legal regimes should be the goals of any program of telehealth cybersecurity. Different stages of development and implementation will likely require different kinds of programs to work toward information security. One process model includes the following four steps: monitoring; analysis; warning; and, response.[33] This taxonomy anticipates an existing system, one that can already be monitored. Where a new system or initiative is proposed, the steps must include mapping out the confines of the initiative and considering how each of the Security Rule's requirements apply.

The following questions may help lawyers and their clients think through telehealth initiatives from the planning stages up through the operational phases.

1. What steps must be completed to develop the initiative, from conception, to planning, to development, to testing, to implementation, and to ongoing operation?

Different kinds of projects will involve different steps. Knowing exactly how the project will proceed from conception through to completion and operation will provide a basis for gauging the application of the Security Rule to the situation at hand. By developing a bird's eye view of the project, those responsible can gain a better understanding of how the pieces fit together. Developing good documentation from the start of the project will allow even later additions to the team or the leadership to have a better chance at understanding how changes in technology and personnel might alter the confidentiality of protected information.

2. Who will be involved at each step of the project, and in what roles?

Will inside stakeholders be involved in initially conceiving the project, at which time it will be turned over to an outside consultant for development? What information will be used during conception? Will mock or real patient information be used? Will the system be tested using real patients or stand-ins? If the latter, how will the situation differ once real patients (and perhaps physicians) are involved in the system? What additional uncertainties will live use

of the system raise from the individual and technological side?

Monitoring who is involved, who has left the project and who has joined it, will assist in meeting the Security Rule's Administrative Safeguards requirement, as well as assist with the Rule's organizational requirements. In addition, some people involved in a project might not have valid reasons for accessing protected information, and it may be necessary to use mock records and data to construct the system to avoid inappropriate disclosures.

3. Who will be involved in considering the confidentiality of PHI at each step from development through continued operation?

Telehealth projects should have someone involved in them who is responsible for thinking about cybersecurity and PHI as the project progresses. In this capacity, are lawyers involved in the project throughout its existence, or is responsibility for confidentiality and privacy left with technologists or medical professionals? At what point is responsibility for confidentiality handed over from person to person as project development continues? Developing a well-considered rationale for who is responsible for the confidentiality of protected health information will help telehealth projects meet the Administrative Safeguard's requirements, and will also assist in keeping the core element of the HIPAA Security Rule—privacy and confidentiality of protected health information—in play throughout the project.

4. Who will be responsible for ensuring the integrity and continued functioning of systems throughout their use? Who will implement software patches and hardware upgrades and oversee user and information technology employee and consultant changes?

In their paper, *After the Breach: Cybersecurity Liability Risk*,[34] Judith Germano and Zachary Goldman describe the following scenario:

> On May 7, 2014, agreement was reached on the largest fine to date to settle allegations of patient privacy violations—$4.8 million—between New York Presbyterian Hospital and Columbia University Medical Center and the Office for Civil Rights (OCR) at the Department of Health and Human Services (HHS). The case involved HIPAA violations pertaining to records of 6,800 patients (including patients' status, vital signs, medication and lab test results) that inadvertently were exposed to the Internet in 2010, when a Columbia University physician who had developed applications for the hospital and the university attempted to shut down a personally owned computer server on the network. The OCR reported that, due to the lack of technical safeguards, this deactivation resulted in ePHI (electronic protected health information) being accessible on Internet search engines. The breach was revealed when an individual discovered, via an Internet search, a deceased partner's hospital medical records[.][35]

Telehealth systems involve many parts, often under the control of disparate individuals. In the Presbyterian Hospital case, a physician's personal computer was part of the system, and the removal of that system component exposed PHI. Anyone looking holistically at the system in question, with access to and an understanding of the complete project, should have seen the potential for problems in including a personal server in the system. If not, had procedures been in place for making hardware changes to the system that required notice of such changes, testing could have identified the problem that eventually occurred before sensitive and protected information had been exposed on the Internet. It is these kinds of procedures that the Security Rule encourages and, to a large extent, requires.

5. What plans have been made to identify vulnerabilities in the systems and to address unexpected events either within or outside of the control of the project's developers and operators?

In 2014 a serious vulnerability in a basic and widely used encryption protocol was exposed through security research. Dubbed the "heartbleed" vulnerability, the software bug potentially allowed access to encryption and other secure data on a server that was communicating with another system through an encrypted connection. One security researcher said the following when discussing the "catastrophic bug": "On a scale of 1-10, this is an 11."[36] This development was completely out of the hands of nearly all systems developers and operators. They most likely would not have identified it or found it on their own, and they were well within industry practices in using the software in question. If telehealth systems were using the affected software on the day the vulnerability was announced it is unlikely they could have been found in violation of the Security Rule, even if the vulnerability had been used prior to that date, and unknown to them, to breach confidential systems.

Liability would arise, however, if telehealth systems did not take the steps already available on the day the vulnerability was publicized to secure their systems. Not taking these steps would likely violate the Security Rule, and a breach that followed such a lax response would almost

certainly lead to fines from the Department of Health and Human Services.

This means that having a plan for regularly testing systems, even systems that have been secure for extended periods, is an essential part of any telehealth initiative. Technology changes rapidly. A system secure one day may be rendered insecure by a new bug, by new methods or technologies of hacking, or by the introduction of existing hacking methods introduced by a worker, participant, or contractor. Monitoring, testing, and evaluating systems must be built into the telehealth process and must be an ongoing and regular part of any such initiative.

In order to plan for and thus to mitigate risks in telehealth projects, the changing nature of the technology, its implementation and use, and the environment in which it is used must be considered. Technology experts must be consulted and utilized, and their involvement must be pursuant to agreements with restrictions sufficient to protect PHI throughout the system. Where changes in personnel, equipment, and methodologies occur, the systems must be reevaluated, and ongoing evaluation must take place even where telehealth systems are relatively static.

6. How are difficulties that arise in the day-to-day operation of the telehealth initiative going to be addressed, especially where they relate to program access and benefits?

What happens if a patient who wishes to gain the benefits of a telehealth initiative does not have the necessary technology available to participate securely in the program? Are exceptions made? Microsoft has phased out support, including virus and bug fixes, for Windows XP as of April 8, 2014. If a patient using Windows XP attempts to connect to a live diagnostic session conducted via a telehealth project, will the attempt be rejected because of the patient's outdated technology? What about patients who use old versions of web browsers, or have devices using very old versions of the iOS or Android operating systems? Should telehealth programs be concerned if patients are connecting to telehealth resources over open WiFi, such as that available in coffee shops and airports?

Each of these questions raises important concerns that require a balance between confidentiality and cybersecurity and patient access. The rules allow this balance to be struck, but it must be done purposefully and with a thorough vetting of the risks and benefits. If patients cannot reasonably access the resource using other technology, whether because of their remote location or because of their financial situation, then access may be appropriate. If that access opens the system up to greater threats because of the patient's insecure technology, then this must be taken into account and some patients may have to be denied participation in some telehealth initiatives on this basis. Hard and fast rules cannot be stated without the context and facts of the particular issue being known. Once they are known, however, an articulated and documented reason for making one choice or another is required by the Security Rule.

IV. Conclusion

Building a telehealth initiative is not the same as building a physical building. You cannot simply build it and then use it, ignoring changes in technological and security developments. Lawyers must ensure that those involved in telehealth projects are aware of the need to follow current developments, implement technological best practices, and assess the implications of changes in any of the many and varied parts of telehealth systems, from the hardware, to the software, to the network protocols, to the professionals and patients for whose benefit the systems are being developed. Telehealth systems do not need to be foolproof or unhackable. Unhackable or uncompromisable systems do not exist. Consider recent news reports of breaches outside of the health field, such as the Target Point of Sale breach,[37] in which cash registers were hacked so that customer financial information could be stolen, or the Sony breach,[38] in which details of accounts and media files—including unreleased films—were copied and distributed. In the Target case, a subcontractor's errors introduced the vulnerability into the system, but it was not discovered even though evidence pointing to its existence was noted by those responsible for the systems. In the Sony case, passwords were kept in unencrypted text files in folders with names such as "passwords." This occurred because technology administrators were left to their own devices and the departments responsible for the protection of Sony's assets were not sufficiently invested or involved in securing the technological operations of the corporation. In telehealth projects, walled gardens such as these are a path to fines from the Department of Health and Human Service's Office of Civil Rights under the Security or Privacy Rule (or both).

Even though the computer and network systems necessary for telehealth initiatives to benefit patients and society cannot be perfectly secure or even perfectly predictable in their future operation, we will still develop and use them as the benefits of their use are significant. But these systems must be built, operated and documented with the goal of protecting patient information, and must exist in accordance with HHS's Security Rule (and related requirements). The systems must be kept updated and secured according to industry practices designed to protect health information to the degree possible given the project in question. The lawyer's job is to help the project along the way and to push for safer, more secure, more reliable systems that meet or exceed federal requirements for protecting patient confidentiality.

Endnotes

1. I will use the term telehealth in this article, as it is the broader of the two terms and arguably includes the term telemedicine within its definition. *See What is telehealth? How is telehealth different from telemedicine?* HealthIT.gov, http://www.healthit.gov/providers-professionals/faqs/what-telehealth-how-telehealth-different-telemedicine, last visited, November 28, 2014. The World Health Organization treats the terms as synonymous. World Health Organization, *Telemedicine: Opportunities and developments in Member States*, p. 9 (2009) ("Some distinguish telemedicine from telehealth with the former restricted to service delivery by physicians only, and the latter signifying services provided by health professionals in general, including nurses, pharmacists, and others. However, for the purpose of this report, telemedicine and telehealth are synonymous and used interchangeably.").
2. *See* Frederick P. Brooks, Jr., THE MYTHICAL MAN-MONTH: ESSAYS ON SOFTWARE ENGINEERING, Anniversary Edition (2nd Edition) (Addison-Wesley Professional, 1995).
3. National Security Presidential Directive 54/Homeland Security Presidential Directive 23, p. 3 (Jan. 9, 2008) (Pres. George W. Bush).
4. 18 U.S.C. § 1030.
5. 18 U.S.C. §§ 2510 *et seq.* §§ 2701 *et seq.* and §§ 3121 *et seq.*
6. New York Penal Code Article 156 (§§ 156 *et seq.*).
7. Food and Drug Administration, *Guidance for Industry: Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software* (2005).
8. Federal Communications Commission, *Cyber Security Planning Guide* (2012).
9. Executive Order, February 12, 2013.
10. Presidential Policy Directive, PPD-21, February 12, 2013.
11. *See* Ross Anderson, *Why Information Security is Hard: An Economic Perspective*, 17th Annual Computer Security Applications Conference (2001) (http://www.acsac.org/2001/papers/110.pdf).
12. NIST, *Framework for Improving Critical Infrastructure Cybersecurity*, Version 1 (February 12, 2014).
13. *Id.* at 4.
14. *See* Greg Stults, *An Overview of Sarbanes-Oxley for the Information Security Professional* (Sans Institute INFOSEC Reading Room, 2004) (http://www.sans.org/reading-room/whitepapers/legal/overview-sarbanes-oxley-information-security-professional-1426).
15. The Cybersecurity Workforce Assessment Act, H.R. 2952, Pub. L. 113-246 (2014); The Cybersecurity Enhancement Act of 2014, S. 1353, Pub. L. 113-274 (2014); The National Cybersecurity Protection Act of 2014, S. 2519, Pub. L. 113-282 (2014); and, The Federal Information Security Modernization Act of 2014, S. 2521, Pub. L. 113-283 (2014). All were signed into law by the President on December 18, 2014. *See* The White House, Office of Communications, "Statement by the Press Secretary [on bills signed into law]," 2014 WL 7183744 (White House, 2014) (http://www.whitehouse.gov/the-press-office/2014/12/18/statement-press-secretary-hr-669-hr-1067-hr-1204-hr-1206-hr-1281-hr-1378).
16. S. 1353 (2014), Pub. L. 113-274 (2014).
17. S. 1353, § 101(b), amending 15 U.S.C. § 272.
18. S. 1353, § 101(b), 15 U.S.C. §272(e)(1): "In general, [i]n carrying out the activities under subsection (c)(15), the [NIST] Director (B) shall not prescribe or otherwise require—

    (i) the use of specific solutions;

    (ii) the use of specific information or communications technology products or services; or

    (iii) that information or communications technology products or services be designed, developed, or manufactured in a particular manner."

    The Senate Report on the bill also reflects this focus on a voluntary process: "The bill would require NIST to, on an ongoing basis, facilitate and support the development of a voluntary, industry-led set of standards, guidelines, best practices, methodologies, procedures, and processes to reduce cyber risks to critical infrastructure." Report of the Committee on Commerce, Science, and Transportation on S. 1353, Report 113-270, at 10 (Nov. 12, 2014).
19. New York State Department of Financial Services, *Report on Cyber Security in the Banking Sector* (May 2014).
20. *Governor Cuomo Launches Inquiry Into Cyber Threats at Largest Insurance Companies*, May 28, 2013 (http://www.governor.ny.gov/news/governor-cuomo-launches-inquiry-cyber-threats-largest-insurance-companies).
21. 45 CFR Part 160 and Subparts A and E of 45 CFR Part 164.
22. 45 CFR Part 160 and Subparts A and C of 45 CFR Part 164.
23. 45 CFR § 164.530(c).
24. The distinction between PHI and ePHI is that simple: PHI is protected health information regardless of form; ePHI is PHI kept in electronic form. For our purposes here we will assume the PHI we are discussing is in electronic format and will refer to it simply as PHI.
25. 45 CFR §§ 164.308-164.316.
26. 45 CFR § 164.306.
27. *See* Department of Health and Human Services, *HIPAA Security Series, Number 1: Security 101 for Covered Entities*, p. 7 (2007). Additional guidance in each of the Security Rule's areas are available from HHS at: http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html.
28. *Id.*
29. 45 CFR § 164.308.
30. 45 CFR § 164.310.
31. 45 CFR § 164.312.
32. 45 CFR § 164.314.
33. Henry Norwood and Sandra Catwell (eds), CYBERSECURITY, CYBERANALYSIS AND WARNING, p. 3 (Nova Science Publishers, 2009).
34. Judith Germano and Zachary Goldman, *After the Breach: Cybersecurity Liability Risk* (NYU Law School Center on Law and Security, 2014).
35. *Id.* at 3.
36. Rusty Foster, *The Internet's Telltale Heartbleed*, The New Yorker (April 9, 2014) (http://www.newyorker.com/tech/elements/the-internets-telltale-heartbleed).
37. Teri Radichel, *Case Study: Critical Controls that Could Have Prevented Target Breach*, Sans Institute INFOSEC Reading Room (August 5, 2014) (http://www.sans.org/reading-room/whitepapers/casestudies/case-study-critical-controls-prevented-target-breach_35412).
38. Andrea Peterson, *Hackers gave Sony Pictures Entertainment a major headache Thanksgiving week*, Washington Post, December 1, 2014 (http://www.washingtonpost.com/blogs/the-switch/wp/2014/12/01/hackers-gave-sony-pictures-entertainment-a-major-headache-thanksgiving-week/).

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Telepsychiatry: What Every Health Care Attorney Needs to Know

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I. Introduction

Just three years after Alexander Graham Bell's invention of the telephone, a report of a physician's use of the instrument to diagnose a child's cough and to reassure the child's grandmother appeared in 1879 in the *Lancet*.[1] Since then, the telephone and other electronic methods have become the major means of rapid access and communication between patients and clinicians. The number of telemedicine consultations has increased substantially over the past ten years, and in primary practice today an increasing proportion of patient contact time is via technology. In the mental health field, telecommunication systems have been central to the development of crisis hot lines, consultations, teaching and treatment programs for remote areas and underserved populations. More recently, telemedicine and telepsychiatry via telephone, video teleconferencing and even electronic mail have been used in the direct delivery of care in a variety of settings and across the diagnostic spectrum. For purposes of this article, the term "telemedicine" refers to the delivery of health care services by means of real time two-way electronic audio-visual communications.[2] "Telepsychiatry" is the application of telemedicine to the practice of psychiatry and mental health care.

The growth of this area of medical and mental health service delivery has been both exciting and fraught with challenge. Telepsychiatry provides access to care for those individuals who live far from direct on-site care, creates the possibility for specialist consultation where it otherwise would not be available, and allows for the delivery of mental health care in a consistent and timely manner irrespective of travel, temporary translocations or logistics. It provides a flexibility that traditional office visits cannot accommodate. In psychiatry and mental health treatment, where the therapeutic alliance between clinician and patient is critical to the treatment and its disruption clinically costly, this benefit may be accentuated. In 1957 Lewis reported on the use of closed circuit television in the care of the mentally ill, but it was not until low cost videoconferencing became widely available that the means to recreate a virtual office visit became feasible.[3] Studies published in the scientific literature have reported no major difference in the quality of care delivered between in-office and virtual in-office visits.[4] At the same time there has been increasing acceptance among the public of the use of telephonic means for everyday communication and an improvement in reimbursement for remote visits. As a result there has been an explosive growth in the virtual delivery of medical care, including mental health care. As the technology and its applications evolve, there are concomitant questions that arise regarding the therapeutic, ethical, legal, and even logistical elements of telemedicine. In spite of these advances, the "laying on of hands" has historically been perceived as a critical component of care with the departure from standard care often initially perceived by both patient and therapist as an experiment in treatment.[5] In this article we will present some of the issues that have arisen in the practice of telepsychiatry, their real life application and possible solutions to consider.

II. Why Practice Telepsychiatry?

In psychiatry and mental health telemedicine methods have been applied to essentially all diagnostic categories including mood, anxiety and cognitive disorders, substance abuse, and post-traumatic stress disorder. As in other areas of medicine and health care, telepsychiatry was originally used for consultative and diagnostic purposes with a steady expansion into ongoing maintenance care. Through telepsychiatry, psychiatric and mental health services that can be and are delivered remotely include mental health assessment, consultations, treatment, education, and monitoring. These clinical encounters occur in a wide variety of settings as do traditional face-to-face visits and may include outpatient clinics, emergency room settings, schools, nursing facilities, prisons and homes. The ultimate goal of telepsychiatry is to deliver quality mental health care while reducing disparities in access to treatment in an effective and efficient manner.

Traditionally most patients would prefer traditional office visits, but many are unable to come to an outpatient office on a regular basis because of distance and their physical condition, as well as other impediments to accessing health care. For individuals who reside in rural communities and individuals with disabilities or mobility problems the telephonic voice and video methods are frequently the sole avenue for psychological counseling and psychiatric care. Therefore, it is a major therapeutic tool in working with such patients. Telepsychiatry methods can reduce the isolation patients and/or clients often feel, help them maintain a sense of connectedness to others, and decrease their fears of abandonment and being "forgotten by society."[6] As location is no longer limiting, there have been recent reports of group therapy for specific conditions via telepsychiatry with members "attending" from all over to promote similar benefits.[7] Follow-up contact by telephone

or other or other internet-based technologies can improve compliance and lessen the utilization of medical services by providing consistent and on-ongoing care.

While in most cases telemedicine methods solve practical problems such as site of service or medical manpower availability, in mental health there have been several reports on the application of telepsychiatry for unique psychotherapeutic issues such as stigma and the patients' fear of intimacy.[8] This modality offers a means of treatment for individuals, such as those suffering from social phobia, who may find it too anxiety provoking to express themselves in person in the office setting but who are able to interact with the psychotherapist via the telephone or related technology. Telepsychiatry can also offer treatment for individuals who feel a sense of shame associated with being ill and may avoid in-person contact with others because of this fear. For example, a young woman was so traumatized by her chemotherapy-induced alopecia that she took a leave of absence from work and effectively became housebound, which exacerbated the intensity of her depression and threatened her compliance with medical care.[9] Psychiatric intervention was initially conducted via the telephone, which allowed her to receive the psychotherapeutic treatment she required while responding to her emotional needs. For others, the stigma associated with mental illness prevents individuals from seeking treatment and on-going compliance is adversely affected by their fear of "being found out." Telepsychiatry can provide a means of delivering care with an additional layer of privacy.

Another feature of telephonic video methods or other technologies is the equalization of the power between patient and therapist. Traditionally the patient comes to the professional's office. However, in home-based telephonic or videoconference sessions both the patient and the practitioner remain in their own space. This relative empowerment may be particularly therapeutic for those struggling with dependency. Moreover, this shift to a more peer-like relationship may be particularly beneficial in crisis intervention where therapeutic suggestion and advice can be pivotal elements in the treatment.[10]

Telepsychiatry also provides the opportunity to support clients in between or in lieu of in-office visits. During the course of treatment individuals may experience a crisis and require a "here and now" session with a professional, yet the client or the professional's schedule and location may not allow them to meet in office. Telepsychiatry can be used to offer clients therapeutic services in the comfort of their own home during a time of need. Other uses of psychotherapy by telephone or other electronic means include clinical situations in which either therapist or patient was absent for prolonged periods of time or, in some cases, made a permanent move to another city. In those situations, the use of telepsychiatry can be convenient for maintaining a therapeutic relationship from a distance. Telephone or internet-based sessions make it possible for the practitioner to continue to provide oft-times much needed support electronically, at least during the period of transition to a new treatment provider in the new location.[11]

Last, but certainly not least, telepsychiatry can offer quality mental health care treatment in a cost-effective manner. Telemedicine methods allow for medical and mental health consultations to occur in a timely manner on an as needed basis, which increases access to specialist care in a financially feasible manner. It also reduces travel costs and may save waiting time. Government insurance programs such as Medicare and Medicaid recognize some forms of telemedicine services, but coverage is not uniform across insurance carriers and its application is complicated by the regulations and policies of the individual carrier.[12]

Despite all of these benefits, there are several drawbacks to the use of telepsychiatry due to the absence of face-to-face contact. Without having the ability to meet a client in the office there can be a serious limitation on the assessment, diagnosis or treatment of a mental health issue. For example, telephone calls and e-mail do not allow the treating professional to view the non-verbal and visual cues of a client such as facial expressions or body language. Even when video is added to the technology there are still limitations on the information available and perhaps even elements of the physical exam such as the feel of a patient's skin that cannot be ascertained remotely. For all health care professionals, evaluating the client's appearance as well as the functional assessments of self-care, such as dressing appropriately, showering, and grooming are often essential to completing a full assessment. Though much of this information can be elicited by history, there are elements that may be only partially obtainable in telemedicine exams. In addition, the medical or mental health care providers cannot see how a patient behaviorally or physically reacts to certain topics or questions.[13] With the advances in the technology such as speed of transmission, remote visits increasingly approach, yet may not have reached, traditional face-to-face clinical encounters.

In the field of telepsychiatry there are additional considerations and cautions to consider. Since there are limitations to the cues that can be elicited, there have been reports of complex psychological processes that have developed. In one case that was reported, all contact during the first six months of treatment was by telephone.[14] When the patient and therapist finally met, the patient was so upset that the therapist resembled her own daughter, whom she experienced as uncaring and not the older person she imagined, that she refused to meet face-to-face again. With the addition of visual cues this risk has lessened but is not eliminated. As Williams and Douds noted, if patients can

make of the counselor what they will, they might also be able to make of the counselor what they need.[15] Hence in telepsychiatry practice, it may be preferable to conduct at least the initial evaluation in person.

III. Ethical and Legal Limits of Your License

Telepsychiatry is a form of medical care and as in standard face-to-face treatment, the delivery of such care requires attention to ethical and legal requirements. Additionally, practitioners of telemedicine have the obligation of translating the principles governing medical ethics such as beneficence, fidelity, integrity, justice and respect into best practice for virtual care.[16]

In general, medical and mental health practitioners are charged with providing care that they believe has benefits and will do no harm. As with many treatments, such as chemotherapy agents, this is not absolute, but rather reflects an assessment of the risk-to-benefit ratio. Telemedicine is able to increase the reach of medical and mental health care but attention must be paid to the competence of clinicians practicing in this area as well as to any alterations in the therapeutic relationship and care system that result from the newer technologies. While there is strong evidence for patient satisfaction, the field is too new for a robust outcome literature long term. Before beginning treatment, providers have an obligation to have a frank discussion about telemedicine practice including the benefits, the limits on scope, as well as such as how to handle crises, including emergencies and non-compliance.[17]

The therapeutic alliance, which is critical to a health care provider's work, would not be possible in the absence of the provider's fidelity to his or her patients and the trust it engenders. Unlike in-office care, in telepsychiatry visits there is less direct clinician control over the setting. Furthermore, there is often a concomitant decreased ability to ensure privacy, which is counter to the patient's right to confidentiality. At the onset of any treatment by telephone or other electronic means, it is important to establish clear parameters to the setting. In order to achieve the appropriate standard of care for privacy, it becomes critical to choose technology that is security enabled. In addition, practitioners are responsible for employing techniques that provide for the best care delivery such as continuous high quality connections and monitors with sufficient resolution and speed for synchronous exchanges in real time.[18] However, there may still be a discrepancy in different settings in the quality standards and equipment used which belie the justice ethic.

Finally, in all areas of health care, respect for an individual is expressed in the right to choose with self-determination at its core. In clinical practice this is the ethical underpinning of informed consent and allows for shared decision making. The application of telemedicine may create a system where medical care is determined by what technology is available, limiting the treatment options offered to patients. Telemedicine allows for wider access to care, but at the same time may inadvertently create a system in which attention to patient preferences is curtailed.

Another barrier to the use of telemedicine or telepsychiatry services is the concern about legal or regulatory limits on the professional's license and the ability or inability to offer services across state lines. In the United States, individual state governments are responsible for licensure regulations of health care professionals.[19] The telephone and other electronic methods allow medical and mental health professionals to reach patients anywhere, but state licensing laws generally do not permit out-of-state professionals to provide telemedicine services to in-state consumers.[20] Telemedicine providers are often subject to the licensure rules of the states in which the patient is physically located and where the practitioner is licensed.[21] In most cases, this means that clinicians limit their online practice to serving clients who reside within their state.

There are several opportunities to overcome this licensing barrier that many states have already utilized, or should consider implementing. For example, many states, including New York, have created guest licensure provisions that allow out-of-state licensed psychologists to practice for a short period of time under certain circumstances.[22] Several states also allow a physician who is not licensed in a particular state to practice medicine in that state at the request of and "in consultation" with a referring physician.[23] The consultation exception, however, is limited in duration and scope and therefore not suitable for regular treatment of a patient or client. Unfortunately there are no current uniform licensure standards for the practice of telemedicine. Clinicians must learn to work within the limits of their individual state laws.

Additionally, such licensure requirements create several problems for medical and mental health professionals involved in the practice of telemedicine or telepsychiatry. First, the process of obtaining a professional license requires money, time, research, and paperwork. Then, once the professional obtains a license in another state there may be requirements for continuing education or renewing the license. Also, each state has its own set of laws and regulations that the professional must follow, including specific confidentiality requirements. Last, but certainly not least, practicing medicine without a license could result in civil and criminal penalties.[24]

IV. Privacy and Confidentiality

Telepsychiatry providers must be aware of the enhanced requirements for privacy and confidentiality that is afforded to patients receiving mental health care via electronic methods. A telepsychiatry professional has the

same duty to safeguard a patient's records and keep their information confidential as those professionals providing face-to-face care. The same precautions and care taken to store paper documents must be taken when storing electronic files, images and audio or video tapes.[25]

Telepsychiatry providers must receive adequate training in using the hardware and software involved in the treatment to be provided. Training should include familiarity with equipment, its operation and limitations, and means of safeguarding confidential information. Telepsychiatry providers should be educated on proper intake procedures and screening, use of electronic medical records, transmission of prescriptions or lab orders, if applicable, and licensing, liability and malpractice insurance issues.[26]

Additionally, new HIPAA rules now regulate the delivery and storage of protected health information online.[27] All health care providers and any "covered entity" engaging in telemedicine must abide by the rules of HIPAA and the HITECH Act to protect the privacy and security of health information.[28] Covered entities may also need a business associate agreement with the vendor of the technology.[29] To preserve confidentiality and meet all requirements of HIPAA, professionals must use a private internet connection and encryption software for all electronic transmissions and records.[30] HIPAA requires that practitioners inform their patients about the procedures, safeguards, and risks to privacy that may be involved.[31]

Overall, it is important for telemedicine providers to observe procedures and protocols that ensure the privacy of their patients and are HIPAA and HITECH compliant. The provider is responsible for providing patients with a complete privacy policy before the initial session and for maintaining a confidential record of the patient's care. It is also the responsibility of the patient, however, to ensure the privacy of their own computer, internet connection and the location from which they engage in telemedicine. These electronic communications are subject to the same state and federal privacy laws as in-person interactions and must be protected accordingly.

V. How to Protect Yourself and Your License

There are several ways that a psychiatrist or other mental health professional can ensure online safety and security, while at the same protecting his or her license. First, to protect the patient's safety and the provider's license, it is advisable to have a licensed health care or mental health professional conduct an initial assessment of the patient in person. The face-to-face initial assessment allows the provider to get a full history, properly identify the patient, and assess grooming, hygiene, odors, substance abuse, movement and speech, general health, and social skills.[32]

Second, health care providers must obtain their patient's informed consent in writing, including a description of the potential risks and benefits of telemedicine services. The elements of informed consent include informing the client of the nature of the treatment, possible alternative treatments and the potential risks and benefits of the treatment. Providers should ensure that all prospective clients understand the limits to treatment and privacy online as well as attendant risks, including delays resulting from faulty equipment and the potential for security breaches.[33] Telepsychiatry providers should also obtain written consent to contact family members or other treating professionals in the client's local area in case of an emergency.[34]

Third, physicians and other licensed professionals should contact all applicable state licensing boards and their malpractice insurance carrier. Telepsychiatry providers must determine whether an additional license is needed to practice via telephonic methods in-state or in other states. Failure to comply with state licensure requirements could result in disciplinary action for practicing medicine without the proper license. Providers must also notify their insurance carrier that they intend to practice telepsychiatry and the location of their patients. Telepsychiatry practitioners are vulnerable to increased privacy exposure of communications and medical records. They must confirm that telepsychiatry services, both in-state and across state lines, are covered under their medical malpractice liability insurance policy in order to avoid the denial of coverage in the event of a lawsuit.

While telemedicine services can be as effective as in-person delivery of services it is essential to follow protocols to ensure the safety of the patient and the protection of the provider's license.

VI. Conclusion

Telepsychiatry services are a major therapeutic tool in light of the challenges and increased complexities of access to health care in the United States and around the world. Working with patients via electronic methods allows health care providers to reach individuals in remote areas or suffering from a disability that would not otherwise be able to access such care. In the mental health world, telepsychiatry offers individuals the services they need in the privacy of their own home, protected from any shame or embarrassment due to the stigma against mental illness. However, this relatively new system of delivering health care comes with risks that practitioners must consider and address. Telemedicine and telepsychiatry providers must be thoroughly trained on how to provide adequate telemedicine services and must work within the ethical and legal limits of their license. Overall, the virtual delivery of medical care has provided increased access to necessary treatment in a cost-effective manner.

Endnotes

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Findings on Telemedicine and Medical Malpractice in New York

By Courtney Alpert

Advances in medicine have the power to change the way medicine is practiced. Yet such advances are not exclusive to therapeutics, medications and vaccines. Other ways in which medicine can be advanced include the way in which the profession is practiced. One example of this is "telehealth," which "encompasses a broad variety of technologies and tactics to deliver virtual medical, health, and education services."[1] There are various forms of telehealth which include "[t]ransmission of recorded health history…through a secure electronic communications system to a practitioner, usually a specialist, who uses the information to evaluate the case or render a service outside of a real-time or live interaction"[2]; where health and medical data of an individual is sent to a practitioner in another location, which allows the practitioner to track the health of the patient[3]; and mobile health-related technologies, in which "[h]ealth care and public health practice and education [are] supported by mobile communication devices such as cell phones, tablet computers, and PDAs."[4] Finally, the fourth type includes what may be referred to as "telemedicine,"[5] live two-way interaction between an individual and practitioner—this is known as a "synchronous"[6] form of telehealth, and can be used for "consultative and diagnostic and treatment services."[7] This is the type of telehealth that this article will focus on.

A barrier to implementation of telemedicine includes that physicians fear the possibility of malpractice liability resulting from care provided through such technology.[8] Medical malpractice is the negligence of a physician[,][9] and in a New York medical malpractice action, the "plaintiff must prove (1) 'the standard of care in the locality where the treatment occurred, (2) that the defendant breached that standard of care, and (3) that the breach was the proximate cause of the injury[.]'"[10] While the elements of a regular malpractice action have been established under New York law, given that telehealth and telemedicine allow physicians to provide care through a different mechanism the same legal tests may not apply in such an action. The aim of this article is to examine the ways in which issues related to a medical malpractice claim may be interpreted in the context of telemedicine: these issues include preliminary litigation-related issues such as personal jurisdiction and conflicts of laws, as well as the formation of a physician-patient relationship, and what the standard of care may be. A problem in common with all but the physician-patient relationship is that the final determination of how these issues are analyzed will depend on where the physician providing services is deemed to be practicing as well as where care is deemed to be provided, thus where the malpractice occurs.

The standard of care is of particular significance to many physicians because it determines the care they must provide in order to avoid liability. This article lays out what the current standard of care is in a traditional medical malpractice action, and also details what can cause the standard of care to change. The standard of care can change in two ways—in one, a new legal doctrine is adopted, and in the second, the context and circumstances in which the standard of care is applied changes instead—this second form of change is what this article will focus upon.

Issue #1: Personal Jurisdiction

This issue of whether a court can exercise personal jurisdiction over a defendant physician in a medical malpractice case has the potential to be particularly applicable to the practice of telemedicine given the potential for communications regarding patient care to cross state lines. One unique issue raised by telemedicine required for a personal jurisdiction analysis is where the medical care which the cause of action is based upon occurs.[11] In determining this, where the cause of action occurs will be critical to determining if personal jurisdiction can be exercised.

The CPLR states that long-arm jurisdiction can be exercised over a defendant who "commits a tortious act within the state,"[12] or where he or she "commits a tortious act without the state causing injury to persons or property within the state.…"[13] In the case of a "tortious act without the state[,]" the "situs" of the injury has been determined to mean where the "event giving rise to the injury occurred, and not where the resultant damages occurred. In a medical malpractice case, the injury occurs where the malpractice took place."[14] However, with telemedicine it is not clear if an out-of-state physician providing care outside of New York has actually committed a "tortious act within the state" since he or she is not physically there. Furthermore, in the case of a "tortious act without the state" where the "malpractice took place" is unclear—on one hand, with an out-of-state physician, the physician physically provides that care outside of New York; however, on the other, the patient receives the care in New York; thus it is arguable that the medical malpractice occurs there.

Currently, the only state-based guidance on this issue comes from the Board for Professional Medical Conduct's statement made in 2000 that in terms of physician licensing requirements, when care is provided through telemedicine, the location of the patient is where the care is considered to be provided.[15] Since the statement was not made to address where an injury occurs for litigation purposes, it is not certain that this statement would control in a personal jurisdiction analysis; however, given the lack of clear guidance on this issue, it is conceivable that it might be relevant to a court's decision. Thus, it is possible that in a medical malpractice action, even if a court found that the out-of-state defendant committed a "tort without the state" a court may find the "situs of the injury" is New York. Additionally, even if a court found this provision of the CPLR insufficient or inapplicable, given the Board for Professional Medical Conduct's determination that care is deemed to be provided where the patient is located, jurisdiction potentially could be asserted because the CPLR allows for jurisdiction to be asserted over an out-of-state defendant who "commits a tortious act within the state." However, since the Board's determination was not created for the purpose of analyzing issues related to personal jurisdiction, what a New York court would rule cannot be determined with certainty. What is clear, though, is that where the malpractice is deemed to occur will be an important consideration in determining issues related to personal jurisdiction in a telemedicine-based case.

Issue #2: Conflict of Laws

Where the laws of two states are at issue in a case involving telemedicine, the New York courts must decide which law to apply. Similarly to personal jurisdiction, in deciding this matter, the court will need to determine where the malpractice occurred. In a traditional action involving issues related to conflicts of laws, the court in *Scharfman v. National Jewish Hospital & Research Center* stated that in New York the "courts must apply the law of the jurisdiction which 'because of its relationship or contact with the occurrence or the parties, has the greatest concern with the specific issue raised in litigation[.]'"[16]

Thus, in a medical malpractice action where the patient was located in New York when he or she received treatment, it is possible that a New York court could find the Board for Professional Medical Conduct's statement detailed above relevant in its analysis. Depending on how persuasive it found the Board's statement, a court might apply New York law given that the care provided to a patient located in New York would be the occurrence from which litigation arose. However, as indicated above, the Board's statement was made in relation to physician licensing; moreover, a court may find it relevant to consider where the care was physically provided from, rather than where it was physically received. Thus, it cannot conclusively be determined if the Board's statement would be influential in this area of litigation, but even if it were not found to be, it is clear that similar to personal jurisdiction determinations, in a telemedicine-based case, where the medical care constituting the malpractice occurred will be important for determining which state's law will apply.

Issue #3: The Physician-Patient Relationship

In New York, face-to-face contact between a patient and a physician is not necessary in order for a physician-patient relationship to be formed,[17] and given that it has been found to exist from a telephone call, it is likely it could also be found to exist where care is provided through telemedicine. A physician-patient relationship can arise through a telephone call where it is "shown that it was foreseeable that the patient would rely on the advice and that the prospective patient did in fact rely on the advice[.]"[18] A situation where a patient receives care through telemedicine is similar to that where one receives medical advice over the telephone in the sense that there is no physical face-to-face contact. Except in unusual circumstances, most individuals would likely not participate in care provided by telemedicine if their local physician could provide the services the distant-site physician was providing, or if they did not need medical help which they could not otherwise obtain locally. Thus, it is probable a court would find it foreseeable that where a physician provides medical advice through the use of telemedicine, it will be relied upon. Accordingly, where the patient is injured from such advice and subsequently commences a medical malpractice lawsuit, a physician-patient relationship could be found to exist. However, telemedicine has the potential to have greater access to a patient than one would have through a telephone—with telemedicine a physician can potentially see and virtually examine the patient as well as speak with him or her.[19] Given this difference, it is possible a different standard could be found to exist for a situation involving telemedicine. Furthermore, because with telemedicine there may be greater access to the patient than with a telephone, a lower threshold may exist for establishing a physician-patient relationship than that which is in place where one is created over the telephone.

Telemedicine also allows for a patient lacking access to a specialist to connect to one in a different area.[20] Thus, it is important to determine if a consulting physician in these situations would form a physician-patient relation-

ship through providing services through telemedicine. In a traditional medical malpractice case, a court may find a physician-patient relationship is formed between a patient and a consultative physician where the patient's local treating physician is not free to disregard the consultative physician's advice or treatment plan.[21] This can occur for a variety of reasons, including the local physician's lack of expertise or training,[22] or because the consultative physician plans to be actively involved in the case.[23]

Unlike physicians practicing in large metropolitan areas with access to specialists or other advanced technological resources, many physicians may use telemedicine in the first place because neither they, nor other physicians where they practice, possess the expertise required to diagnose or treat a patient; thus, they are not in a position to use their independent medical judgment and disregard that of the consultative physician. Given that in a traditional medical malpractice case, reliance due to lack of training by the local treating physician on the consultative physician's advice or treatment plan may be a factor in finding a physician-patient relationship exists,[24] a court may find the above rule particularly relevant where telemedicine is used. This is because unlike in areas where there are many specialists to consult with, physicians who do not practice in these localities may not have such access, and are thus forced more so than their urban counterparts to rely on the consultative physician's advice or treatment plan. Accordingly, in an action involving telemedicine, where a patient's local physician lacks the proper medical expertise to treat or diagnose the patient and lacks access to providers who do, subsequently consults another physician using telemedicine, and follows the proposed treatment plan of the consultative physician, it is possible a physician-patient relationship will be found to exist between the patient and the consulting physician.

The rule stated above that a physician-patient relationship may be formed between a patient and a consultative physician where the patient's local treating physician is not free to disregard the consultative physician's advice or treatment plan was reflected in *White v. Harris*.[25] Here, the defendant psychiatrist provided a consultation through telemedicine.[26] The court found it to be significant that the defendant psychiatrist was consulted to assist in the patient's treatment through his expertise, in requesting the consult the treatment team sought the defendant's advice regarding the plaintiff's medication, and subsequent to the consultation the defendant provider his treatment recommendation.[27] Other factors considered included that he was provided extensive information regarding the plaintiff's medical and psychological condition, and was aware of the serious nature of decedent's recent behavior.[28] While in *White* it was unclear if any individuals on the treatment team had the expertise whereby they could disregard the consultative physician's recommendations in place of their own professional judgment, it is likely no member of the treatment team did, seeing as they chose to have the patient consult with the distant-site provider in the first place. Thus, *White* potentially demonstrates that the above rule relating to a physician-patient relationship being formed with a consultative physician may also be applicable to telemedicine-based cases. Given the analysis above, it is possible that in a telemedicine-based malpractice case, a physician-patient relationship will be found to exist.

Issue #4: The Standard of Care

In New York no statute, rule or regulation provides a standard of care for telemedicine; however, medical malpractice case law provides some guidance on how this might be determined. Case law provides some guidance; however, in order to fully apply the relevant standard of care jurisprudence, there will need to be some decision by the New York courts as to where a physician providing care through telemedicine is deemed to be practicing.[29]

In New York, the Court of Appeals, citing *Pike v. Honsinger,* requires a physician to "exercise 'that reasonable degree of learning and skill that is ordinarily possessed by physicians and surgeons in the locality where [the doctor practices[.]'"[30] He or she must also "use reasonable care and diligence in the exercise of his skill and the application of his learning…[and] use his best judgment in exercising his skill and applying his knowledge."[31] The Court also summarizes the "reasonably prudent physician standard," charging physicians with "the duty to exercise due care, as measured against the conduct of his or her own peers," and to "employ their best judgment."[32] New York courts have interpreted this to mean that the standard of care may be higher for physicians "with knowledge and skill that exceeds local standards" such as board-certified specialists.[33] In such cases, the requirement to exercise best judgment may require physicians to adhere to a standard "even if it exceeds that of the average provider in the locality."[34] In *McCullough v. Rochester Strong Memorial Hospital*, the Fourth Department explained that "[a] court may deviate from the locality rule and instead apply a minimum state wide standard of care"[35] (if the standard practiced in a particular locality "is less demanding than the minimum skill or expertise which [physicians]are required to achieve to attain and maintain licensure in the State"),[36] "or even a national standard of care"[37] ("where there are minimum standards applicable throughout the United States[.]")[38] The court in *McCullough* concluded that "[i]n any event, the standard of care in a medical malpractice action is measured against local, statewide or national standards, and the

'superior knowledge and skill' that a provider actually possesses[.]'"[39]

The court in *Nestorowich* does not explicitly state whether "peers" means all physicians in the country, in New York State, or in the locality where a particular doctor practices. Based on their indication in *Nestorowich* that the *Pike* standard "remains the touchstone by which a doctor's conduct is measured and serves as the beginning point of any medical malpractice analysis" and that it is "applicable to each" malpractice case,[40] it seems reasonable to conclude that the Court may have used the term "peers" to mean those in the community where a defendant physician practices medicine.

However, *McCullough* indicates that the standard to be applied should depend on the actual knowledge and skill possessed by the physician.[41] This is consistent with *Nestorwich*, which indicates that although the reasonably prudent physician test is meant to be objective, "[t]he resolution of medical malpractice cases…is dependent on the specific facts surrounding each claim."[42] Additionally, the *Nestorwich* court explicitly states that the *Pike* locality-based standard "serves as the beginning point of any medical malpractice analysis," and indicates the need for collateral doctrines to complete the analysis.[43] Thus, a determination of "peers" could very likely depend on the particular knowledge and skill possessed by the physician, as opposed to any locality-based consideration.

Given, however, that the locality-based standard remains "the *beginning point* of any malpractice analysis"[44] it is highly probable that the standard of care in a medical malpractice action involving telemedicine would *at least* require that a physician "exercise 'that reasonable degree of learning and skill that is ordinarily possessed by physicians and surgeons in the locality *where [the doctor] practices[.]*'"[45]

Yet, the reality of telehealth and telemedicine introduces ambiguity into the meaning of "where the doctor practices." In order to use the locality-based standard in a telemedicine malpractice case, the court would have to decide whether this means the physician's or the patient's locality. Unfortunately, no court has yet addressed this issue; thus, it remains an open question as to how the courts would rule. As indicated above, the Board for Professional Medical Conduct has stated that, for the purpose of determining whether a physician must be licensed in New York, care via telemedicine is deemed to be provided where the patient is located.[46] It is conceivable that the courts could extend the Board's reasoning, using the patient's location to determine the local standard of care. However, ending the analysis here could have unintended negative effects. Telemedicine is often employed to provide care to patients in rural or urban areas that do not have access to proper care. These areas are also traditionally the same areas that have a lower local standard of care, precisely because they lack large medical institutions, high concentrations of providers, and the latest equipment. But only holding physicians, who may have the benefits of additional knowledge and resources, to the lower standard of the patient's locality, is seemingly unjust.

Additionally, it may not comport with adherence to due care, as required by the courts. The aspect of due care as a component of the standard of care may negate the potentially negative effect of just applying a strictly interpreted locality rule by also requiring physicians practicing through telemedicine to still use their "knowledge and skill that exceeds local standards"[47] where it "exceeds that of the average provider in the locality"[48] where the patient is located. Thus, while the beginning point of the standard of care may be lower where the patient's locality is used, the requirement that a doctor exercise due care would likely prevent the standard of care from being drastically lower than what it would be if the physician's locality were used.

Furthermore, the locality rule was originally developed to ensure that physicians would not be held to the standards of others with significantly more knowledge and resources as a result of their location of practice. Yet, if a physician intentionally renders care to those outside of the physician's locality, the courts could conceivably waive the physician-locality protection because of the physician's decision to render care elsewhere.

On the other hand, telemedicine can allow for physicians to provide their services to individuals all over the country. Because of this, a court could find it unfair to require a physician—attempting to help a New York resident by providing him or her with medical services—to acquire knowledge of and follow the standard of care in every state where the patients they provide telemedical services reside.

Clearly, when the standard of care in a telemedicine-based malpractice case must be determined, the court will have multiple issues to consider. However, it is clear that similar to personal jurisdiction and issues related to conflicts of laws, it will be critical to determine other issues first—here, it must be determined where the physician is considered to be practicing, while in the case of the latter issues, it must be first determined where the care from which the malpractice claim arises is deemed to be rendered.

Issue #5: What Can Influence the Standard of Care?

As stated above, in a malpractice action it will be necessary to determine where a physician is considered to be practicing in order to figure out which standard of care to apply. That being said, for any locality's standard of care, various factors, detailed below, can influence what it consists of, and thus provide physicians with some guidance in determining some aspects of what they can do to avoid malpractice liability. These include changes in medical education and the dissemination of information, state and federal law, medical research, and guidelines for the provision of medical care.

The court of claims in *Hirschberg v. State* believed that the locality rule was outdated because "[t]he 'distinctions based on geography are no longer valid in view of modern developments in transportation, communication and medical education, all of which tend to promote a certain degree of standardization within the profession.'"[49] Thus, the *Hirschberg* court used a broadened version of the locality rule:[50] "[a] qualified medical practitioner should be subject to liability, in a malpractice action, if he fails to exercise that degree of care and skill expected of the average practitioner in the class to which he belongs, having regard for the circumstances under which he must act, the advances of the procession, and the medical resources reasonably available. Of course the financial resources and territorial expanse of an area as well as its population density and patient's particular requirements will always have a bearing in determining the skill and care required."[51]

Using the reasoning from *Hirschberg*, where a physician or hospital does not have the resources or knowledge to diagnose or treat a patient, but does have access to other providers through telemedicine, the standard of care may require a physician to connect a patient to a provider with more or specialized expertise through the use of such technology. Conversely, where a physician or hospital has access to connect patients to such providers through telemedicine but for some reason chooses not to, under the *Hirschberg* analysis, this could be found to be a deviation from the standard of care.

In some cases, state or federal law may influence the standard of care. For instance, in *Yamin v. Beghel*, where plaintiff alleged malpractice based on a fall she experienced under the care of the defendant physician, the Third Department stated that "determining whether defendants breached their duty to exercise reasonable care in safeguarding Yamin requires a consideration of the standard of care customarily exercised in similar facilities in the community[.]"[52] In *Yamin*, state and federal laws, rules and regulations regarding restraints were also pertinent to the analysis, with particular emphasis placed on NYCRR language.[53] Yamin suggests that state and federal laws and regulations can impact how a court determines the standard of care. Thus, it could be helpful in providing certainty to physicians regarding what the standard of care is when providing care through telemedicine if state regulations were promulgated that provided guidance on this issue.

Additionally, results available from recent medical research may change what constitutes the standard of care. In *Burton v. Brooklyn Doctors Hospital*,[54] the plaintiff developed a retrolental fibroplasis (RLF) as a result of prolonged oxygen exposure provided by the hospital after birth, which led to plaintiff's permanent blindness and other related conditions and suffering.[55] The issue raised in *Burton* was whether a verdict finding the 2 of the 3 appellants liable for medical malpractice should stand, and thus, "whether defendants followed sound medical practice at the time, when they were aware of the possibility that RLF might result."[56] At the time plaintiff was born, a large portion of the medical community believed the use of oxygen on premature babies prevented brain death or damage; however, many individuals in the medical community believed that it contributed to RLF.[57] The court noted that at the time plaintiff was born and provided with oxygen at the defendant hospital "the view that increased oxygen was a necessary life saver, had…become suspect. New York Hospital, for instance, had [prior to plaintiff's birth,] conducted its own study of the effects of oxygen on premature infants and concluded that prolonged oxygen therapy may be related to the production of RLF. The results of [the study] were announced by the [defendant] hospital [weeks before plaintiff's birth] at a meeting attended by its pediatricians and ophthalmologists."[58]

In upholding the liability of all but one appellant, the court explained: "Although the conventional medical wisdom at the time believed that increased oxygen was essential to the survival of premature babies, the hospital and Dr. Engle cannot avail themselves of the shield of acceptable medical practice when a number of studies, including their own, had already indicated that increased oxygen was both unnecessary and dangerous, particularly for an otherwise healthy baby, and especially when the attending physician, who had primary responsibility for the patient's health, had recommended a decrease."[59]

Accordingly, *Burton* stands for the idea that though a physician is generally required to conform to accepted medical practice in the community in which he or she practices, where a physician has reason to know, due to recent medical developments, that a current medical prac-

tice may cause unnecessary injury, he or she must deviate from such a practice or face liability for not using his or her "best judgment and whatever superior knowledge, skill and intelligence he [or she] has."[60] Furthermore, the case emphasizes that doctors are expected to maintain awareness of recent medical advances, especially when information about these is easily available. Because of this, it is possible that there could be a medical malpractice case in the future premised on a hospital failing to suggest telemedicine as an option to connect a patient to a specialist despite the physician or hospital having the technology to do so.

Additionally, guidelines may have some influence the determination of what the standard of care is. The Court of Appeals in *Hinlicky v. Dreyfuss* has stated that in a medical malpractice action, guidelines cannot be used as "stand alone proof" of the standard of care.[61] However, they can be admitted into evidence and can "have some significance in identifying" it.[62] Reiterating this, the First Department in *Halls v. Kiyici* stated that [g]uidelines [are] not the same as standards of care and…the jury [is] required to make its determination based on the particular circumstances of the case, not on the [g]uidelnes alone."[63]

In terms of guidance from a state agency, in 2000 the Board for Professional Medical Conduct stated that for care provided through telemedicine, "[a]ll the current standards of care regarding the practice of medicine apply. The fact that an electronic medium is utilized for contact between parties or as a substitute for face-to-face consultation does not change the standards of care."[64] Later, in 2013, in a bill under consideration, and not yet enacted, the text provides that, along with care providers, the Commissioner shall "identify standards determined to be necessary for telehealth/telemedicine services… from: (I) the American Telemedicine Association, The Food and Drug Administration and/or other generally recognized standard-setting organizations as the Commissioner may determine; [and] (II)…the education law and regulations thereto, this chapter and regulations thereto and, as applicable, the standards of relevant professional or accrediting bodies.…"[65]

Hinlicky v. Dreyfuss and *Halls v. Kiyici* both show that guidelines published by professional organizations can impact what the standard of care is determined to be. Furthermore, as indicated above, while in 2000, the Board for Professional Medical Conduct indicated that "the current standards of care regarding the practice of medicine apply[,]"[66] in 2013, the proposed bill described above states that standards will be established, in part, with reliance on professional organizations that set guidelines such as the American Telemedicine Association. This shows that over the 13 years, the state's idea of what the standard of care should be may have changed from saying it must remain the same to giving some deference to other professional medical organizations. Interestingly, some of these organizations, such as the Federation of State Medical Boards, reiterate the idea that the same standard of care applies whether a patient is treated face-to-face or through telemedicine.[67] Thus, guidelines promulgated by professional medical organizations may be influential in determining the standard of care in any future medical malpractice actions involving telemedicine. Furthermore, their promulgation might be beneficial to physicians by providing them with increased certainty in terms of knowing what they have to do to avoid being found liable in a malpractice lawsuit involving the use of telemedicine. However, even if physicians and lawyers are aware of factors that can change the standard of care, it still needs to be determined which locality's standard of care to use as the "beginning point" of the standard of care analysis,[68] and as mentioned earlier, this cannot be done until courts analyze where a doctor using telemedicine to provide services is considered to be practicing.

Conclusion

Medical care provided through telemedicine has great potential to connect patients with medical care they otherwise they otherwise would not be able to obtain. However, until more case law regarding telemedicine-based medical malpractice is available in this area, it is unlikely that doctors can be provided with any concrete answers regarding their risk of malpractice liability and what steps they can take to avoid such liability. Given that one barrier to increased implementation of telemedicine is the fear of physicians of being sued for malpractice,[69] such technology may not be widely used until courts address such cases that involve telemedicine, and until then lawyers and physicians will have to patiently rely on previous malpractice case law, making parallels as appropriate to care provided through this form of recent technology.[70]

Endnotes

1. What is Telehealth? The National Telehealth Policy Resource Center, Center for Connected Health Policy, http://cchpca.org/what-is-telehealth (last visited Nov. 16, 2014).
2. *Id.*
3. *Id.*
4. *Id.*
5. *See* What is Telemedicine? American Telemedicine Association, http://www.americantelemed.org/about-telemedicine/what-is-telemedicine#.VGl1P9F0zug.
6. What is Telehealth? *supra* note 1.
7. *Id.*

8. Christopher J. Caryl, *Malpractice and Other Legal Issues Preventing the Development of Telemedicine*, 12 J.L. & Health, 173, 192-93 (1997/1998) (citations omitted).
9. NY Pattern Jury Instruction 2:150 Malpractice.
10. *Fernandez v. Elemam*, 809 N.Y.S.2d 513, 514 (3d Dept. 2006) (citations omitted).
11. *O'Brien v. Hackensack Univ. Med. Ctr.*, 305 A.D.2d 199, 202 (1st Dept. 2003) (citations omitted).
12. CPLR 302(a)(2). Applies except for cases of defamation. *Id.*
13. NY CPLR 302(a)(3). Except for defamation. *Id.*
14. *O'Brien v. Hackensack Univ. Med. Ctr.*, 305 A.D.2d 199, 202 (1st Dept. 2003) (citations omitted).
15. *Statements on Telemedicine*, http://www.health.ny.gov/professionals/doctors/conduct/telemedicine.htm (last visited Nov. 16, 2014).
16. 122 A.D.3d 939, 940 (citation omitted).
17. *See generally Miller v. Sullivan*, 214 A.D.2d 822 (3d Dept. 1995).
18. 214 A.D.2d 822, 823 (3d Dept. 1995) (citation omitted).
19. *See* What is telehealth? http://cchpca.org/what-is-telehealth (last visited Nov. 16, 2014).; What is Telemedcine?, http://www.americantelemed.org/about-telemedicine/what-is-telemedicine#.VGl1P9F0zug.
20. What is telehealth? http://cchpca.org/what-is-telehealth (last visited Nov. 16, 2014).
21. *See Gilinsky v. Indelicato*, 894 F.Supp. 86 (EDNY, 1995); *Tom v. Sundaresan*, 107 A.D.3d 479 (1st Dept. 2013; *Raptis-Smith v. St. Joseph's Med. Ctr*., 302 A.D.2d 246 (1st Dept. 2003).
22. *See Gilinsky v. Indelicato*, *supra* note 21.
23. *Tom v. Sundaresan*, *supra* note 21.
24. *Gilinsky v. Indelicato*, *supra* note 21.
25. 2011 VT 115 (2011).
26. 2011 VT 115 at P2.
27. 2011 VT 115 at P8.
28. *Id.*
29. *Nestorowich v. Ricotta*, 97 N.Y.2d 393, 398 (*citing Pike v. Honsinger*, 155 N.Y. 201, 209 (Ct. Appeals, 1898)).
30. *Id*.
31. 155 N.Y. at 209.
32. *Nestorowich* at 398 (citations omitted).
33. *Riley v. Wieman*, 137 A.D.2d 309, 315 (citation omitted).
34. 17A.D.3d 1063, 1064 (citation omitted).
35. 17 A.D.3d 1063, 1064.
36. *Hoagland v. Kamp*, 155 A.D.2d 148, 150.
37. 17 A.D.3d 1063, 1064.
38. *Payant v. Imobersteg*, 256 A.D.2d 702, 705 (citations omitted) (3d Dept. 1998).
39. 17 A.D.3d 1063, 1064 (4th Dept. 2005) (citation omitted).
40. 97 N.Y.2d at 398.
41. 17 A.D.3d 1063, 1064 (4th Dept. 2005) (citation omitted).
42. *Nestorowich* at 398.
43. *Id.*
44. 97 N.Y.2d at 398. Emphasis added.
45. 97 N.Y.2d at 398 (citation omitted).
46. *Statements on Telemedicine*, *supra* note 15.
47. *Riley v. Wieman*, 137 A.D.2d 309, 315 (citation omitted).
48. 17A.D.3d 1063, 1064 (citation omitted).
49. 91 Misc. 2d 590 at 597 (citation omitted).
50. 90 Misc. 2d 590, 597-98 (citations omitted); *Prooth v. Wallsh*, 105 Misc. 2d 653, 654 (1980) (citation omitted).
51. 91 Misc. 2d 590 at 597-98 (citations omitted).
52. 284 A.D.2d 778, 779 (citations omitted).
53. 284 A.D.2d 778 at 779.
54. 88 A.D.2d 217.
55. 88 A.D.2d 217, 218 (1st Dept. 1982).
56. 88 A.D.2d at 222.
57. 88 A.D.2d 217 at 218.
58. 88 A.D.2d 217at 219.
59. 88 A.D.2d 217 at 222-23.
60. 88 A.D.2d at 222-224 (citation omitted).
61. 6 N.Y.3d 636 at 647 (citation omitted).
62. 6 N.Y.3d at 647.
63. 104 A.D.3d 502 at 502.
64. *Statements on Telemedicine*, *supra* note 15.
65. 2013 Bill Text N.Y. S.B. 4023,§2799-u (4)(a), (amended May 2013).
66. *Statements on Telemedicine*, *supra* note 15.
67. CTEL Comments on FSMB Telemedicine Guidelines, Apr. 23, 2014, http://ctel.org/2014/04/ctel-comments-on-fsmb-telemedicine-guidelines/ (last visited Aug. 12, 2014).
68. 97 N.Y.2d at 398.
69. Christopher J. Caryl, *Malpractice and Other Legal Issues Preventing the Development of Telemedicine*, 12 J.L. & Health, 173, 192-93 (1997/1998) (citations omitted).
70. Author's Note: Sources supporting uncited article content include: Caryl, *supra* note 8; CPLR 302(a)(2); Miller, Nestorowich, Hirschberg, Burton, and Yamin, *supra* notes 17, 29, 49, 52 and 54; 2013 Bill Text NY SB 4023, *supra* note 65; Lynn D. Fleisher & James C. Dechene, *Telemedicine & E-Health Law* § 1.04 (Lexis Nexis) (2014); Derek F. Meek, *How an Apple (or Another Computer) May Bring Your Doctor Closer*, 29 CUMB. L. REV. 173 (1998/1999); Kelly K. Gelein, *Are Online Consultations a Prescription for Trouble? The Uncharted Waters of Cybermedicine*, 66 BROOKLYN L. REV. 209 (2000); and Jeffrey L. Rensberger, *Choice of Law, Medical Malpractice and Telemedicine: The Present Diagnosis with a Prescription for the Future*, 55 U. MIAMI L. REV. 31 (2000).

Terminological Analysis for Telehealth and Telemedicine

By Rebecca Cerny

Introduction

Modern medicine continues to expand, incorporating newer and more technological resources. A particular area of these advancing resources involves the use of telehealth and telemedicine. While the progression of our healthcare delivery system depends on a clear and consistent understanding of all tools that are available, the use of these particular terms is inconsistent among the states.

The eHealth and Information Systems Committee Workgroup on Telehealth and Telemedicine believes this lack of uniformity is a major barrier to adaption and integration of information and network-based technologies into mainstream healthcare. Thus, the workgroup created a goal of coming to a common understanding of these often interchangeable and inconsistently used terms. First, the terms telehealth and telemedicine were researched individually among all 50 states. Then the data was combined and the definitions given through statutes, regulations and program guidance were selected and analyzed further in order to find a common ground.

Methodology

Telecommunications

In analyzing telehealth and telecommunications, it was found that the terms included, or excluded, the use of four types of telecommunications:

- Synchronous, i.e. live videoconferencing
- Asynchronous, also called "store and forward"
- Remote Patient Monitoring
- Mobile Health

The definitions varied from including only one type of telecommunication, to all four of them. States used a variety of ways to include or exclude, some using explicit language, while others implied whether the type was covered under their interpretation of the term. The following chart includes examples of states that clearly include all types of telecommunications, those that implicitly include them, and those that explicitly excluded them by only mentioning specific ones.

Explicitly inclusive of all telecommunications	
West Virginia	"'Telemedicine services' means the use of synchronous video conferencing, remote patient monitoring, and asynchronous health images or other health transmissions supported by mobile devices (m-Health) or other telecommunications technology by a health care provider to deliver health care services at a site other than the site where the provider is located relating to the health care diagnosis or treatment of a patient."
New Mexico	"'Telemedicine' means the use of interactive simultaneous audio and video or store-and-forward technology using information and telecommunications technologies by a health care provider to deliver health care services at a site other than the site where the patient is located, including the use of electronic media for consultation relating to the health care diagnosis or treatment of the patient in real time or through the use of store-and-forward technology."
Implicitly inclusive of all telecommunications	
Massachusetts	"For the purposes of this section, 'telemedicine' as it pertains to the delivery of health care services, shall mean the use of interactive audio, video or other electronic media for the purpose of diagnosis, consultation or treatment."
Explicitly exclusive of some telecommunications	
New York	"Telemedicine means the delivery of clinical health care services by means of real time two-way electronic audio-visual communications which facilitate the assessment, diagnosis, consultation, treatment, education, care management and self management of a patient's health care while such patient is at the originating site and the health care provider is at a distant site."

Data Results

Telehealth

Researching the definition of telehealth revealed 34 sources covering 25 states and the District of Columbia.

- 33 sources had a definition that included the use of synchronous data.
- 30 sources included the use of asynchronous data, remote patient monitoring and mobile health.
- 21 sources mentioned distance or the physician's location being different from that of the patient.
- 5 sources specifically stated that only using a telephone or facsimile machine was not included within the definition of telehealth.

Telemedicine

Researching the definition of telemedicine revealed a total of 66 sources covering 44 states.

- All 66 sources included the use of synchronous telecommunication within their definitions.
- 47 sources considered asynchronous, remote patient monitoring, and mobile health within the scope of telemedicine.
- 35 sources referenced distance in some way, such as the doctor needing to be at a different location than the patient.
- 16 of the sources specifically identified that using only a telephone or facsimile machine as a means of telecommunicating would not be considered telemedicine.

Telehealth v. Telemedicine

While there are definitely differences between the definitions of telehealth and telemedicine among the states, they are all largely similar. The only definition that clearly stood out was South Dakota's definition for telehealth. However, this is because it is the only definition among all 99 sources to exclude the use of synchronous telecommunication. In a broad context the definition is still comparable to the other 98 sources.

Additionally, the definitions for telehealth and telemedicine seemed to follow different patterns. Telemedicine definitions tended to be more specific than the definitions for telehealth. Twenty-five of the 44 states that define telemedicine include a reference to telemedicine being related to the delivery of health care services or related to patient-doctor contact. Twenty of those states specifically mention the health care services being related to the diagnosis or treatment of a patient and Delaware, Florida, and New York each make reference to this by stating that telemedicine involves clinical health care.

Of the 25 states that provide definitions for telehealth, 15 tended to define the term as being broader than the generalized scope of telemedicine. While the majority of states limited telemedicine to diagnosis and treatment, 12 of the states specifically expanded telehealth to include those purposes in addition to others, including continuing professional education, public health, and administrative and program planning.

All 50 states have a definition for either telehealth or telemedicine but only 20 of the states have a definition for both. Nine states define the terms as being essentially equivalent to one another. One the other hand, 11 of the states have definitions of the two terms that seem to indicate telehealth as being a broader term then telemedicine.

States such as Georgia and Hawaii make it explicitly clear that telemedicine is a subsection of telehealth. Georgia's Medicaid policy states, "[c]losely associated with telemedicine is the term 'telehealth,' which is often used to encompass a broader definition of remote healthcare that does not always involve clinical services." Similarly, Hawaii includes the following in its definition of telemedicine, "'[t]elehealth'…includes 'telemedicine' as defined in this section."

Other states, such as Florida and Oklahoma, don't explicitly state that telemedicine is a part of telehealth, but their definitions clearly imply it. An Oklahoma regulation defines telehealth as meaning "the use of telecommunication technologies for clinical care (telemedicine), patient teaching and home health, health professional education (distance learning), administrative and program planning, and other diverse aspects of a health care delivery system." This regulation clearly singles out telemedicine as only one aspect of what is encompassed within the meaning of telehealth. While Florida's Medicaid policy isn't as obvious as defining telehealth as broader, in looking at the separate definitions it is clear that telemedicine was intended to be a subcategory since the purpose given is to provide "clinical care" while telehealth has a "wide array" of purposes including "consultative and diagnostic health care."

Florida	Telehealth Definition	Telemedicine Definition
Medicaid Policy	"The use of electronic communications to provide or support the off-site provision of a wide array of health-related activities, such as professional continuing education, professional mentoring, community health education, public health activities, research and health services administration, as well as consultative and diagnostic health care."	"Telemedicine is defined as the use of telecommunication and information technology to provide clinical care to individuals at a distance and to transmit the information needed to provide that care." pg. 80, policy and procedure handbook glossary and "the use of electronic communications to provide or support clinical care at a distance."

Wyoming seems to be an oddity in that its definition of telehealth is less inclusive than its definition for telemedicine. A regulation provides that telehealth must be "performed via a real time interactive audio and video telecommunication system." However, a statute provides that telemedicine "means the practice of medicine by electronic communication or other means from a physician in a location to a patient in another location." Telehealth clearly excludes non-synchronous telecommunications while telemedicine seems to allow all four telecommunications that were discussed earlier.

Where Definitions Are Found

Definitions can be found in a variety of legislation. Many states provided definitions for telehealth and telemedicine generally, covering multiple areas of health specialties. Some states, such as Oklahoma and Louisiana, actually have telehealth-specific statutes where they provide these definitions. Other states include the definitions in statutes and regulations covering insurance policies and the medical profession. Thirteen states provide a definition of the terms under more specialized statutes. South Dakota and Texas provide a definition of telehealth as it relates to speech language pathology and South Carolina provides a definition of telemedicine as it relates to veterinary services. Virginia goes as far as creating a new word and provides a definition of "teledentistry." The largest trend of where definitions were found was within insurance statutes and Medicare guidance's. Nineteen states included a definition of either telehealth or telemedicine within one of these sources.

Other Common Terms

Other common terms within the realm of telehealth/telemedicine include some of the types of telecommunications including asynchronous or store-and-forward technologies, remote patient monitoring, and mobile health (mHealth). While, as referenced above, many states included these types of telecommunications within their meaning of the telehealth/telemedicine, very few actually included the types within the definitions. Only 12 states include reference to asynchronous or store and forward within of their definitions. Additionally, only a few states include specific references to remote patient monitoring and mobile health. Interestingly, whenever a state specifically included a type of telecommunication within its definition, it did so inclusively of telehealth/telemedicine, rather then to state those types were not incorporated within the meaning.

While every state has a definition for either telehealth or telemedicine, definitions of other related terms are not as prevalent. Only three states revealed definitions for "store and forward." The definitions for store and forward are particularly similar and the definitions given for Mississippi and Tennessee are almost identical in parts.

State	Store and Forward Definition
California	Asynchronous store and forward means the transmission of a patient's medical information from an originating site to the health care provider at a distant site without the presence of the patient.
Mississippi	Store-and-forward telemedicine services means the use of asynchronous computer based communication between a patient and a consulting provider or a referring health care provider and a medical specialist at a distant site for the purpose of diagnostic and therapeutic assistance in the care of patients who otherwise have no access to specialty care. Store-and-forward telemedicine services involve the transferring of medical data from one (1) site to another through the use of a camera or similar device that records (stores) an image that is sent (forwarded) via telecommunication to another site for consultation.
Tennessee	Means the use of asynchronous computer-based communications between a patient and healthcare services provider at a distant site for the purpose of diagnostic and therapeutic assistance in the care of patients; and Includes the transferring of medical data from one (1) site to another through the use of a camera or similar device that records or stores an image that is sent or forwarded via telecommunication to another site for consultation.

Only one state definition for remote patient monitoring was found. Ironically, the state does not even include the term within its definitions of telehealth or telemedicine. Mississippi defines remote patient monitoring as meaning "the delivery of home health services using telecommunications technology to enhance the delivery of home health care, including: (i) Monitoring of clinical patient data such as weight, blood pressure, pulse, pulse oximetry and other condition-specific data, such as blood glucose; (ii) Medication adherence monitoring; and (iii) interactive video conferencing with or without digital image upload as needed."

Lastly, no currently definitions for mobile health were found. Four states referenced mobile health as being "medical and public healthcare transmissions supported by mobile devices," but such references were only made in bill texts.

Purpose

An interesting trend among a few states was to provide a purpose or reason for the use of telehealth/telemedicine. Arkansas, California, Idaho, and North Dakota all express that the use of telecommunications can improve health care access in rural communities. Illinois specifically states that telehealth is to be used "to provide medical services between places of lesser and greater medical capability and/or expertise," while Iowa cites "developing a comprehensive statewide telemedicine network or education" as its purpose in using telemedicine.

Analysis

Definition Uses and Scope

With 19 states including a definition for telehealth or telemedicine within an insurance statute or Medicaid guidance, it seems to suggest that reimbursement is a major reason for defining these terms. While reimbursement is definitely an important issue in the face of new technologies, the notion of defining a term based on one aspect of its meaning is sure to cause problems and confusion. No definitions, of either term, for any state, were broken up in such a way that they gave the definition of telehealth or telemedicine and then narrowed the concept of what was reimbursable as healthcare.

Should telemedicine and telehealth be limited by reimbursement? The advancement of technology is making the possibilities of telehealth and telemedicine grow exponentially. There are already so many limitations and barriers within the field, such as the security of patient information and the standards associated with health care given through telecommunication,[1] that further limitation could prevent modern medicine from expanding. Telemedicine "promises a series of breakthroughs to problems that beset the delivery of services to our patients… [but] is struggling to grow against the weight of legal and governmental restraints."[2] We can now track patients at home, while they are climbing a mountain, and provide medical care through a smart shirt. And this is all because of telehealth and telemedicine.[3] Why would we want to stop there? Should a smart shirt that delivers emergency treatment not be considered telemedicine because a state doesn't think the cost should be reimbursed by Medicaid? Defining telehealth and telemedicine only by reimbursement is an unnecessarily limit to the scope of the terms. It limits how we think about terms, even outside of reimbursement, and can limit how the telecommunications expand to fit the needs of society.

An example of a more effective way of define telemedicine can be seen in a Mississippi Senate Bill recently enacted in 2014 (2014 Miss. S.B. 2646). The bill separately defines key terms such as telemedicine, store and forward, and remote patient monitoring. Telemedicine is defined as "the delivery of health care services…through the use of interactive audio, video, or other electronic media," including that there must be a "real-time" consultation. Even though the definition limits telemedicine to synchronous communications, the bill makes it clear that "[a]ll health insurance and employee benefit plans in this state must provide coverage and reimbursement for the asynchronous telemedicine services of store-and-forward telemedicine services and remote patient monitoring services based on the criteria set out in this section." Because the definition and the description of what services are reimbursable are separate, there is a strong inference that the legislatures feel the definition for telemedicine is that actual meaning of the term and not just what services they think should get reimbursement. A clear divide between definition and policy would bring every party to a common and consistent understanding.

Additionally, as mentioned before, South Dakota's definition of telehealth is as it relates to speech language pathology, and many more states define either telemedicine or telehealth from the scope of a health care specialty. The effect of limiting the scope by specialty could mean numerous definitions of telehealth and telemedicine within one state. If South Dakota were to define telehealth as it relates to nursing, and osteopathy, and numerous other specialties, the general term telehealth will lose its meaning. Restricting the terms telehealth and telemedicine by the needs of each specialty seems unnecessary as only a few states opted to do so. States such as Louisiana, which passed the Louisiana Telehealth Access Act, more effectively communicate their intent by cultivating a general term that incorporates all aspects of the health care system.

Telehealth v. Telemedicine

A large quantity of states limit telemedicine to only diagnosis and treatment. In general it seems to be limited to using telecommunications for the treatment and care of patients. Oppositely, telehealth is largely expanded to encompass more areas of healthcare other than those two areas, such as education and administrative planning. Fifteen of the 25 states that define telehealth tended to expand the definition beyond providing services for diagnosis and treatment. Additionally, over half of the states that have definitions for both terms define telehealth in a broader way. While only a few states explicitly state that telehealth is more inclusive, no state explicitly states that it is not. Therefore, the data seems to suggest that telemedicine is a subset of telehealth.

The two terms should definitely have two separate definitions, and the majority of states that define both agree. Given the new nature of telehealth and telemedicine consistently defining them as separate will alleviate confusion and foster growth and adoption. However, it would also make sense to have telemedicine be defined as a subset of telehealth. First, of the states that define both, none of them excludes telemedicine from its definition of telehealth. Secondly, when used in generalized terms, medicine is a subset of health and healthcare. Health and healthcare are broadly encompassing while medicine tends to be more limited. Having telehealth and telemedicine follow the definitions of their root words may add in comprehension and use.

Additionally, having telemedicine include diagnosis, treatment and in general the delivery of medical care, while having telehealth be inclusive of that as well as other health care categories utilizing telecommunications as a standard, could be a good option. Having general and standard definitions for the terms can help people understand what telehealth and telemedicine are, as well as make it easier to cultivate and utilize.

Conclusion

Inconsistency is a major barrier to telemedicine and telehealth adoption. In looking at how each state defines the terms we can see just how inconsistent they are. However, we can also see a lot of uniformity as well and for some issues there are definitely trends. The majority of states think that both synchronous and asynchronous telecommunications are included in the terms and the majority of states seem to consider telemedicine as less inclusive then telehealth. Unfortunately, the limitation of telehealth and telemedicine to specialties and reimbursement seems to harm the continuation of that uniformity. Finding common grounds as to core concepts of the terms could make understanding and adoption must easier.

Endnotes

1. B. Stanberry, *and Opportunities in the 21st Century,* https://higherlogicdownload.s3.amazonaws.com/NYSBA/Telemedicine%20Barriers%20and%20Opportunities%20in%20the%2021st Telemedicine: Barriers%20Century1.pdf?AWSAccessKeyId=AKIAJH5D4I4FWRALBOUA&Expires=1408504131&Signature=W%2BPbP93hUQFbRaS1C3eUqTUvR%2BE%3D.
2. Susan E. Volkert, *Telemedicine: Rx for the Future of Health Care*, 6 Mich. Telecomm. Tech. L. Rev. 147.
3. *Id*.

Concierge Medicine: A Legal Analysis

By Deniza Gertsberg

I. Introduction

With labels such as "concierge medicine," "VIP medicine," "boutique medicine," "exclusive practice," "premium practices," or "platinum medicine," direct patient-doctor contractual[1] arrangements have received their share of negative attention from the press as well as certain lawmakers since their inception in 1996.[2] Perceived as medicine for the rich, some academics and ethicists worry that such "elitist" practices may cause access to care problems and would further "exacerbate the already tiered healthcare system, accelerate the fragmentation of insurance risk pools through cherry picking of the healthier patients, and promote the nonmedical services and amenities."[3]

These days, however, "concierge medicine" appeals to broader segments of the population as physicians offer more affordable contracts to patients.[4] While the term "concierge medicine" remains popular, many, including some state legislatures, are switching to the more neutral terms of "retainer-based medicine"[5] or "direct practices,"[6] to better reflect (and regulate) the varied and more accessible forms of these contractual relationships between patients and physicians.

Attorneys advising physicians in starting or transitioning to retainer-based care should pay close attention to the legal and ethical risks these new practice models may implicate for their clients.

II. Background

Faced with decreased reimbursement rates,[7] increased malpractice costs, increased operating, administrative and regulatory burdens,[8] threat of criminal and civil sanction for innocent billing errors,[9] and high patient panels,[10] some physicians, whether by choice or necessity, switch to retainer-based medicine. Moreover, the pressure to find alternative methods of practicing has intensified for some practitioners after the passage of the Patient Protection and Affordable Care Act.[11] The law, with its emphasis on preventive care, has added millions to insurance rolls within a matter of months while the number of primary care physicians available to treat additional patients is still catching up,[12] adding additional burden on already overburdened primary care physicians.[13]

While retainer-based practices offer enhanced reimbursement opportunities, it is not all about the money for the physicians and not all that make the transition are successful.[14] Retainer-based medicine offers many physicians the opportunity to reduce their patient loads to more manageable numbers (from 2,000-3,000 to 400-600 patient loads), spend more time with patients, allow more time for their families, and accrue less stress and burnout.[15] According to one study, physicians who transitioned to retainer-based care reported greater overall satisfaction with practicing medicine.[16]

III. General Characteristics of Retainer Based Medicine

Direct care is an approach to practicing medicine in which physicians charge their patients a membership fee in return for enhanced services or amenities.[17] In general, retainer-based practices concentrate on primary care services.[18] Since patient pools tend to be smaller than in a typical third-party reimbursement model, physicians are able to offer, depending on the practice: same day, next day or Saturday appointments; extended visits; house calls; 24-hour pager, cell phone or home phone access to the physician; telephone and email consultation; upscale waiting rooms and spa-like amenities;[19] wellness planning; nutrition planning; smoking cessation support; and stress reduction counseling.[20]

The cost to patients varies depending on the practice model. For example, a Government Accountability Office 2005 Report ("2005 GAO Report") found that the concierge care membership fees ranged from $60 to $15,000 a year for an individual, with the average fees ranging $1,500 to $1,999.[21] A recent three-year industry analysis estimated the annual concierge membership fees ranged from $600 to $1,800 and higher.[22]

Some retainer-based physicians are affiliated with a franchise,[23] others are independent solo- or two-doctor practices; several practices have been documented to have seven physicians, and some practices are based in academic centers.[24]

IV. Legal Pitfalls

A. Federal Laws

Enrolled physicians who have not opted out of Medicare have to be concerned with staying on the right side of the Medicare billing rules. The law prohibits physicians who accept Medicare assignment from billing extra for services already covered by Medicare.[25] Those physicians who do not accept assignment (non-participating) cannot charge more than 115% of the applicable fee schedule amount (*i.e.*, limiting charge).[26] Violation of these rules could result in civil money penalties, exclusion from Medicare and other Federal healthcare programs as well as a possible False Claim Act prosecution.[27]

While retainer-based practices still represent a relatively small slice of the healthcare market—there are an estimated 10,000 concierge doctors in the United States

versus 691,400 practicing physicians and surgeons[28]—concerns from lawmakers and regulators about this form of practicing medicine arose shortly after its inception. For example, Sen. Bill Nelson sponsored legislation in 2003, the Equal Access to Medicare Act of 2003, which would prohibit physicians and other health care practitioners from charging membership or other incidental fee (or requiring purchase of other items or services) as a prerequisite for the provision of an item or service to a Medicare beneficiary. In support for the bill, Sen. Nelson argued that concierge medicine is "a dangerous [practice] model that causes significant disparities in the care available to Medicare beneficiaries," and called on members of Congress to "end this egregious practice."[29]

Expressing a similar sentiment, in 2002, five members of Congress wrote to the then-Secretary of Health and Human Services and the Inspector General, expressing apprehension about one form of concierge model and urged the regulators to "take rapid action."[30] The lawmakers claimed that under that particular arrangement, Medicare beneficiaries were required to first pay the concierge practice a fee before they could receive Medicare-covered services[31] and the fee charged allegedly "represents a substantial and illegal overcharge of the patient."[32]

While the Secretary responded that "[i]nsofar as the retainer fee under such agreement is truly for noncovered services, such fees would not appear to be in violation of Medicare law," he also warned that "[w]e will continue to monitor such situation carefully—especially for any evidence of coercive activity relating to such agreements - and consider whether any further steps are indicated."[33]

The government indeed continued to monitor the situation, and not long thereafter, the Office of Inspector General ("OIG") issued a fraud alert reminding physicians that charging Medicare patients for services already covered by Medicare constitutes a potential violation of the assignment agreement.[34]

The OIG alert was concerned with certain physicians practices that sought from patients additional fees for what could be considered Medicare-covered services. The OIG alert referenced a settlement with a Minnesota physician for $53,400, where the government alleged that the annual contract that the physician's patients signed included "at least some services" that were already covered and reimbursable by Medicare, "in violation of the physician's anti-assignment agreement."[35]

In another settlement with the OIG, a North Carolina physician agreed to pay $106,600 to settle alleged violations of the Civil Monetary Penalties law by requesting payments from Medicare beneficiaries.[36] The government claimed that the physician had requested an annual fee in exchange for providing the following services: (1) an annual comprehensive physical examination; (2) same-day or next-day appointments; (3) support personnel dedicated exclusively to members; (4) 24 hour-a-day and 7 day-a-week physician availability; (5) prescription facilitation; (6) coordination of referrals and expedited referrals, if medically necessary; and (7) other service amenities as determined by the practitioner. Such an arrangement, the OIG alleged, potentially violated the physician's assignment agreement with Medicare.[37]

While additional settlement details in both cases would be helpful in further understanding the OIG's position,[38] one thing is clear: physicians cannot rest easy with the government's general assurances that participating physicians can charge Medicare beneficiaries extra for "noncovered" items and services without violating the law. The rub is determining what constitutes "covered services"[39] at any point in time given that this concept is subject to constant revision and change.[40]

Retainer practices also tend to be vulnerable to accusations of violations of the anti-kickback statute and rules prohibiting improper remunerations. "If concierge practices are seen as offering amenities such as bath robes, hot towels, free transportation to office visits, and additional physician services to induce Medicare patients to use their services they may risk violating the Medicare-Medicaid Antikickback Statute, and the Medicare Patient Inducement statute."[41]

B. State Laws

1. Insurance or Not?

One of the most pressing state law issues for retainer-based practices is whether they violate state insurance laws. "To the extent that concierge practices charge members a fixed, prepaid amount for a bundle of guaranteed services, they could be found to be providing insurance in violation of state law."[42] States that are more active in regulating or issuing opinions on concierge practices include New York, New Jersey, Washington, Oregon, Utah, Maryland and West Virginia.[43]

i. New York

Whether a proposed concierge plan offered to patients is in violation of New York Insurance laws has to be tested against the controlling statute. New York laws prohibit any person, firm, association corporation or joint-stock company from doing an insurance business, and, *inter alia*, from making or proposing to make, as an insurer, an insurance contract, to residents of the State, unless authorized by a license or exempt from licensure.[44]

An "insurance contract" is any:

> agreement or other transaction whereby one party, the "insurer," is obligated to confer benefit of pecuniary value upon another party, the "insured" or "beneficiary," dependent upon the happening of

> a fortuitous event in which the insured or beneficiary has, or is expected to have at the time of such happening, a material interest which will be adversely affected by the happening of such event.[45]

The statute further defines a "fortuitous event" as "any occurrence or failure to occur which is, or is assumed by the parties to be, to a substantial extent beyond the control of either party."[46]

Even before retainer-based physician practices began attracting so much attention, the New York Department of Insurance ("Department") issued several opinions which set out the permissible parameters of similar membership plans. In general, a subscription or membership plan would constitute the doing of an insurance business within the meaning of the statute if, for a fixed membership fee, the service provider obligates itself to provide services which are depended upon the occurrence of a fortuitous event and where such events are beyond the control of the patient or the service provider.[47] In such circumstances, the service provider would be assuming the risk of loss if the cost of rendering such services exceeds the paid fees and would be in violation of the law if done without an insurance license.[48]

Pursuant to this long-standing view, the Department, for example, decided, that a chiropractor's offering patient contracts that provide unlimited chiropractic care for a fixed fee would violate New York insurance laws, which prohibit doing an insurance business without a license.[49] For the same reason the Department nixed another doctor's attempt to establish a solo family clinic in New York City that would have provided uninsured patients with a flat fee arrangement for medical care irrespective of the number of office visits per month.[50]

In 2009, the Department once again prohibited yet another doctor, Dr. Muney, from offering unlimited office visits for a flat monthly fee, even where a per visit co-pay applied.[51]

Small modifications to a plan, however, may take it outside the purview of the insurance laws. The Department, for example, has repeatedly opined that a plan with a prepaid membership fee may offer services for no charge or a nominal separate charge, so long as the services are not dependent upon the happening of a fortuitous event.[52] A routine annual examination at no additional charge is permissible, for example, because the examination is not dependent upon the happening of a fortuitous event.[53] Furthermore, practices can avoid being considered "insurers" if they charged an additional fee, even at discount, for services occasioned by a fortuitous event. In such cases "the making of the service plan would not constitute the doing of an insurance business, so long as the fees cover the cost rendition, including reasonable overhead."[54] Dr. Muney, for example, resolved the Department's violation notice by agreeing to, *inter alia*, charge patients an additional fee of $33 for services stemming from fortuitous events.[55]

ii. Other States

Several other states have also passed measures regulating retainer practices.[56]

In 2006, for example, Washington's insurance commissioner determined that retainer-based practices constitute the doing of an insurance business.[57] West Virginia's commissioner also reached a similar conclusion in 2006.[58] In both cases, however, the States' legislatures stepped in and enacted measures which not only clarified that retainer practices are not insurers but also found that such practice models could provide greater access to care.[59] The Washington rulemakers, for example, permitted concierge or direct practices to operate without having to meet certain financial obligations and filing requirements.[60]

Maryland's Insurance Administration also voiced concerns about certain retainer-based practice arrangements resembling insurance plans.[61] Specifically, a 2009 report urged "physicians interested in establishing a retainer practice [to] take certain steps to avoid engaging in the business of insurance."[62]

2. New York Managed Care Contracts

Concierge practice physicians who accept private insurance plans must also observe their contractual obligations with those plans. Contracts between providers and managed care plans typically include a "hold harmless" provision that protects enrollees from facing balance billing charges by a network provider for covered services.[63] Such providers therefore are contractually prohibited from seeking reimbursement from an enrollee beyond payment of applicable cost sharing requirements such as copayments, co-insurance or deductibles for services covered by the managed care plan.[64]

Underpinning those contractual obligations, however, is a comprehensive system of State laws regulating managed care plans. New York's Department of Health ("DOH"), for example, issued a stern letter to a CEO of a company in 2004 interpreting Public Health Law 44 and its implementing regulations as a bar to certain practices advanced by retainer based models of care.[65] "A member being solicited by physician network providers to pay an additional charge as a pre-requisite for continuation of already covered care and treatment from such provider, is, in [DOH's] view, neither a legitimate component of managed care nor an acceptable practice."[66]

The enrollee, opined DOH, "does not expect that, in addition to a premium, he/she will also be liable to a participating provider for an additional retainer for such services, particularly if they are also 'covered services.'"[67]

Furthermore, declared DOH, "[n]either Article 44, Subpart 98-1, nor the Guidelines contemplate permitting the practice by providers/physician, of charging enrollees retainer fees."[68]

As in the context of Medicare, another one of DOH's concerns revolved around duplicative payments for covered services. DOH warned that "many of the services being described as enhancements are, services already covered by the enrollees' HMO subscriber contract, e.g., a guarantee for 24 hour coverage, and case management," as well as coordination of necessary referrals, and, as such, "these services may duplicate those covered by most comprehensive health plans, and physicians charging additional fees risk violating their provider contracts."[69]

DOH also found that certain practices would be discriminatory and thus unlawful under New York law. For example, "making an individual wait a longer time for an appointment based on source of payment would be viewed as discriminatory."[70] Since the plan is supposed to promote access to care based on need, restriction on that access due to "an inability to pay for concierge services would run afoul of 10 N.Y.C.R.R. 98-1.11(h)(7)."[71] Even having better waiting rooms for concierge patients was viewed as discriminatory "especially where provider may serve individuals enrolled in public programs."[72]

Managed care laws of other states may similarly require plans to have nondiscrimination clauses which would prohibit a physician from differentiating in its "treatment of a plan member based on form of payment."[73]

3. New York's Stricter Limiting Charges Law

In addition to Federal laws regulating Medicare billing practices, New York physicians should also be wary of the State's limiting charge law that goes further than Congress in regulating Medicare billing practices to protect Medicare beneficiaries.[74] In 1990, New York enacted Section 19 of the Public Health Law, which capped the charge for physicians who balance bill federal Medicare beneficiaries at 115% of the Medicare allowable charge as of 1991.[75] In subsequent years the limiting charge was to be reduced to 110% or 105% of the reasonable charge, if the number of statewide Medicare claims billed at or below Medicare's recognized payment amount did not increase by 5% from the preceding year's level.[76] New York's stricter limiting charge, however, does not apply to office or home visits.[77]

Non-participating physicians and hospitals in New York are subject to fines and refund requirements for violation of Section 19.[78] Courts have also ruled that patients have a private right of action to enforce this law.[79]

Laws regarding patient-abandonment[80] are additional state law issues that New York attorneys as well as those practicing in other states should consider when advising physicians in transition.

4. Ethical Concerns

Certain scholars and ethicists have expressed concerns about the impact of concierge medicine on patient access to physicians[81] and the creation a multi-tiered healthcare system and called for stiffer regulations of these kinds of practice models.[82]

While concierge practices are still relatively new models of practicing medicine, early indications suggest that they may not have an adverse impact as some have anticipated. The 2005 GAO report, for example, noted that "[t]he small number of concierge physicians makes it unlikely that the approach has contributed to widespread access problems," and further that "concierge care does not present a systemic access problem among Medicare beneficiaries at this time."[83] Five years later, a study commissioned by the nonpartisan Congressional Agency, the Medicare Payment Advisory Commission, similarly did not observe any systemic problems with access to care in the survey it conducted.[84] Furthermore, since retainer practices are varied, with increasing number of practices offering more affordable plans, some argue that such arrangements could actually improve access to care[85] and improve quality of care,[86] and lawmakers in several states agree.[87] Lastly, certain healthcare and policy leaders, including the American Medical Association, argue that concierge practices should be encouraged as a "step in the right direction toward more pluralistic healthcare system."[88]

Endnotes

1. There is no shortage of names to describe this direct doctor-patient contractual model of practicing medicine. In addition to "concierge medicine" some doctors and patients also use: Direct Care, Direct Primary Care, Direct Practice, Cash Only Medicine, Personal Care, Patient Choice Healthcare, and Private Medicine. *See* Michael Tetreault, *Three Year Analysis of Concierge Medicine Shows Encouraging Signs For Boosting Primary Care Medicine In U.S.*, Concierge Medicine Today, Jan. 8, 2013, *at* http://conciergemedicinenews.wordpress.com/2013/01/08/three-year-analysis-of-concierge-medicine-shows-encouraging-signs-for-boosting-primary-care-medicine-in-u-s/.

   For purposes of this article the terms "direct care," "retainer based," or "concierge" will be used interchangeably.

2. *See, e.g.*, Paul Sullivan, *Putting Your Doctor, or a Whole Team of Them, on Retainer*, N.Y.Times, April 29, 2011 ("[e]ven as more people are struggling to pay medical bills and being rushed through office visits with their doctors, an elite group with money has another option: exclusive medical care, around the clock and anywhere in the world, including on a yacht or private plane"), *at* http://www.nytimes.com/2011/04/30/your-money/30wealth.html?pagewanted=all; Abagail Zuger, *For a Retainer, Lavish Care by 'Boutique Doctors'*, N.Y.Times, Oct. 30, 2005 (quoting Rep. Pete Stark, (D-CA) "[c]oncierge care is like a new country club for the rich"), *at* http://www.nytimes.com/2005/10/30/health/30patient.html?pagewanted=all; *see also* 149 CONG. REC. S2188 (Feb. 11, 2003) (statement of Sen. Nelson) (introduced a bill, S.345 to amend the title XVIII of the Social Security Act to prohibit

physicians and other health care practitioners from charging membership or other incidental fees (or requiring purchase of other items or services) as a prerequisite for the provision of an item or service to a Medicare beneficiary; concierge medicine, according to Sen. Nelson, creates "a growing problem of doctors shutting down their practices and opening new ones, only accepting those patients willing to pay a membership fee"); Government Accountability Office (GAO), Report to Congressional Committees, Physicians Services: Concierge Care Characteristics and Considerations for Medicare, GAO-05-929 (Aug. 2005), at 9 ("[t]he origins of this practice approach are often traced to a medical practice founded in Seattle, Washington, in 1996"), *at* http://www.gao.gov/assets/250/247393.pdf [hereinafter "GAO Report"].

3. Robert M. Portman and Kate Romanow, *Concierge Medicine: Legal Issues, Ethical Dilemmas, and Policy Challenges*, 1 J. Health & Life Sci. L., 3, 32 (2008) (internal citations omitted); Steve Hargreaves, *Cash Only Doctors Abandon the Insurance System*, CNN, June 11, 2013 (quoting director of a consumer policy group concerned that concierge practice physicians "cherry-pick among their patient population to serve only the wealthier ones. It certainly creates a barrier to care."), *at* http://money.cnn.com/2013/06/11/news/economy/cash-only-doctors/.

4. Kara Byers, *Concierge Medicine No Longer Reserved for Rich and Famous*, CBS46, March 29, 2014, *at* http://www.cbs46.com/story/24852919/concierge-medicine-no-longer-reserved-for-rich-and-famous; *see also* Tetreault, *supra* note 1 (citing a three year industry study from 2009-2012 that found that "thirty-three percent (33%) of patients inside a concierge medicine practice earned an average combined household income of less than $100k each year from 2009-2012"); Hargreaves, *supra* note 3 (quoting a doctor most of whose patients are "self-employed, small business owners, or employed at small firms that have found the monthly fee, combined with a high-deductible plan, a cheaper option than traditional insurance... [and] [b]y cutting out the middleman, [the doctor] said he can get a cholesterol test done for $3, versus the $90 the lab company he works with once billed to insurance carriers. An MRI can be had for $400, compared to a typical billed rate of $2,000 or more.").

5. *See* Elizabeth Hargrave, et al., Retainer Based Physicians: Characteristics, Impact, and Policy Considerations, No. 10-9, at 14 (Oct. 2010), *at* http://www.medpac.gov/documents/contractor-reports/Oct10_RetainerBasedPhysicians_CONTRACTOR_CB.pdf?sfvrsn=0 [hereinafter "MedPac"].

6. *See, e.g.*, State of WA Office of the Ins. Commissioner, *Direct Practices, Annual Report to the Legislature* (Dec.1, 2012) *at* http://www.insurance.wa.gov/about-oic/commissioner-reports/documents/2012-direct-practices-report.pdf.

7. David W. Hilgers, *Physicians Post-PPACA: Not Going Bust at the Healthcare Buffet*, 24 Health Lawyer 1, Feb. 2012, at 1 ("[d]ue to a number of factors, physician reimbursement declined by 25 percent from 1995 to 2008.... This decline in reimbursement naturally has resulted in a corresponding decline in physicians' compensation."); *see also* Ginia Bellafante, *Enhanced Medical Care for an Annual Fee*, N.Y.Times, Dec. 6, 2013 (citing one doctor whose reimbursements for office visits had been, in some cases, reduced to a tenth of what they were in the previous decade).

8. Hilgers, *supra* note 7 at 1-3 (argues that "[t]he regulatory pressures on physicians are overwhelming. Pressures to comply with false claims provisions, compliance plans, [Antikickback statute] and Stark regulations, [HIPAA], [OSHA], the Controlled Substance Act and licensing requirements, coupled with potential recovery audit contractor...audits and Medicaid fraud unit investigations and increased scrutiny from [CMS] as well as potential prosecution by the U.S. attorney's office all combine to exhaust the resources of even the largest healthcare providers. To smaller medical groups, the resources that must be dedicated to these regulatory demands are impossible to financially support.").

9. Portman, *supra* note 3 at 33.

10. *Id*. at 4.

11. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified in scattered sections of 42 U.S.C.); Roni Caryn Rabin, *You're on the Clock: Doctors Rush Patients Out the Door*, April 20, 2014 ("Patients—and physicians—say they feel the time crunch as never before as doctors rush through appointments as if on roller skates to see more patients and perform more procedures to make up for flat or declining reimbursements.... And the problem may worsen as millions of consumers who gained health coverage through the Affordable Care Act begin to seek care—some of whom may have seen doctors rarely, if at all, and have a slew of untreated problems."), *at* http://www.usatoday.com/story/news/nation/2014/04/20/doctor-visits-time-crunch-health-care/7822161/; *see also* Healthcare Association of the State of New York, Doctor Shortage: Outpatient and Primary Care Need Growing; Results of HANYS' 2013 Physician Advocacy Survey (2013) ("[i]n recent years, numerous published articles and studies have predicted that the shortage of primary care physicians will worsen as more people become insured through the Affordable Care Act (ACA). Several factors enter into these predictions, including the aging of the primary care workforce, diminishing numbers of new physicians who choose to practice primary care, combined with an aging population with multiple comorbidities and increased life expectancy."), *at* http://www.hanys.org/communications/publications/2013/2013_physician_advocacy_survey.pdf [hereinafter "HANYS"].

12. *See* Rabin, *supra* note 11 ("many doctors may face greater financial pressure as many insurers offering new plans through the health law's exchanges pay them even less, offering instead to send them large numbers of patients"); *see* HANYS, *supra* note 11 at 9 ("[r]espondents to HANYS' survey reported a total need for 1,026 physicians, of which 266 are primary care physicians (26%). Seventy percent of respondents indicated that recruitment of primary care physicians was very difficult, often due to a shortage (75%) and the aging of the primary care workforce (70%). Sixty-three percent of hospital/health system respondents said that their primary care capacity was insufficient to meet patient needs. Seventy-seven percent plan to directly employ primary care physicians for their outpatient sites, but are having difficulty recruiting them.").

13. *See* Roni Caryn Rabin, *With Expansion of Health Insurance, Are We Burning Out Our Doctors?*, The Florida Times Union, Apr. 18, 2014 (arguing that tired primary care physicians are leaving their practices or changing the way they practice but "[t]he timing couldn't be worse," as this is happening "[j]ust as millions of Americans are obtaining insurance coverage through the federal health law"), *at* http://members.jacksonville.com/news/health-and-fitness/2014-04-18/story/expansion-health-insurance-are-we-burning-out-our-doctors. Early indications also suggest that not all physicians want to participate with the exchange plans, while others are seeking to limit the number of patients with the exchange plans that the doctors will treat due to low reimbursement rates. *See* Jayne O'Donnell, *Some Doctors Wary of Taking Insurance Exchange Patients*, USAToday, Oct. 28, 2014, *at* http://www.usatoday.com/story/news/nation/2014/10/27/insurers-aca-exchange-plans-lower-reimbursements-doctors/17747839/ ("[b]cause these exchange plans often have lower reimbursement rates, some doctors are limiting how many new patients they take with these policies, physician groups and other experts say....'Physicians who are in solo practices have to be careful to not take too many patients reimbursed at lower rates or they're not going to be in business very long.'").

14. MedPac, *supra* note 5 at 16-17; *see also* Wayne Lipton, *Tackling the Assumptions of Concierge Medicine,* PhysicianPractice, Feb. 28, 2013 ("I've seen some heartbreaking failures where physicians put their faith in a concierge program, say goodbye to the majority of their patients, drop their insurance contracts, put up their shingle, and within a few months, fail or find themselves struggling."), *at* http://www.physicianspractice.com/blog/tackling-assumptions-about-concierge-medicine.

15. MedPac *supra* note 5 at 16; *see also* Roni Caryn Rabin, *supra* note 13 (while no national data on physician burnout exists "nearly half of more than 7,200 doctors responding to a survey published in 2012 by the Mayo Clinic reported at least one symptom of burnout. That's up from 10 years ago, when a quarter of doctors reported burnout symptoms in another survey").

16. *See* MedPac, *supra* note 5 at 16 (respondents reported greater overall satisfaction with answers such as: "I like medicine again," "this is the kind of doctor I envisioned myself being," and "I'm practicing the way I was trained to practice medicine."). The American Academy of Private Physicians promotes concierge medicine to physicians interested in joining with statements such as these on its website: "[i]t's time to restore the doctor-patient relationship," "breathing life back into preventative medicine" and "create the time you need to serve your patients with integrity," *at* http://www.aapp.org/ (last visited April 1, 2014).

17. GAO *supra* note 2 at 1.

18. *See* Portman, *supra* note 3 at 5; *see also* MedPac, *supra* note 5 at 14 ("[t]he vast majority of retainer physicians are primary care physicians").

19. *See* Portman, *supra*, note 3 at 5; *see also* Bellafante, *supra* note 7 (citing one doctor who closed off his office for four hours to provide patient enhanced privacy during a colonoscopy, provides allergy shots at home, and "accompaniment to a stressful M.R.I. where Dr. Goldberg held the patient's toe to supply comfort"); MedPac, *supra* note 5 at 7 (services offered by retainer based practices studied included: in-depth annual physicals lasting up to 90 minutes for some physicians; offering breathing, hearing, and vision tests, EKGs, Alzheimer's and depression screening, diet, nutrition and weight loss programs; smoking cessation services, medication management, among others); Sandra J. Carnahan, *Currents in Contemporary Ethics: Concierge Medicine: Legal and Ethical Issues*, 35 J.L. Med. & Ethics 211 (Spring 2007) ("[o]ther amenities include luxury robes, shower facilities, personal toiletries, cable television and internet access.").

20. Frank Pasquale, *The Three Faces of Retainer Care: Crafting a Tailored Regulatory Response*, 7 Yale J. Health Pol'y L. & Ethics 39, 60 (Winter 2007).

21. GAO Report, *supra* note 2 at 2 and 11; *see also* Bellafante, *supra* note 7 (describing a New York-based concierge practice where patients "will pay $25,000 a year for unfettered access to the doctors").

22. Tetreault, *supra* note 1.

23. *See* Portman, *supra* note 3 at 6.

24. MedPac, *supra* note 5 at 15.

25. 42 U.S.C. § 1395(u)(h); *see also* Medicare Enrollment and Claims Submission Guidelines, Pub. L. No. ICN 906764 (August 2013), *at* http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedicareClaimSubmissionGuidelines-ICN906764.pdf [hereinafter ("MLN Enrollment"].

26. 42 U.S.C. § 1395w-4(g)(2)(C); *see also* MLN Enrollment, *supra* note 25.

27. 42 U.S.C. § 1320a-7a(2); OIG Alert, *OIG Alerts Physicians About Added Charges for Covered Services* (Mar. 31, 2004), *at* http://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA033104AssignViolationI.pdf; Portman *supra* note 3 at 10; *see also* GAO Report, *supra* note 2 at 8 ("[p]hysicians who impose charges on beneficiaries beyond the Medicare limits may be subject to civil monetary penalties").

28. *Concierge Medicine: How At-Home Doctor Visits Yield Savings*, ABC News, Oct. 13, 2014, *at* http://abcnews.go.com/blogs/health/2014/10/13/concierge-medicine-how-at-home-doctor-visits-yield-savings/; Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook (2014-15 Edition), *available at* http://www.bls.gov/ooh/healthcare/physicians-and-surgeons.htm.

29. *See* 149 Cong. Rec. S2188, *supra* note 2.

30. Letter from Representatives Waxman (D-CA), Sherrod Brown (D-OH), Pete Stark (D-CA), Benjamin Cardin (D-MD) and Senator Richard Durbin (D-IL) to Tommy Thompson and Janet Rehnquist (Mar. 4, 2002).

31. *Id*. According to the Letter, MDVIP would provide "amenities" to patients, such as, physician availability 24/7, travel medical services, coordination of referrals, claims facilitation for members, among others, while continuing to bill insurers for most medical visits. "For Medicare beneficiaries, this means that each covered visit would be billed to the federal government the same as it would be in a non-MDVIP practice," wrote Rep. Waxman. "The key difference, of course, is that MDVIP physicians require a $1,500 fee to obtain these Medicare services."

32. *See id*. ("Even absent an overlap [of covered and noncovered services], it is not accurate to say that payments are solely for noncovered services. Conditioning the provision of Medicare services on the annual fee means that the patient is paying for the opportunity to receive covered services.").

33. Letter from Sec' Tommy Thompson to Representative Henry Waxman (D-CA) (May 1, 2002).

34. OIG Alert *supra* note 27; *see also* MLN Matters, *OIG Alert About Charging Extra For Covered Services*, SE041, *at* http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE0421.pdf.

35. OIG Alert, *supra* note 27.

36. Office of the Inspector General, *Overcharging Beneficiaries*, *at* http://oig.hhs.gov/fraud/enforcement/cmp/overcharging.asp (last visited April 21, 2014).

37. *Id*.

38. *See* Portman, *supra* note 3 at 11 (adding that "…the lack of details on how the OIG came to the conclusion that some of the services were covered is troublesome for concierge practices. As Medicare now pays for 'Welcome to Medicare' physician examinations, some preventative screenings (e.g., diabetes, cardiovascular, cancer) and smoking cessation services, [the OIG's Alert] likely narrows the range of services that concierge practices can offer to Medicare patients.").

39. *See e.g.,* Items and Services That are Not Covered Under the Medicare Program, Pub. L. No. ICN 906765 (Sep. 2013), *at* http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Items_and_Services_Not_Covered_Under_Medicare_BookletICN906765.pdf. Given the intricate and constantly changing coverage rules, staying compliant with regulations will require constant monitoring of the Medicare coverage rules as well as regular adjustments to contract terms, the latter which may not be desirable or practical. *See e.g.,* Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015, 79 Fed. Reg. 40318 (proposed July 11, 2014) (proposing to expand and create more flexibility to recently enacted rules that make separate and additional payment for non-face-to-face chronic care management services for Medicare beneficiaries who have multiple, significant chronic conditions. One of the elements of chronic care management services includes availability of a means for the beneficiary to make contact with health care practitioners in the practice to address a patient's urgent chronic care needs and the provision of services outside the normal business hours). Moreover, even items of services that are identified as not covered often have exceptions (*e.g*., routine or annual physical check-ups are not covered but the Annual Wellness Visits and the initial Preventative Physical Examination are; Medicare will also not pay for screening tests and examination therapies for which the beneficiaries has no symptoms, yet counseling to prevent tobacco use for asymptomatic beneficiaries is covered.).

40. *See* Pasquale, *supra* note 20 at 59 ("[t]he distinction between covered and non-covered services is a term of art of federal health care financing. Medicare tends to follow the diagnosis and management codes developed by the AMA. Unfortunately, neither regulations nor guidance documents appear to clarify application of this legal distinction to retainer care.") (internal citations omitted).

41. *See* Portman, *supra* note 3 at 16 (noting, however, that "[t]his may be more of an issue for practices with lower access fees").

42. Portman, *supra* note 3 at 16; *see also* Pasquale, *supra* note 20 at 89.

43. Portman, *supra* note 3 at 17-20; *see also infra* note 56 and 59.

44. *See* NY Ins. Law §1102(a) and §1101(b)(1).

45. *See* NY Ins. Law §1101(a)(1).

46. *See* NY Ins. Law §1101(a)(2).

47. *See e.g., Re: Contracts for Provision of Unlimited Chiropractic Services To Patients*, Opinion No. 03-07-30 (2003 NY Insurance GC Opinions LEXIS 211); *see also Re: Ambulance Subscription/ Membership Plan*, Opinion No. 08-07-30 (2008 NY Insurance GC Opinions LEXIS 191); *Re: Ambulance Subscription Plans*, Opinion No. 01-05-27 (2001 NY Insurance GC Opinions LEXIS 120); *Re: Family Practice Clinic for Uninsureds*, Opinion No. 00-05-16 (2000 NY Insurance GC Opinions LEXIS 81); *Re: Proposed Medical Service Plan*, Opinion No. 09-11-01 (2009 NY Insurance GC Opinions LEXIS 86); *Re: ABC Home Care Services, Inc.*, Opinion No. 02-11-20 (2002 NY Insurance GC Opinions LEXIS 240).

48. *See supra* text accompanying note 47; *see also* Letter from New York State Ins. Dep't to John Muney, MD, *Re: Doing an Insurance Business*, Feb. 2, 2009 (hereinafter "Letter to Dr. Muney").

49. *See supra* note 47, *Re: Contracts for Provision of Unlimited Chiropractic Services To Patients*, Opinion No. 03-07-30.

50. *See supra* note 47, *Re: Family Practice Clinic for Uninsureds*, Opinion No. 00-05-16.

51. *See supra* note 48, Letter to Dr. Muney; *see also* Jennifer Fermino, *State Slaps Dr. Do-Good* (Mar. 4, 2009), *at* http://nypost.com/2009/03/04/state-slaps-dr-do-good/.

52. *See supra* note 47, *Re: Proposed Medical Service Plan*, Opinion No. 09-11-01.

53. *Id.* (internal citations omitted).

54. *Id*; *see also supra* text accompanying note 47.

55. *See* Letter from New York State Ins. Dep't to Jonathan S. Feinstein, Esq., attorney for Dr. Muney and his practice, *Re: AMG Medical Group (AMG)*, Mar. 6, 2009. As a way to redress the Commissioner's adverse view of retainer practices, the New York State Legislature introduced a bill in 2013 that would authorize primary care physicians to establish, offer and operate health care retainer programs which provide primary health care services for a flat fee for a specified period of time without being considered insurance plans. *See* New York State Assembly, A06395 Memo, *at* http://assembly.state.ny.us/leg/?default_fld=&bn=A6395&term=&Memo=Y.

56. Under Utah's law, for example, "medical retainer agreements" are permitted, provided certain requirements are met, including, among others, that the contract between the provider and patient state that the retainer agreement is not insurance. *See* Utah Code Ann. §31A-4-106.5. In 2006, West Virginia passed a law authorizing a preventative care pilot program that would allow health clinics and private medical practitioners to provide primary and preventive health services for a prepaid fee. *See* W.Va. Code §16-2J-3 (program is set to expire in 2016). An Oregon law exempts retainer medical practice from application of Insurance Code but requires the providers to be certified by Department of Consumer and Business Services as retainer medical practice and to meet certain other requirements. *See* ORS §731.036; 735.500.

57. *See* State of WA Office of the Ins. Commissioner, *supra* note 6 at 13.

58. *Id*.

59. *See* W.Va. Code §16-2J-1(a) ("[t]he Legislature finds that a program that would allow health clinics and private medical practitioners to provide primary and preventive health services for a prepaid fee would enable more West Virginians to gain access to affordable health care and to establish a medical home for purposes of receiving primary and preventative healthcare services"); Wash. Rev. Code Sec. 48.150.060 (direct practices are not insurers, health carriers, health care service contractors or health maintenance organizations) and finding that direct payment models could improve access to care. *See* Wash. Rev. Code. Sec. §48.150.005 ("[i]t is the public policy of Washington to promote access to medical care for all citizens...Washington needs a multipronged approach to provide adequate health care to many citizens who lack adequate access to it. Direct patient-provider practices, in which patients enter into a direct relationship with medical practitioners and pay a fixed amount directly to the health care provider for primary care services, represent an innovative, affordable option which could improve access to medical care, reduce the number of people who now lack such access, and cut down on emergency room use for primary care purposes, thereby freeing up emergency room facilities to treat true emergencies."). *See also* Doug Trapp, *Direct Primary Care Model: Cutting Out the Insurer*, Amednews.com, Aug. 1, 2011, *at* http://www.amednews.com/article/20110801/government/308019949/4/.

60. *See* State of WA Office of the Ins. Commissioner, *supra* note 6 at 13 (noting that the WA law prohibits concierge practices from billing insurance companies for services provided by the direct practice arrangements).

61. Maryland Insurance Administration, *Report on "Retainer" or "Boutique" or "Concierge" Medical Practices and the Business of Insurance 2009 Report* (Jan. 2009), *at* http://www.mdinsurance.state.md.us/sa/docs/documents/home/reports/2009retainermedicinereport-final.pdf.

62. *Id*.

63. Kaiser Foundation, *State Restriction Against Providers Balance Billing Managed Care Enrollees*, *at* http://kff.org/private-insurance/state-indicator/state-restriction-against-providers-balance-billing-managed-care-enrollees/ (last visited April 16, 2014).

64. *Id.*; *see also* Portman, *supra* note 3 at 23; Carnahan, *supra* note 19 at 212.

65. *See* NY Dep't of Health, Commissioner Letter (April 16, 2004).

66. *Id*.

67. *Id*.

68. *Id*.

69. *See id*. DOH interpreted NY PHL §4403(1)(c) and 10 NYCRR 98-1.5(b)(6)(ii) as relieving enrollee from liability for covered services in exchange for a premium or periodic charge.

70. *See id*.

71. *Id*.

72. *Id*.

73. *See id; see also* Portman, *supra* note 3 at 19 and 23 (citing a New Jersey Department of Health and Senior Services notice that prohibited physicians serving on HMO or PPO panels from requiring a concierge fee from patients, even as physicians on those panels argued that they were providing services that were complimentary to those they were required to provide as network physicians. The authors point out that New Jersey 's Department of Health and Senior Services was concerned that "services were not available to all plan members, but only offered to those who could afford the extra fees); *see also* Carnahan, *supra* note 19 at 211-12.

74. *See* Pub. Health Law § 19; *New York State Soc. of Orthopaedic Surgeons, Inc. v. Gould*, 796 F. Supp. 67, 71 (E.D.N.Y. 1992) ("[t]he legislature's purpose in enacting section 19 was to prevent physicians who use balance billing 'from charging medicare [*sic*] beneficiaries excessive amounts for certain services...[and] to increase the number of 'fully participating physicians' who, rather than balance bill, would accept the 'reasonable rate as full payment for all services for all medicare [*sic*] patients'"); *see also Medical Soc'y v. State Dep't of Health*, 83 NY.2d 447, 452 (1994) ("[t]he Legislature's purpose in enacting section 19 was to prevent physicians who use balance billing 'from charging medicare [*sic*] beneficiaries excessive amounts for certain services'"); *Medical Soc'y of New York v. Cuomo*, 976 F.2d 812, 815 (1992); *Medicare Beneficiaries Defense Fund v. Memorial Sloan Kettering Cancer Ctr.*, 159 Misc. 2d 442, 446 (N.Y. Sup. Ct. 1993) (purpose of legislature is to protect Medicare beneficiaries from incurring burdensome expenses for physicians' services).

75. *See* Pub. Health Law § 19(1); *New York State Soc. of Orthopaedic Surgeons, Inc.*, *supra* note 74; *Medical Soc'y of New York v. Cuomo*, *supra* note 74.

76. *See* Pub. Health Law § 19(1)(b); *Medical Soc'y*, *supra* note 74, at 451.

77. *See* NY Pub. Health Law § 19(2). It is interesting to note that despite lawsuits concerning this law, the agency tasked with producing reports that determine the limiting charge for New York non-participating physicians, the New York State Office of the Aging ("NYSOFA"), has not issued reports that identify the limiting charge. In response to the author's inquiries requesting reports and other documents identifying the limiting charge for New York non-participating physicians, the agency stated that "funds were never appropriated" for this function and "NYSOFA has never implemented this statute." (E-mail dated November 25, 2014). Legislation proposed in 2013 and referred to the Senate Committee on Health would eliminate the requirement that NYSOFA produce reports identifying the limiting charge for New York non-participating physicians and would instead permanently limit Medicare charges by New York non-participating physicians to 105% of established Medicare payment rate, including any deductibles, co-insurance, or copayments for that service. *See* 2013 Bill Text NY A.B. 7838.

78. *See* NY Pub. Health Law § 19(4) ("a physician who is determined, after opportunity for a hearing, to have violated the provisions of this section shall be subject for the first violation to a fine of not more than one thousand dollars nor less than the greater of three times the amount collected, or, if not collected, three times the amount charged, in excess of the limitations set forth in subdivision one of this section, and, for each additional violation committed within five years of the date of an immediately preceding violation of this section, to a fine of not more than five thousand dollars nor less than the greater of one thousand dollars or three times the amount collected, or, if not collected, three times the amount charged, in excess of the limitations set forth in subdivision one of this section; provided, however, that in no event shall the fine for an individual violation of this section be greater than five thousand dollars. In addition, where the provisions of this section have been violated, the physician shall refund to the beneficiary the amount collected in excess of the limitations set forth in subdivision one of this section.").

79. *See Sterling v. Ackerman*, 663 NYS 2d 842, 843 (1st Dep 1997); *see also Medicare Beneficiaries Defense Fund*, 159 Misc. 2d 442, 445-46, *supra* note 74.

80. *See, e.g.*, N.Y.Ed. Law §6530(30).

81. *See* Carnahan, *supra* note 19 at 212 ("[t]he dark side of concierge medicine is that every physician reducing her patient load from 2500 to 500 leaves 2000 former patients who must find a new primary care physician at a time when these physicians are in an increasingly short supply, and fewer physicians are accepting Medicare patients.").

82. *See* Portman, *supra* note 3 at 35.

83. GAO Report, *supra* note 2 at 4.

84. MedPac Report, *supra* note 5 at 4.

85. *See, e.g.*, Jen Wieczner, *Pros and Cons of Concierge Medicine*, The Wall Street Journal, Nov. 10, 2013, *at* http://online.wsj.com/news/articles/SB10001424052702303471004579165470633112630 ("[o]n one end, patients pay thousands of dollars a month for lavish celebrity-type treatment at traditional concierge practices. On the other, pared-down clinics charge roughly $50 to $100 a month for basic primary-care medicine, more accessible doctors, and yes, money savings for those looking to reduce their health spending.").

86. ABC News, *supra* note 28 (quoting a consumer health advocate: "(parents) don't have to take off work. They don't have to find babysitters, ...[t]hey can be in the comfort of their own home.").

87. *See supra* text accompanying notes 56 and 59; *see also* Michael Tetreault, *Rx Compliance Improves Among Concierge Medicine Patients*, Jan. 14, 2013 ("[c]oncierge medicine practices may actually help to improve medication compliance, which is the patient's consistency in taking prescribed medications over time. In 2011, preliminary research was conducted by The Concierge Medicine Research Collective and Concierge Medicine Today. They found that among concierge physicians across the U.S., when physicians were asked to 'grade their concierge medical patients' on medication compliance,' 96.3% of the doctors indicated that 75% of their patients comply with prescription regimens all or most of the time.").

88. Portman, *supra* note 3 at 37; AMA Code of Medical Ethics, Opinion 8.055 (concierge models of medicine delivery "are consistent with pluralism in the delivery and financing of health care").

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The Court of Appeals Declines to Impose Strict Liability on Health Care Organizations

By Karen M. Richards

Introduction

It is well-settled that "[i]n the absence of any negligent behavior by an employer, liability for acts of an employee may generally be imposed upon the employer pursuant to the doctrine of *respondeat superior* if the employee was acting within the scope of his employment."[1] There are a few exceptions to this doctrine, but the Court of Appeals has consistently declined to create an exception that would impose strict liability upon hospitals for the torts of employees who were acting outside the scope of employment.[2] A case in point is *Cornell v. State of New York*.[3] In *Cornell*, where a 14-year-old patient was raped by an employee of a state mental health facility, the Court refused to "impose absolute liability upon the State for any injuries suffered by patients at State institutions at the hands of State employees, even if those employees are not acting in the scope of their employment and the State is free from any fault."[4]

In *N.X. v. Cabrini Medical Center*, the Court again declined to adopt a rule of heightened duty premised on a patient's sedated condition, where a surgical resident sexually molested a woman recovering from surgery.[5] Although a hospital has a duty "to safeguard the welfare of its patients, even from harm inflicted by third persons, measured by the capacity of the patient to provide for his or her own safety," the Court stated that "[a]s with any liability in tort, the scope of a hospital's duty is circumscribed by those risks which are reasonably foreseeable."[6]

While *Cornell* and *Cabrini* clearly established that the Court will not impose absolute liability upon a hospital when an employee commits a sexual assault, the Court did not address whether its refusal to adopt a heightened duty on hospitals applied to other situations, such as when an employee breaches the fiduciary duty of confidentiality. This issue was addressed by the New York Court of Appeals in *Doe v. Guthrie Clinic, Ltd*.[7]

The U.S. District Court's Decision in *Guthrie*

Despite the Court of Appeals' consistent refusal to expand hospital liability, the plaintiff in *Doe v. Guthrie Clinic, Ltd*. urged the Court to impose absolute liability on the defendants for an employee's dissemination of the plaintiff's confidential medical information.[8] When Doe was being treated for a sexually transmitted disease at one of the defendants' clinics, a nurse employed by the clinic recognized John Doe as the boyfriend of her sister-in-law.[9] She accessed his medical records, learned that he was being treated for a sexually transmitted disease, and sent unauthorized cell phone text messages to her sister-in-law informing her of Doe's condition.[10]

Doe filed a diversity action in district court, alleging eight claims against the clinic.[11] Citing *Community Health Plan-Kaiser Corporation* in support of his claim of breach of fiduciary duty of confidentiality over patient personal health information, Doe argued that *Kaiser* "abrogated the traditional analysis of vicarious liability in situations involving unauthorized disclosure of health information, and enunciated a new standard of strict liability for corporations in cases where its employees, without authorization, disclosed confidential health information."[12]

In *Kaiser*, the plaintiff, who received psychiatric services from a social worker at the defendant's facility, alleged a medical records clerk employed by the defendant disclosed confidential medical information contained in her patient file.[13] The majority acknowledged that a private cause of action could not be predicated on statutes, which required certain health care providers and medical corporations to protect the confidentiality of patient information gained during the course of treatment, and reasoned that since a medical corporation can only act through its agents, servants, or employees, any breach of the duty owed to a patient to protect patient confidentiality makes the corporation directly responsible.[14] "To hold otherwise would render meaningless the imposition of such a duty on a medical corporation, since the wrongful disclosure of confidential information would never be within the scope of the employment of its employees."[15]

Two justices dissented, opining that the majority, in its effort to furnish the plaintiff with a basis for recovery against the defendant

> merely selected fragments from various statutory provisions prohibiting the unauthorized disclosure of confidential information necessarily gained or imparted in connection with the rendering of professional health care services and engrafted them on existing tort law. In so doing, it has fashioned a hybrid cause of action, hitherto unknown to the law and bearing essentially no resemblance to the one pleaded by plaintiff. The cause of action so created not only provides plaintiff with a basis of recovery, it imposes strict liability, thereby permitting plaintiff to recover against [the defendant medical corporation] for its nonprofessional

> employee's disclosure of confidential information regardless of fault.[16]

Kaiser's dissenting judges "seriously question[ed] the wisdom of having an intermediate appellate court create a new legal remedy every time it discovers an unserved need."[17]

The *Guthrie* district court found *Kaiser's* justification for altering vicarious liability "flawed" and "[did] need not be followed."[18] Despite an extensive search, it was "unable to find any case other than [*Kaiser*] suggesting that an employer may be held strictly liable in cases where an employee has, without authorization, violated a duty of confidentiality owed by the employer" and it noted that the Court of Appeals in *Cabrini*, which was decided after *Kaiser*, did not adopt *Kaiser's* strict liability standard.[19] The district court therefore declined to "extend a standard of strict liability to employers where the New York State Legislature and Court of Appeals have declined to do so" and found that Doe failed to establish that the clinic breached any duty of care to him when the nurse, without authorization, and acting outside the scope of her employment, revealed Doe's confidential health information to his girlfriend.[20]

The Second Circuit Court of Appeals' Decision in *Guthrie*

On appeal, the Second Circuit found *Kaiser's* "broad theory of medical corporate tort liability," which expanded a common law cause of action against a physician who improperly discloses confidential medical information to include a direct right of action against a medical corporation for breach of medical confidentiality by a non-physician employee

> subject to question. Indeed, two justices dissented from the [*Kaiser*] majority's decision, which, as the Second Circuit noted, cited no statutory authority or case law to support its analysis.[21]

The Second Circuit hesitated to rely exclusively on *Kaiser* because it was "mindful that direct corporate liability generally rests on the doctrine of *respondeat superior* and is not implicated by the *ultra vires* acts of employees."[22] It was also mindful that while *Cabrini* addressed whether the doctrine of *respondeat superior* applied to a physician's intentional tort, *Cabrini* did not address an action for breach of a fiduciary duty arising from the unauthorized dissemination of a patient's confidential medical information.[23]

With only "sparse" case law and with no precedential decision from the Court of Appeals, the Second Circuit could not "predict with confidence" how the Court would rule on this issue and certified this question to the Court:

> 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?[24]

The New York Court of Appeals in *Guthrie*

Rejecting *Kaiser*, the Court of Appeals answered the certified question in the negative.[25] Citing to *Cornell* and *Cabrini*, the majority noted that "[s]ubjecting hospitals and other health care entities to strict liability for the acts of an employee that were not only unauthorized, but motivated entirely by personal reasons is contrary to well-established precedent."[26] It held, "[f]or the same reasons stated in *Cabrini*, a medical corporation's duty of safekeeping a patient's confidential medical information is limited to those risks that are reasonably foreseeable and to actions within the scope of employment."[27]

Justice Rivera, dissenting, wrote "that a medical corporation's duty extends beyond an employee's conduct within the scope of employment."[28]

> As the majority notes, it is the medical corporation itself, not merely the employees, which owes the duty to the patient. New York's Public Policy would be furthered by permitting a cause of action for breach of medical confidentiality, even in cases where the employee has acted outside the scope of employment, because patients must reveal medical data in order to obtain care from the medical corporation and the patient has no way of protecting against its unauthorized disclosure or means of controlling who has access to it.[29]

She reasoned that it was unrealistic for a patient to withhold confidential information to prevent its disclosure because:

> [a] patient cannot expect delivery of medical services without disclosing such data. Indeed, the medical profession encourages full disclosure by the patient of a comprehensive medical history.[30] In order to receive treatment, a patient must reveal personal information; a patient withholds such data at his or her peril. Having turned over private information to ensure proper and adequate treatment, the patient is at the mercy of the medical corporation's ability to protect its

> confidentiality. A hospital should owe a duty to keep a patient's health information confidential, and a hospital should be directly liable for its own failure to prevent breaches of confidentiality by employees who act outside the scope of their employment…In order to protect the patient's privacy interests given the competing need to disclose, such a cause of action would provide a powerful incentive to medical corporations to implement protections against disclosures.[31]

Justice Rivera further reasoned that "[a] cause of action directly against a medical corporation, unhampered by questions as to whether an employee's conduct occurred within the scope of employment, ensures the fullest protections for patients and best addresses the current realities of medical service delivery"[32] and "would provide a powerful incentive to medical corporations to implement protections against disclosure."[33] In addition, it would further "the State's public policy in protecting the confidentiality of medical records."[34]

The majority found that imposing "strict liability on medical corporations for *any* disclosure by an employee" was "an approach that is unnecessary and against precedent."[35] It was unnecessary, according to the majority, because even though a cause of action against an employer may fail because the employee was acting outside the scope of employment:

> a direct cause of action against the medical corporation for its own conduct, be it negligent hiring, supervision or other negligence, may still be maintained. A medical corporation may also be liable in tort for failing to establish adequate policies and procedures to safeguard the confidentiality of patient information or to train their employees to properly discharge their duties under those policies and procedures. These potential claims provide the requisite incentive for medical providers to put in place appropriate safeguards to ensure protection of a patient's confidential information.[36]

However, in *Guthrie*, Doe's claims for negligent hiring, retraining, supervising, and training were dismissed by the district court. As Justice Rivera noted, "the instant case well illustrates, those causes of action alone are inadequate to remedy a breach of the duty to maintain the confidentiality of personal data, and they provide cold comfort to a patient whose personal data is disclosed due to the status of the employee and regardless of the actions of the employer that facilitated disclosure."[37]

Conclusion

Justice Rivera recognized the "ease with which confidential patient information can now spread through personal digital devices and across social networks,"[38] and given the federal government's incentives for medical practitioners to implement electronic health records or lose compensation under Medicare and Medicaid and the State of New York's support of integration among regional health information organizations, more and more patient information is susceptible to breach or misuse. While the *Guthrie* majority opined that a strict liability approach was not necessary because a patient may have a direct cause of action against a health care organization for failing to establish policies and procedures to safeguard patient information or to train employees to properly discharge their duties under those policies and procedures, there are no uniform standards regarding protection of patient information. Perhaps it is time to impose a standard of duty on health care organizations to adopt and implement effective policies and procedures to guard against the improper dissemination or misuse of confidential medical information.

Endnotes

1. *Cornell v. State of New York*, 46 N.Y.2d 1032, 1033 (1979); *Kirkman v. Astoria General Hospital*, 204 A.D.2d 401, 402 (2nd Dept. 1994), *leave to appeal denied*, 84 N.Y.2d 811 (1994), *reargument denied*, 85 N.Y.2d 858 (1995).

   The mere fact that an employee committed the acts during the time of employment does not conclusively demonstrate that the actions were within the employee's scope of employment or were performed in furtherance of the employer's business. *Cornell v. State of New York*, 46 N.Y.2d 1032 (1979); *N.X. v. Cabrini Medical Center*, 97 N.Y.2d 247 (2002).
2. *Cornell v. State of New York*, 46 N.Y.2d 1032 (1979); *N.X. v. Cabrini Medical Center*, 97 N.Y.l2d 247 (2002).
3. *Cornell v. State of New York*, 46 N.Y.2d 1032 (1979).
4. *Id.*, 46 N.Y.2d at 1033-34 (and to the extent that this rationale may have been employed in *Foster v. State of New York*, 57 Misc. 2d 281, the Court rejected that decision).
5. *Cabrini*, 97 N.Y.2d at 252 (stating "A sexual assault perpetrated by a hospital employee is not in furtherance of hospital business and is a clear departure from the scope of employment, having been committed for wholly personal motives").

   The appellate court also declined the invitation "to depart from settled law and expand the outer limits of hospital liability." *Cabrini*, 280 A.D.2d 34, 35 (1st Dept. 2001).
6. *Cabrini*, 97 N.Y.2d at 253-54.
7. It is well-established in New York that a patient may maintain a common law cause of action for breach of fiduciary duty against his or her physician where the physician discloses the patient's medical records without authorization. *Guthrie*, 710 F.3d 492, 496 (2nd Cir. 2013), *citing Burton v. Matteliano*, 81 A.D.3d 1272 (4th Dept. 2011); *Tighe v. Ginsberg, M.D.*, 146 A.D.2d 268, 270 (4th Dept. 1989). "The duty not to disclose confidential personal information springs from the implied covenant of trust and confidence that is inherent in the physician patient relationship, the breach of which is actionable in tort." *Burton*, 81 A.D.3d at 1274, *reargument denied*, 83 A.D.3d 1603, *leave to appeal denied*, 17 N.Y.3d 703.

   "A physician's duty to maintain the confidentiality of information regarding the treatment of his patient is one which is well known

and recognized by society in general. Almost every member of the public is aware of the promise of discretion contained in this Hippocratic Oath, and every patient has a right to rely upon this warranty of silence." *Tighe v. Ginsberg, M.D.*, 146 A.D.2d 268, 270 (4th Dept. 1989).

8. *Doe v. Guthrie Clinic, Ltd*., 22 N.Y.3d 480, 484 (2014).
9. *Guthrie*, 2012 WL 531026 at *1 (W.D.N.Y.2012).

   The defendants were Guthrie Clinic, Ltd.; Guthrie Health; Guthrie Healthcare System; Guthrie Health Plan; Inc.; Guthrie Clinic Inc.; Guthrie Clinic, A Professional Corporation; Guthrie Clinics Group Practice Partnership, L.L.P.; Guthrie Medical Group, P.C.; Guthrie Enterprises, Twin Tier Management Corporation. In this article, the defendants are referred to as the "clinic."

10. *Id.*
11. The other claims were: breach of contractual duty of confidentiality over patient personal health information; breach of privileged patient personal health information under CPLR 4504; breach of privileged patient personal health information under CPLR 4410; breach of patient right to privacy under Public Health Law §2803-c; negligent hiring, training, retention and/or supervision of employees; negligent infliction of emotional distress; and intentional/reckless infliction of emotional distress.
12. *Id.*
13. *Community Health Plan-Kaiser Corporation*, 268 A.D.2d 183, 186 (3rd Dept. 2000) (referring to CPLR 4504 and 4508 and Public Health Law §4410(2)), *rejected by*, *Doe v. Guthrie Clinic, Ltd*., 2014 WL66644 (2014), *declined to follow by*, *Doe v. Guthrie Clinic, Ltd*., 2012 WL531026 (W.D.N.Y. 2010).
14. *Id*., 268 A.D.2d at 187.
15. *Id*.
16. *Id.* at 188.
17. *Id*. at 190.
18. *Guthrie*, 2012 WL 531026 at *5.
19. *Id.* at *6 (stating "the determination of whether or not strict liability may be imposed on a party is a question properly left to legislatures, not courts").
20. *Id*. The district court granted the defendant's motion to dismiss the complaint.
21. *Guthrie*, 710 F.3d 492, 297 (2013) (noting that New York courts were "virtually silent about the ability of a plaintiff to sue a medical corporation directly for a non-physician employee's *ultra vires* disclosure of the plaintiff's confidential medical information").

    The plaintiff did not pursue his statutory claims on appeal, and his other claims were disposed in a separate summary order on March 25, 2013. 2013 WL 1188969 (2nd Cir.2013).

22. *Id*., 710 F.3d at 495.
23. *Id*., 710 F.3d at 497 (therefore, it was not clear to the Second Circuit that *Cabrini* was intended to apply to a more specific breach of fiduciary claim relating to confidential medical information).
24. *Id*. at 498.
25. *Guthrie,* 22 N.Y.3d at 484.
26. *Id*. at 485 n*.
27. *Id*.
28. *Id*. at 485-86.
29. *Id*. (citations omitted).
30. *Id*. at 488, *citing* AMA Code of Med. Ethics Op. 10.02[2].
31. *Id*.
32. *Id*. at 486.
33. *Id*. at 488-89.
34. *Id*. at 489.
35. *Id.* at 485 (and also finding the dissent's reasoning flawed for being too broad).
36. *Id*.
37. *Id*. at 487 fn*.
38. *Id*. at 486.

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NEWS flash

What's Happening in the Section

The 2015 Annual Meeting

On January 28, 2015, the NYSBA Health Law Section held a program as part of the NYSBA 2015 Annual Meeting in NYC. The program included:

- Hot and Upcoming Topics in New York Health Law;
- The Delivery System Reform Incentive Payment (DSRIP) program;
- New York's new out-of-network law;
- Developments in managed care;
- Overpayments and Department of Justice actions;
- IT update: the Statewide Health Information Network for NY (SHIN-NY), RHIOs and providers; and
- The New York State Justice Center.

Other Recent Programs

HIPAA/HITECH for Lawyers Update 2014 was held on December 3, 2014.

The Ebola Crisis and Global Health Law, a teleconference with Lawrence Gostin, University Professor of Global Health at Georgetown Law School. This was one of a series of public health law webinars held by the Public Health Committee.

The Section held a networking reception on December 16, 2014 in New York City at the offices of Duane Morris.

All members are encouraged to join a committee. Much of the activity of the Section occurs through committees, and membership in a committee is a great way to increase knowledge and get to know other health lawyers. For example, the Medical Research and Biotechnology Committee is involved in an extremely interesting project on technology that enhances human capacity and the legal and ethical issues relating to such.

The Young Lawyers Committee

The Young Lawyers Committee is a new committee that is designed for health lawyers in practice less than ten years. It is just getting off the ground, and would welcome participation by health lawyers in New York who want additional knowledge and contacts in health law.

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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